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Commonwealth and Latin American Legislators' Toolbox

Introduction

Drafters and policy officers are invited to select tools from this Toolbox when conceiving or amending legislation. The Toolbox contains 345 tools drawn from 55 Commonwealth and Latin American nation states (Annex I) and dozens of sectors (Annex II). Almost all tools are presented with at least one Commonwealth and one Latin American reference, enabling legislators from both geographic regions and legal traditions to identify precedents from similar jurisdictions.

The Toolbox helps avoid reinventing the wheel. It can make legislation more complete and, therefore, more efficient and less open to divergent interpretations. Using these tools can promote a more uniform, consistent and stringent application of the law. In turn, this contributes to creating or preserving a level playing field and, consequently, trust.

To complement this toolbox, we recommend our Cross-sectoral Standard Provisions, its complementary lists and the EU Legislators' Toolbox that contains more than 50 additional entries. The chapter titles in those two documents are similar, enabling you to navigate easily between the corresponding chapters. More recommendations can be found at the end of this document under "Further Tools".

Questions or suggestions? Please contact: manager@regulatoryinstitute.org

This document was conceived and developed by our founder, Manfred Kohler. Our Regional Representative for South America, Central America, and the Caribbean, Fabiola Zambrana Pardo contributed namely to Chapter G. All parts supplemented by Artificial Intelligence have been revised.

Despite two rounds of revision, some errors may have been overlooked. Please contact us if you identify any mistakes or broken links. Although all links were functional at the time of the last revision, some may cease to work over time, as many states do not use permanent links. Wherever possible, we have given preference to official state websites. In a small number of cases, however, we had to refer to privately operated websites containing advertisements. We apologise for any inconvenience.

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A. Interpretation (Rules)

Information System for Aligned Decision-Making, Interpretation and Guidance

Regulatory Function:

Consistency in Interpretation and Implementation Across the Jurisdiction

Problem:

Divergent national authorities practice creates market barriers and non-level playing fields.

Solution(s):

Establish a legally mandated, interoperable information system to share legal and interpretative decisions, case law, and authorisation / certification outcomes.

Reference(s):

Australia, National Vocational Education and Training Regulator Act 2011 (Cth), Sections 157, 209, and 209A.

Guatemala – Organic Law of the SAT (Decree 1-98), Article 3, in relation to the public repository of "Institutional Tax Criteria" of the Superintendency of Tax Administration (SAT). Based on this legal framework, the SAT issues and publishes numbered institutional tax criteria on its official portal (https://portal.sat.gob.gt/portal/criterios-institucionales), which document the administrative interpretation of tax rules for recurring cases and seek to unify criteria among the different units of the tax administration.

Note(s):

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Product or Process Classification Procedures

Regulatory Function:

Classification Consistency and Predictability

Problem:

Conflicting or ambiguous classification impedes enforcement and market entry.

Solution(s):

Define detailed procedures, with powers for central authority to clarify classification where needed.

Reference(s):

Australia – Therapeutic Goods Act 1989 (Cth), Section 41BD and related legislative instruments on boundary products.

Brazil – Lei n.º 9.782/1999, Articles 6 to 8, together with Portaria Anvisa n.º 1.354/2016 and Portaria Anvisa n.º 1.744/2016, which establish and regulate the Product Classification Committee (COMEP) and the procedural flow for deciding the classification of "borderline products" between regulatory categories.

Note(s):

In line with ordinary language, we use here the term “classification” for what is called “qualification” (as a medical device) in medical devices law. “Classification” in medical devices law refers to the attribution of risk classes.

Binding Interpretations by Central Authority

Regulatory Function:

Legal Clarity and Best Practice Support

Problem:

Operators need clear, up-to-date guidance to comply across languages and provinces or territories.

Solution(s):

Right for the central authority to adopt binding interpretations, where guidance/FAQs, or other interpretative communications do not suffice.

Reference(s):

Australia – Taxation Administration Act 1953 (Cth), Schedule 1, Divisions 357–360 (Commissioner's binding rulings).

Chile – Ley N.º 20.255, Artículo 47, N.º 7, which empowers the Superintendencia de Pensiones to issue general norms and instructions.

Note(s):

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Empowerment for Guidance

Regulatory Function:

Legal Clarity and Best Practice Support

Problem:

Operators and authorities need clear, up-to-date guidance to comply.

Solution(s):

Explicit right for the central authority.

Reference(s):

UK – Building Safety Act 2022 (c. 30), Section 16;

UK (Scotland) – Regulation of Legal Services (Scotland) Act 2025, Section 69.

Zambia – Agricultural Credits and Warehouse Receipts Act, 2026, Section 83.

Chile – Ley N.º 20.255, artículo 47, N.ºs 6 and 8, which empower the Superintendencia de Pensiones to issue administrative interpretations of the

regulations and other rules it applies, thereby giving it an explicit legal mandate to adopt non-binding guidance for supervised entities.

Note(s):

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Reference to Agency or "Board/Body" for Binding Interpretation or Arbitration

Regulatory Function:

Conflict amongst Authorities, Provinces, Sub-states or other Territories on Application / Interpretation

Problem:

Unresolved legal ambiguities lead to conflicts, delayed implementation and unequal enforcement.

Solution(s):

Allow to make "preliminary references" to a federal agency or "board/body" with legal personality for official/binding interpretation.

Reference(s):

Canada – Article 1004 Canadian Free Trade Agreement (CFTA), Chapter Ten (Dispute Resolution): Allows federal, provincial and territorial governments to refer disputes on the interpretation and application of CFTA rules to independent panels whose arbitration-style decisions are binding on the parties, thereby resolving conflicting interpretations and promoting uniform implementation across provinces.

Argentina – Ley N.º 19.983, Artículo 2 (conflicts between entities or agencies of the National Public Administration) and Decreto Reglamentario N.º 2481/93 – implements Ley 19.983, detailing the procedure.

Note(s):

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Reference to Courts for Binding Interpretation and Clarification of Legality

Regulatory Function:

Legal Uncertainty or Conflict amongst Authorities on Application / Interpretation

Problem:

Unresolved legal ambiguities lead to conflicts, delayed implementation and unequal enforcement.

Solution(s):

Allow reference to a court in view of a "preliminary ruling" or clarification.

Reference(s):

India – Constitution, Article 143, the President may refer questions of law or fact of public importance to the Supreme Court.

Comunidad Andina – Tratado de Creación del Tribunal de Justicia de la Comunidad Andina and Estatuto del Tribunal (Decisión 500), Capítulo 3, provisions on prejudicial interpretation of Andean law.

Note(s):

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Standards, International and Informal Document to guide Interpretation

Regulatory Function:

Clarity and Predictable Implementation

Problem:

Vague or ambiguous legal provisions risk inconsistent application.

Solution(s):

Refer to groups of standards, international and informal documents to steer interpretation, without making these documents formally binding.

Reference(s):

UK – General Product Safety Regulations 2005 (SI 2005/1803), Regulation 6(3).

Mexico — Ley Federal de Protección al Consumidor, Artículo 94: Establishes that in the absence of specific Mexican Official Standards (NOMs), the quality and safety of products and services shall be determined by non-official Mexican standards.

Note(s):

Making documents controlled by non-governmental entities formally binding might be legally / constitutionally problematic as the documents can be subject to later changes. Better use binding references only where you can refer to a precise version of a document that is not subject to later changes.

Preambles and Recitals to guide Interpretation

Regulatory Function:

Clarity and Predictable Implementation

Problem:

Vague or ambiguous legal provisions risk inconsistent application.

Solution(s):

Use detailed preambles or recitals with examples, interpretative principles and explicit guidance on intended meaning.

Reference(s):

Canada – Interpretation Act, s. 13, explicitly directs that preambles are part of an enactment and are intended to assist in explaining its purpose and object, thereby giving detailed preambles a recognised interpretative role without making them independently enforceable.

Latin America (civil-law tradition) – preámbulos, exposiciones de motivos and considerandos in constitutions and statutes are generally non-binding but widely recognised in doctrine and case law as interpretative tools. Courts and authorities rely on these detailed recitals—setting out objectives, context, principles, and sometimes examples—to resolve ambiguity and to apply provisions consistently with the legislator's stated purposes.

Note(s):

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Interpretation Principles

Regulatory Function:

Clarity and Predictable Implementation

Problem:

Vague or ambiguous legal provisions risk inconsistent application.

Solution(s):

Set out interpretation principles such as "The meaning of an enactment must be ascertained in the light of its purpose" or "In case of doubt, the interpretation of this act must ensure that … " (e.g. optimise the protection of a certain group of persons or the provision of economic freedom or of another right).

Reference(s):

New Zealand – Interpretation Act 1999, Section 5(1).

Guatemala – Decreto núm. 44-2016 (Código de Migración), Article 22.

Note(s):

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Implementation Principles

Regulatory Function:

Clarity and Predictable Implementation

Problem:

Vague or ambiguous legal provisions risk inconsistent application.

Solution(s):

Set out implementation principles.

Reference(s):

Fiji – Forestry Act 2025 (Act 28 of 2025), Section 5.

Colombia – Ley 99 de 1993, Artículo 1 (Principios Generales Ambientales).

Bolivia - Ley No. 450 de 4 de Diciembre de 2013 (Protección a Naciones y Pueblos Indígenas), Article 3.

Note(s):

The last reference contains, in its Article 2, collective rights, meaning rights for groups of persons that are to be respected. Bolivia and other jurisdictions start attributing rights to the earth, "nature" or parts of nature, such as rivers or mountains; see e.g. the Bolivian Ley No. 071 of 2010 (Protección de la Madre Tierra), Article 7. These collective rights and rights of natures have a function similar to implementation principles, but can be enhanced and thus become operational and more effective via rules on standing in defense of the rights. See the entry "Third Party Rights (Standing) in Regulatory Appeals and Independent Procedures" towards the end of Chapter L.

B. Scope, Application and Harmonisation Approaches

Empowerment to clarify Applicability of an Act

Regulatory Function:

Legal Certainty, Scope and Applicability

Problem:

Uncertainty arises as to whether a legislative act applies in borderline or evolving scenarios.

Solution(s):

Empowerment for the government to clarify the applicability via binding acts.

Reference(s):

Canada – Statutory Instruments Act, Section 20, empowering the Governor in Council, by regulation, to exempt or bring within the application of the Act specified classes of regulations, effectively clarifying the Act's practical scope and applicability in borderline or evolving regulatory scenarios.

Brazil – Lei n.º 9.782/1999, Articles 6 to 8, together with Portaria Anvisa n.º 1.354/2016 and Portaria Anvisa n.º 1.744/2016, which establish and regulate the Product Classification Committee (COMEP) and the procedural flow for deciding the classification of "borderline products" between regulatory categories.

Note(s):

Helps ensure regulatory certainty and enforceability in fields with rapidly evolving products, services or other processes and social realities.

Province or Substate "Opt-Out" or "Opt-In"

Regulatory Function:

Flexibility for Divergent Interests of Provinces or Substates

Problem:

A small number of provinces or substates need a regulation or a certain regulatory element that some others do not want.

Solution(s):

Permit provinces or substates to opt out, avoiding unnecessary blocking of further harmonisation. Or establish an opt-in mechanism.

Reference(s):

Opt-out: Canada – Constitution Act 1982, Section 38(3), allowing a province to 'opt out' of a constitutional amendment that transfers a matter from provincial to federal jurisdiction, so that the amendment applies to the rest of the federation but not to that province, with possible financial compensation in limited fields.

Opt-in: Argentina – "ley convenio" technique, as recognised in Article 75(2) of the Constitution (here in English) and Senate analyses, where a federal law establishes a national regime in an area of shared or provincial competence and explicitly invites provinces to adhere by their own legislation. Provinces that do not adhere remain outside that regime, while the framework can still operate for adhering provinces.

Opt-in: Australia – Mutual Recognition Act 1992 (Cth); Automatic Mutual Recognition (AMR) schemes for regulated professions have been adopted by some states and territories (NSW, Victoria, ACT, Western Australia, …), but not by all.

Note(s):

A similar technique consists in adopting conventions or agreements at federal level, as sometimes practiced in Canada and - again - in Argentina; see e.g. the acts referred to in Article 25 of Ley General del Ambiente (Ley 25.675).

Exemptions or Specific Regimes for Outermost Regions

Regulatory Function:

Tailoring Regulation for Non-Continental Markets

Problem:

Common rules may be misaligned or overly burdensome for distant territories (outermost regions).

Solution(s):

Permit exemptions or special regimes for such regions or sectors.

Reference(s):

United Kingdom – Overseas Territories application of sanctions and similar regimes (e.g. SI 2025/1092).

Chile – Constitución Política, artículo 126 bis, recognising Isla de Pascua and the Juan Fernández archipelago as "territorios especiales" whose government and administration will be governed by special statutes, and Ley N.º 16.441 ("Ley Pascua") and Ley N.º 21.070, which establish tax and residence/stay regimes that deviate from general national law for Isla de Pascua.

Note(s):

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Exemptions in Case of "Public Interest Override"

Regulatory Function:

Balancing Rights and Interests

Problem:

Absolute rules may bar vital actions in cases of overriding public interest (e.g., national security, civil protection).

Solution(s):

Greater good exemptions defined and allowed through precise procedures, with transparency and accountability safeguards.

Reference(s):

Australia – Privacy Act 1988 (Cth), Part VI and Part VIA, allow the Information Commissioner to issue public interest determinations authorising otherwise non-compliant acts where the public interest in the act outweighs the public interest in compliance, and create specific emergency/disaster exemptions for handling personal data, all with defined tests and transparency requirements.

Namibia — Vehicle Mass Act, 2024, Section 22: exemption for certain public institutions by decision of the Minister.

Argentina – Ley 27.275, Article 8, allows public bodies to refuse access to information only in narrowly defined cases, such as when information is classified for defence or foreign policy and disclosure would pose a real, identifiable risk of significant harm to a legitimate public interest. The law requires a harm and proportionality analysis and reasoned, reviewable decisions, thereby implementing a structured public-interest override to balance transparency with national-security and other overriding interests.

Note(s):

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"Flexibility Clauses" – Adaptation to Local Contexts

Regulatory Function:

Subsidiarity/Proportionality

Problem:

One-size-fits-all regulation may not fit all local circumstances.

Solution(s):

Legal flexibility for alternative methods or timings, subject to criteria and notification. Recognition of equivalent legal regimes.

Reference(s):

Canada – Species at Risk Act, ss. 108–119, authorises "alternative measures" agreements instead of prosecution where doing so is consistent with the Act's purposes and detailed conditions are met. The agreements are subject to Attorney General and ministerial control, must be filed in court, and may be regulated by the competent minister, providing structured flexibility with transparency and accountability.

Argentina – Ley General del Ambiente (Ley 25.675), combining national "presupuestos mínimos" of environmental protection with provincial competence to adopt their own instruments in Article 26, directing competent authorities to establish context-appropriate systems (including voluntary commitments and self-regulation) to protect environmental quality.

Note(s):

Similarly, the Canadian Environmental Protection Act 1999 (SC 1999, c. 33), Section 10 provides that the Minister of Environment may enter into an equivalency agreement with a province or territory under which federal regulations do not apply in that province if it has equivalent standards — the province requests equivalency and the federal Minister decides.

Micro-Enterprise and De Minimis Exemptions

Regulatory Function:

Proportionality and Administrative Burden Reduction

Problem:

Full compliance burden may overwhelm micro-enterprises.

Solution(s):

Explicit exemption or simplified regime for micro-enterprises or activities below a quantitative threshold.

Reference(s):

United Kingdom — Companies Act 2006, Part 15, Chapter 1 (Sections 384A to 384B): Establishes a specific "micro-entity" category for companies meeting strict quantitative thresholds (e.g., turnover not exceeding £632,000, balance sheet total not exceeding £316,000, and no more than 10 employees). Qualifying micro-entities are granted significant exemptions from full financial reporting and audit requirements, allowing them to file highly simplified "micro-entity accounts" to reduce administrative burden while maintaining basic transparency.

Ecuador – Ley Orgánica de Simplificación y Progresividad Tributaria, Article 38: The "Régimen Impositivo para Microempresas" provides a simplified tax regime for micro-enterprises (1–9 workers and annual gross income up to USD 300,000). The regime eases formal and substantive tax obligations to facilitate compliance by micro-enterprises.

Note(s):

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Language Collision Clauses and Official Translations

Regulatory Function:

Legal Certainty and Avoidance of Conflict

Problem:

Potential inconsistencies if parallel language versions.

Solution(s):

Stipulate which language version(s) prevail(s) or how else conflictual wordings should be interpreted. Or create official translations.

Reference(s):

Bangladesh – Energy Regulatory Commission Act, 2003 (Act No. 13 of 2003), Section 65. The English version is declared to be "authentic" as a translation, but not to be the original.

Paraguay – Ley Nº 4251 de Lenguas (2010), Articles 14 (implying the obligation to make available a translation into Guaraní) and 20 2nd sentence (giving legal priority to the original version, meaning Spanish for laws).

Note(s):

Evidently, the Bangladeshi approach is difficult to defend in constitutional settings providing for equality of languages.

Compatibility ("Coherence") or Collision Clauses

Regulatory Function:

Legal Certainty and Avoidance of Conflict

Problem:

Potential inconsistencies if parallel sectoral legislation applies.

Solution(s):

Stipulate which provision or act prevails or define in another way the relationship between the two acts.

Reference(s):

Canada (Alberta) – Freedom of Information and Protection of Privacy Act, Section 5.

Australia – Water Act 2007 (Cth), Part 11A, collision rules relating to law of the states.

Namibia — Vehicle Mass Act, 2024, Section 18(5): standards conflicting with regulations are deemed to be regulations so that classic collision rules apply = clarification by upgrading of standards.

Colombia – Ley 1116 de 2006 (Régimen de Insolvencia Empresarial), Article 88: in case of conflict between this law and an international treaty obligation of Colombia, the provisions of that treaty or agreement prevail.

Note(s):

Ensures a predictable legal order for both authorities and regulated actors. The classic collision rules (lex posterior derogat lex anterior; lex specialis derogat lex generalis) may lead to unclear results; therefore clear collision rules are preferable.

"Without Prejudice" Clauses

Regulatory Function:

Legal Clarity and Cross-Regime Compliance

Problem:

Regulators and operators face uncertainty when rules overlap content-wise (e.g. on competition, data protection, trade secrets).

Solution(s):

Explicit reference that provisions must be applied "without prejudice" to specific other laws.

Reference(s):

Guyana – Sea and River Defence Act (No. 9 of 2024), Article 38.

Colombia – Ley 1116 de 2006 (Company Insolvency), Article 4(2).

Note(s):

The meaning of "without prejudice" is not always clear. Please check whether more precise wording can be found in your case.

Cross-Sectoral "Regulatory Alignment" Mechanisms for Products or Services falling under different Laws

Regulatory Function:

Clarifying Interlocking Legal Regimes

Problem:

Products and services may fall under multiple potentially conflicting sectoral rules.

Solution(s):

Panels or consultation mechanisms to clarify alignment, publish common guides, and resolve cross-sectoral issues.

Reference(s):

Australia – Therapeutic Goods Act 1989 (Cth), ss. 30C–30E: mandatory consultation with the Gene Technology Regulator when therapeutic goods also fall under gene technology regulation, ensuring inter-agency coordination for multi-regime products.

Mexico – Ley de los Órganos Reguladores Coordinados en Materia Energética (2014), arts. 19–22: establishes the Energy Sector Coordination Council to coordinate regulatory actions and resolve cross-sectoral issues where activities fall under multiple energy regulators.

Note(s):

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Maximum Harmonisation Clauses / Approach

Regulatory Function:

Free circulation of products, other items, services, capital and workforce

Problem:

Provinces or substates or contracting parties of international agreements tend to add-on new requirements and sharpen common requirements, partly to protect their population, partly to protect their economy.

Solution(s):

Establish upper limits of what jurisdictions can request from operators, institutions or citizens.

Reference(s):

Dominica – Caribbean Community Act 2005 (Act No. 22 of 2005), Section 3 (giving value of law to the CARICOM Agreement) combined with articles prohibiting the creation of obstacles, e.g. Article 32 of the annexed CARICOM Agreement.

Venezuela – Ley Orgánica de Coordinación y Armonización de las Potestades Tributarias de los Estados y Municipios (N.º 6.755), various articles establishing upper limits for what geographic entities may impose.

Note(s):

- Where both maximum and minimum levels are set for (sub-)states at one specific level, we can speak of "full harmonisation".
- Minimum and maximum harmonisation can also be combined to create a corridor of lawful action for (sub-)states.

Minimum Harmonisation Clauses / Approach

Regulatory Function:

Minimum Protection of Values or Policy Goals combined with Regulatory Flexibility upwards

Problem:

(Sub-)States require flexibility to introduce or maintain higher standards while ensuring a common minimum.

Solution(s):

Include explicit clauses allowing stricter or more detailed (sub-)state provisions beyond the minimum without (disproportionately) compromising alignment.

Reference(s):

Australia — Fair Work Act 2009 (Cth), Section 66: preserves the operation of State or Territory laws to the extent that they deal with entitlements that are "more beneficial to employees" than the National Employment Standards (NES).

Argentina — Constitution, Article 41, and Ley Nº 25.675 (Ley General del Ambiente), Article 6: the national law provides only for "presupuestos mínimos" (minimum standards) for environmental protection.

Brazil — Constituição Federal, Artigo 24, §§ 1º and 2º:

"§ 1º Within the scope of concurrent legislation, the competence of the Union shall be limited to establishing general rules.

§ 2º The competence of the Union to legislate on general rules does not exclude the supplementary competence of the States."

Note(s):

See the note of the previous entry regarding the combination of maximum and minimum harmonisation ("full harmonisation" or creation of a corridor of lawful action of sub-states).

Equivalence/Mutual Recognition

Regulatory Function:

Free circulation of products, other items, services, capital and workforce

Problem:

Differing national rules still cause barriers for goods/services/other processes/professional and other qualifications.

Solution(s):

Mandatory mutual recognition of goods, services or professional qualifications that are lawful in other states.

Reference(s):

Australia – Mutual Recognition Act 1992 (Cth): Automatic Mutual Recognition (AMR) schemes for regulated professions.

CARICOM Revised Treaty of Chaguaramas, 2001 (as amended), Article 35.

MERCOSUR: Sistema Regional de Acreditación de Carreras Universitarias del Mercosur Educativo (ARCUSUR).

Note(s):

Accreditation can be set up as a precondition for mutual recognition, see the second reference.

Regulatory Sandboxes and Experimentation Clauses

Regulatory Function:

Innovation Facilitation

Problem:

Traditional frameworks may restrict the emergence of new technologies or business models.

Solution(s):

Allow temporary, controlled derogations or pilot regimes, with safeguards for experimenting with new concepts.

Reference(s):

Canada (Alberta) – Financial Innovation Act, S.A. 2022, Chapter F-13.2, provisions on regulatory sandbox certificates and temporary exemptions for innovative financial services/fintech.

Trinidad and Tobago — The Virtual Assets and Service Providers Act 2025, Part II.

Peru – 2020 Decreto de Urgencia on fintech and crowdfunding (Nº 013-2020), and Superintendencia de Banca, Seguros y AFP (SBS), Resolución SBS N.º 2429-2021, Reglamento para la realización temporal de actividades en modelos novedosos (sandbox regulatorio).

Note(s):

See also this article on the design of regulatory sandboxes.

Sunset Clauses and Review Triggers

Regulatory Function:

Time-Limited Regulation and Feedback

Problem:

Rules may outlive their suitability; periodic review is often neglected.

Solution(s):

Automatic expiry (sunset), or mandatory evaluation/review deadlines built in.

Reference(s):

Australia, Legislation Act 2003 (Cth), Chapter 3, Part 4.

Mexico — Ley General de Mejora Regulatoria (2018), Artículo 70: Mandates that regulatory authorities must conduct "evaluaciones ex post" (ex-post evaluations) of the general administrative acts they issue, to determine if they have achieved their proposed objectives and to assess the effects, costs, and benefits generated, ensuring built-in feedback and review mechanisms.

Note(s):

Incentivises regular legislative updating; but sunset clauses create an unnecessary burden for the government and legislators where continuity is necessary.

C. Definitions and Connected Rules

Empowerment to Amend Legal Definitions

Regulatory Function:

Legal Clarity and Adaptation to Technical Progress

Problem:

Definitions may become inadequate over time as technology or practice evolves.

Solution(s):

Empower the administration to amend or update legal definitions via delegated acts.

Reference(s):

Canada (British Columbia) – Employment Standards Act, RSBC 1996, c. 113, Section 127(2)(r): empowers the executive by regulation to "defin[e] any word or expression used but not defined in this Act", allowing adaptation of legal terminology over time.

Paraguay – Ley Nº 937/82 "De Metrología", Article 7: power to amend in view of certain committee decisions, thus without full autonomy.

Note(s):

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Indicative Lists and Exclusion List

Regulatory Function:

Legal Clarity and Alignment of Interpretation

Problem:

Definitions may be unclear if very abstract or unintendedly excluding important cases when drafted in a very concrete way.

Solution(s):

Use an "indicative list" of items or situations covered by a certain expression / term. Also use exclusion lists.

Reference(s):

Canada – Information Technology Job Evaluation Standard (Treasury Board of Canada Secretariat); definition of "Information Technology (IT) Group" followed by an explicit non-exhaustive list and an exclusion list which provides further clarity.

Argentina – Integral Women Protection Ley Nº 26.485, Article 6 (indicative list);

Argentina – Decreto Nº 302/1983, Reglamentación de la Ley Nº 20.429 de Armas y Explosivos, Chapter I, Article 3 (exclusion list).

Note(s):

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Dynamic Reference to other Acts for Definitions

Regulatory Function:

Alignment and dynamic Adaptation

Problem:

Definitions diverging between different acts create legal uncertainty. At the same time, some definitions need to be adapted over time.

Solution(s):

Create a dynamic reference to the definitions of other acts.

Reference(s):

Canada – Customs Act, RSC 1985, c. 1 (2nd Supp.), Section 2: several terms "have the same meaning as in … " (other Acts), creating a dynamic reference for definitions.

Uruguay – Ley Nº 19.568 (social security agreement with the U.S.), Article 1(2): for all terms not defined, abstract reference to the definitions of applicable legislation ("Cualquier término no definido en el presente artículo tendrá el significado que se le atribuye en la Legislación aplicable.").

Note(s):

Check whether in your jurisdictions references to other acts are, by default, deemed to be dynamic or static (referring to a precise version of a text, e.g. the version in force at the time of adoption of your act).

D. Authorisation/Licensing Procedures

Mandatory Pre-Market Notification

Regulatory Function:

Early Detection of Non-compliances, Risk Management

Problem:

Without advance notice, authorities may be unprepared for risks linked to new products/services.

Solution(s):

Obligate manufacturers, importers or service providers to notify authorities before entering the market.

Reference(s):

Canada – Food and Drug Regulations (C.R.C., c. 870), under the Food and Drugs Act**,** Section B.28.002(1).

Andean Community – Decision 833 (Productos de Higiene Doméstica y Similares), Article 6.

Note(s):

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Mandatory Electronic Application

Regulatory Function:

E-Government, Efficiency, and Accessibility

Problem:

Paper-based submission increases delay, error, and cost.

Solution(s):

Require or permit the use of online (secure) platforms for applications, reporting, notifications, and data sharing.

Reference(s):

Australia (Queensland) – Land Title Regulation 2022, Section 5(1): designated registry instruments must be lodged via an approved electronic lodgement network, effectively making electronic application mandatory for those dealings.
Mexico – Ley Aduanera (federal), Article 6o, first paragraph: where the law requires transmitting/presenting information or carrying out a procedure before the customs authority, it must be done through the "sistema electrónico aduanero" using an electronic/digital document and e.firma/sello digital (or other technological identification).

Note(s):

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Mandatory Application Content / Form

Regulatory Function:

Efficiency and Fairness

Problem:

Non-standardised applications are more difficult to assess fairly. They often omit important information.

Solution(s):

Ensure that all applications contain certain information and are in a specific order, or make a certain form mandatory.

Reference(s):

New Zealand – Resource Management (Forms, Fees, and Procedures) Regulations 2003, Form 9.

Belize – Belize Agricultural Health Authority (Prevention, Control and Eradication of New World Screwworm) (Cochliomyia Hominivorax) Regulations 2024 (S.I. No. 143 of 2024), Schedule III.

Costa Rica – Reglamento para el Registro Sanitario de Medicamentos, Article 27.2.1.

Nicaragua – Decreto Presidencial Nº 09-2022 - Reglamento para el Control de las Sustancias que Agotan la Capa de Ozono, Article 22.

Note(s):

Uniform forms can sometimes also be used to harmonise/align the practice across jurisdictions where a higher level jurisdiction has no formal competence to regulate. E.g., the European Union has harmonised/aligned the practice of organ transplantation of its Member States partly solely by issuing a form for cross-border communication.

Application Publication

Regulatory Function:

Fairness for third Parties

Problem:

Authorisations might affect third parties.

Solution(s):

Publish applications or oblige applicants to publish applications so that third parties have a fair chance to react.

Reference(s):

New Zealand – Resource Management Act 1991, Sections 95–95G: authority to publish.

Belize – Electricity Licensing and Consent Regulations (S.I. No. 39 of 2024), Section 25(4)(a): applicants to publish.

Peru – Ley General de Minería (Legislative Decree No. 109, consolidated text approved by Supreme Decree No. 014-92-EM), Article 122: unclear who publishes, but probably applicants.

Note(s):

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"One Stop Shop" Registration/Notification Systems

Regulatory Function:

Administrative Simplification and Cost Reduction

Problem:

Multiple registrations and notifications increase costs and complexity for businesses and authorities.

Solution(s):

Implement a single "one stop shop" system or "window" for registration or notification.

Reference(s):

Jamaica – The Customs Act, 2019, Sections 2 (definition of "Customs System")

and 180 ("Establishment of, and authorisation to use, Customs System"), establishing the electronic customs system that operates as the Jamaica Single Window for Trade (JSWIFT) – a single electronic platform through which traders submit all import, export and transit regulatory applications and documents.

Guyana – Planning and Development Single Window System Act No. 11 of 2023: very detailed, comprehensive and complete system, setting out the mechanisms of cooperation between agencies involved.

México – Decreto por el que se establece la Ventanilla Digital Mexicana de Comercio Exterior 2011.

Venezuela – Ley Orgánica de las Zonas Económicas Especiales (2022), Article 22.

Note(s):

This entry deals with "one stop shop" systems by which various authorisation or notification procedures are bundled. There are also "one stop shop" systems by which various geographic entities are covered by one "shop". See for example: European Union Regulation 2016/679 (Data Protection), Articles 56 and 60 – Single representative/registration for non-EU controllers. The two types of "one stop shop" are implicitly combined in European Union Regulation 2016/796 (Railways Agency), Articles 12, 19, 20 and 21.

Stringency correlating to Risk Classes

Regulatory Function:

Proportionate Certification Intensity and Stringency

Problem:

Not all products or services merit the maximum intensity and stringency of verification.

Solution(s):

Define risk classes and link more or less intense and stringent conformity assessment procedures to these classes.

Reference(s):

Australia –Therapeutic Goods Act 1989 (Cth), Section 41DB, and Therapeutic Goods (Medical Devices) Regulations 2002 (Cth), Schedules 2 to 3.

Colombia — Decreto 4725/2005 (INVIMA), Chapters I - IV.

Nicaragua — Decreto Presidencial N°. 06-2025 Reforma al Decreto Ejecutivo N°. 20-2017, Sistema de Evaluación Ambiental de Permisos y Autorizaciones para el Uso Sostenible de los Recursos Naturales (look for the keyword "categoría" spread over the text).

Note(s):

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In advance Administrative Decisions ("Advance Rulings")

Regulatory Function:

Legal Certainty, Reliability, Trust

Problem:

Actors sometimes need to know how administrations would decide under certain conditions (e.g. on a certain investment).

Solution(s):

Authorise in advance / hypothetical administrative decisions.

Reference(s):

Jamaica – The Customs Act, 2019, Part XI, Sub-Part A, Sections 187–193: This

modernised legislation explicitly establishes a statutory framework for 'Advance Rulings' on tariff classification, origin, and valuation, providing binding guidance to traders before goods are imported to ensure predictability.

Argentina – Código Aduanero, Law No. 22.415, art. 226 as amended by Decreto No. 70/23: empowers the customs service to issue "resoluciones anticipadas" (advance rulings) on tariff classification, origin, valuation and related matters, at the operator's request before importation, to provide binding guidance and legal certainty.

Note(s):

This technique stems from fiscal law and is still widely spread in fiscal law.

Deadlines for Decision-Making

Regulatory Function:

Predictable Administration

Problem:

Open-ended administrative procedures cause costly uncertainty.

Solution(s):

Legally prescribe maximum time periods within which authorities must issue decisions, approvals or refusals.

Reference(s):

Kenya – Environmental (Impact Assessment and Audit) Regulations, 2003 (LN 101/2003), Regulation 23.

Colombia – Law 1755 of 2015 (CPACA), Article 14: authorities must decide petitions within 10, 15 or 30 days (depending on type) and may only extend once, up to double, with prior notice and justification.

Note(s):

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Silence = Automatic Consent

Regulatory Function:

Reducing Administrative Delay

Problem:

Administrative bottlenecks can unduly delay legal authorisation or product release.

Solution(s):

Automatic authorisation if the competent authority does not refuse or comment within a set deadline.

Reference(s):

India (Maharashtra) – Maharashtra Regional and Town Planning Act, 1966, Section 45(5).

Peru – Texto Único Ordenado de la Ley N° 27444, Ley del Procedimiento Administrativo General, Articles 33 and 33-A.

Argentina – Decree 1759/1972 (Reglamento de la Ley 19.549), Articles 65 ter, quáter, quinqués.

Note(s):

See also the automatic expiry of sanctioning procedures at the end of Chapter K.

Specification of Language of Application / Documentation

Regulatory Function:

Legal Certainty and Non-Discrimination

Problem:

Operators face cost or exclusion when required to use arbitrary languages.

Solution(s):

State explicitly the languages that may or must be used for official applications, certifications, or documents.

Reference(s):

India – Official Language Rules, 1976, Regulation 7: an employee may submit any application, appeal or representation in Hindi or in English, and applications made in Hindi must be replied to in Hindi, thereby explicitly specifying the languages that may be used for official applications.

Note(s):

See also the Puerto Rico Official Languages Act (Act No. 1 of 28 January 1993), Section 1: Spanish and English are established as official languages, and both languages may be used indistinctively in all government departments, agencies and offices, thereby explicitly permitting applications and official documentation in either language.

Conditional and Provisional Authorisations

Regulatory Function:

Managing Uncertainty and Urgency

Problem:

Urgent societal needs (e.g., COVID-19 medicines) require provisional market access before full data is available.

Solution(s):

Permit time-limited or conditional authorisation subject to ongoing monitoring, obligations and withdrawal provisions.

Reference(s):

India – New Drugs and Clinical Trials Rules, 2019, Rule 101 and Second Schedule: provide for waiver of local clinical trials and accelerated approval (on limited or surrogate data) for specified categories of new drugs (including pandemic-use drugs), subject to post-marketing studies (Phase IV trials) and ongoing safety monitoring.

Argentina – emergency-health legislation (Ley 25.590, especially Articles 1 and 5, and implementing emergency decrees (Decreto 486/2002 et seq.): empower the Ministry of Health and ANMAT to adopt exceptional measures for critical health products during a declared emergencia sanitaria, including conditional or time-limited authorisations for vaccines and medicines, with post-authorisation monitoring and revocation powers.

Note(s):

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Obligation to Notify (Ownership or Control) Changes

Regulatory Function:

Continued Compliance Ensurance

Problem:

Modification of ownership or change of controlling persons may affect the reliability of the applicant or licensee.

Solution(s):

Oblige the applicant or licensee to notify any such change or even to obtain a specific approval.

Reference(s):

Sri Lanka – Gambling Regulatory Authority, Act 17 of 2025, Section 28 (notification obligation).

Argentina – Ley 27.078 (Argentina Digital), Article 13 (approval mechanism).

Note(s):

Can be applied to all changes potentially affecting the compliance.

Automatic Expiry of Non-Implemented Permits

Regulatory Function:

Administrative Clean-Up

Problem:

Unused authorisations or obsolete rules clutter legal systems and markets.

Solution(s):

Create "use it or lose it" provisions—if not acted upon within a set time, the permit or measure lapses.

Reference(s):

Malawi – Local Government Act (Cap. 22:01) building regulations, Section 9(2): where building work is not completed within two years as specified in the notice,

the building permit is deemed to have lapsed, i.e. the unused/unfinished authorisation expires automatically.

Chile – Ordenanza General de Urbanismo y Construcciones, art. 1.4.17: a building permit automatically lapses after three years if the authorised works have not started or have remained paralysed for that period (caducidad automática del permiso de edificación).

Note(s):

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Automatic Expiry in Case of Insolvency, Dissolution or Death

Regulatory Function:

Administrative Clean-Up

Problem:

Authorisations for persons that do not exist anymore or that are insolvent can create legal uncertainty.

Solution(s):

Deem the authorisations "revoked" or let them otherwise become invalid, unless the legal successor should keep them.

Reference(s):

Malaysia – Government Procurement Act 2026, Section 20.

Note(s):

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Consequences of Revocation, Withdrawal or Suspension

Regulatory Function:

Legal Certainty and Continued Safety

Problem:

Where authorisations are revoked (ex tunc), withdrawn (ex nunc) or suspended, it is not always clear which obligations continue to apply and what happens with the acts or activities that have taken place in between. For certain sectors, e.g. the nuclear sector, the continuous fulfillment of obligations is paramount.

Solution(s):

Create precise provisions defining the consequences of the revocation, withdrawal or suspension.

Reference(s):

Malaysia – Government Procurement Act 2026, Section 23.

Cuba – Decreto-Ley Nº 102/2025 sobre el uso de la energía nuclear y las radiaciones ionizantes (nuclear energy and ionizing radiations), Articles 34.1 and 33.4.

Note(s):

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Merging Assessment Procedures

Regulatory Function:

Simplification and Burden Reduction

Problem:

Actors often need to undergo various procedures under various acts. This leads to cumulative burden and unnecessary double assessments of certain aspects.

Solution(s):

Create an option to combine various procedures.

Reference(s):

United Kingdom – Environmental Permitting (England and Wales) Regulations 2016, Section 17 and related provisions: permit a single environmental permit to cover more than one regulated facility (e.g. installations, waste operations, water discharges) at a site, thereby merging multiple assessment procedures that would otherwise apply separately under different Schedules of the Regulations, where this achieves efficient environmental protection.

Mexico – Based on the licensing obligation created by the Ley General del Equilibrio Ecológico y la Protección al Ambiente Article 111 Bis, Acuerdo of 11 April 1997 (DOF 11/04/1997, as amended DOF 09/04/1998) establishes the Licencia Ambiental Única (LAU) – a single environmental licence that integrates multiple environmental authorisations (atmospheric emissions, hazardous waste management, wastewater discharge) into one combined permit and assessment procedure for federal-jurisdiction fixed sources, issued once and definitively.

Note(s):

- The second reference even mandates the single procedure.
- The two references vary as to their approach: the first merges different installations at the same site whereas the second merges different aspects applicable to the same installation.

Integration of Parallel Legislation Requirements in Single Procedure

Regulatory Function:

Avoiding double procedures

Problem:

Various laws regulate different or overlapping aspects in parallel procedures, creating multiple procedural burdens.

Solution(s):

Integrate requirements of parallel legislation and exempt from obligation to undergo the procedure of the parallel legislation.

Reference(s):

United Kingdom: UK Medical Devices Regulations 2002 (as amended), reg. 8(3): incorporate requirements for machinery safety into the specific medical device conformity assessment. Supply of Machinery (Safety) Regulations 2008, Regulation 4(1)(a)(ii): These Regulations apply to products that "do not fall within any of the categories of products specified in Schedule 3 as being products to which these Regulations do not apply". Schedule 3, paragraph 1: "Medical machines in contact with patients" are excluded from the scope of the machinery safety regulations.

Note(s):

This is an alternative to the merged procedure suggested in the previous entry. The approach of the previous entry merges only the procedures, but does not merge the substantive requirements of one law into another, as it is done under this entry here.

Fulfilment of Obligations of other Acts as Fulfilment of other Act

Regulatory Function:

Avoiding double procedures

Problem:

Various laws regulate in parallel procedures, creating multiple procedural burdens. Sometimes they regulate similar aspects.

Solution(s):

Empower the Government to determine equivalences in secondary legislation, determining the conditions under which the fulfilment of obligations under one act also fulfils certain obligations under another act.

Reference(s):

Canada — Canadian Environmental Protection Act, 1999 (CEPA), Section 10 (Equivalency agreements): Empowers the Governor in Council to enter into written equivalency agreements with provincial governments. If a province's laws contain provisions that are equivalent to a federal regulation, the federal regulation is suspended in that province, meaning the fulfilment of the provincial act's obligations legally fulfils the federal obligations and avoids double procedures.

Peru — Texto Único Ordenado de la Ley Nº 27444, Ley del Procedimiento Administrativo General (Decreto Supremo Nº 004-2019-JUS), Article 48.1.10: Establishes the principle that if a citizen or business has already submitted a document to one state entity under a specific procedure, other entities must recognise this fulfilment and cannot demand it again. To make the system work, Article 46 obliges the entities to give other entities access to the collected documentation.

Note(s):

In particular useful where new acts make the fabric of obligations ever more dense.

Recognition of Previous Authorisation for Identical Substance or Item

Regulatory Function:

Assessment Efficiency and Avoidance of Redundancy

Problem:

Testing and authorisations may be unnecessarily repeated for substances or items already reliably tested.

Solution(s):

Allow manufacturers to rely on prior compatible test results and authorisations.

Reference(s):

Canada – Pest Control Products Act, S.C. 2002, Clause 66(1); Pest Control Products Regulations, SOR/2006-124, Sections 17 to 17.17; PMRA Regulatory Directive DIR2010-04: applicants may rely on data from a registered precedent product to support registration of a substantially similar product, avoiding redundant testing through equivalency assessment and reliance on existing data (with letter of access when required); they pay a compensation to the data owner.

Chile – Servicio Agrícola y Ganadero pesticide registration process (Resoluciones N° 1.557/2014 and N° 9.074/2018, see the links under "Marco Legal"): SAG evaluates pesticide registration applications by identity or equivalence, permitting reliance on prior assessments of identical or equivalent active ingredients and formulations, thereby avoiding redundant testing.

Note(s):

Particularly useful where testing involves humans or animals.

Common Procedure and License for Identical Products or Services of Different Actors

Regulatory Function:

Efficient Parallel Processing

Problem:

Duplicated applications for identical products/services waste resources and foster divergent decisions. Product or service identity is determined by the identity of the economic actor. Where two actors offer the same product or service, two procedures are needed.

Solution(s):

Enable joint application channels and "single assessment to multiple decisions" legal routes or recognise licenses / approvals / certificates issued for an identical product or service.

Reference(s):

Mexico (IFT) — Lineamientos para la homologación… (DOF 29-12-2021, telecommunication and radio devices), Capítulo I, Lineamiento Cuarto: certificate "único" that may list and authorise use by multiple legal/natural persons.

Note(s):

See also the following entry.

Company Group Licensing or Recognition

Regulatory Function:

Efficiency for Multinational Operation

Problem:

Group operations trigger the need for multiple authorisations, whilst a joint assessment of all members of the group would be more appropriate.

Solution(s):

Introduce group licensing or recognition of groups for specified sectors/activities.

Reference(s):

Australia – Banking Act 1959, Part II Division 1AA (Sections 11AA–11AE) and Section 11AF; APRA Prudential Standard APS 222 "Associations with Related Entities": establishes authorisation regime for Non-Operating Holding Companies (NOHCs) of banking groups, enabling group-level authorisation and consolidated prudential supervision (Level 2 and Level 3) rather than requiring separate authorisation procedures for each group member, with group-wide risk management policies and information provision to facilitate efficient multinational group operations.

Mexico – Ley para Regular las Agrupaciones Financieras; Comisión Nacional Bancaria y de Valores (CNBV) authorisation regime for Grupos Financieros: establishes authorisation system for financial holding companies (Grupos Financieros) authorised to acquire and administer voting shares of multiple financial entities (banks, securities firms, credit organizations), with CNBV authorising group organisation, operation and functioning on a consolidated basis, thereby enabling group-level authorisation and supervision rather than separate procedures for each group member.

Note(s):

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Licensing in View of Company Group

Regulatory Function:

Ensuring Compliance and Transparency

Problem:

Applicants for licensing are often part of a company/corporate group and therefore formally or informally controlled by another legal person in the same or another jurisdiction. At the same time, being part of a group may increase the applicant's abilities and capacities. Both merits being taken into account when deciding on a license.

Solution(s):

Oblige applicants to disclose and detail the embedding into a company/corporate group.

Reference(s):

Ghana – Banks and Special Deposit Act, 2016, Section 7(2)(c).

Note(s):

See also the references of the previous entry as they cover this aspect as well.

Decentralised Manufacturing or Services

Regulatory Function:

Bundling various Authorisations / Licences / Certifications

Problem:

Procedures often depend on the location of manufacture or service. Accordingly, multiple procedures must be followed.

Solution(s):

Establish provisions, particular requirements and checks for decentralised manufacturing or decentralised provision of services.

Reference(s):

Canada – Food and Drug Regulations, Part C, Division 5, C.05.005 (ix) and (x) ("for each clinical trial site …"), confirmed by Draft Guidance on Decentralized Clinical Trials (Health Canada, December 2025): when decentralised clinical trial activities are overseen by a single qualified investigator, all locations (including remote locations) are considered part of one clinical trial site, requiring only one Clinical Trial Site Information form and one research ethics board approval rather than separate authorisations for each location, thereby bundling regulatory procedures for decentralised service provision.

Brazil – ANVISA RDC 214/2018 (Good Practices for Human Cells) and Instrução Normativa 270/2023 (Good Manufacturing Practices for Advanced Therapy Products), Seção X: establish a regulatory framework for decentralised manufacturing (including "Atividades Terceirizadas") of advanced therapy products, requiring Good Manufacturing Practices Certification (CBPF) for active component and finished product manufacturing sites while exempting decentralised starting material production/testing locations (e.g., cell collection centers for gene therapy) from separate certification, with quality oversight centralised through Cell Processing Centers and risk-based management principles applied across the manufacturing network.

Note(s):

Decentralised manufacturing or services might be regarded as implicitly authorised where there are no particular process requirements and where the manufacturing or service providing site is not subject to any conformity assessment.

"Forum Shopping" Avoidance Provisions

Regulatory Function:

Consistent Application Across Jurisdiction

Problem:

Operators may seek out countries with laxer enforcement or interpretation.

Solution(s):

Stipulate application of rules based on place of use/effect, or provide for centralised control.

Reference(s):

Australia – Mutual Recognition Act 1992 (Cth); Automatic Mutual Recognition (AMR) schemes (NSW, Victoria, ACT, Western Australia, and other participating jurisdictions): disqualify applicants from obtaining occupational registration under mutual recognition in any participating state or territory if they have been refused registration for that occupation in any Australian state or territory, thereby preventing intra-national forum shopping by applicants seeking to avoid an adverse decision in one jurisdiction by applying in another.

Note(s):

A similar issue exists with regard to certification bodies. India avoids forum shopping by attributing certain bodies to certain economic operators.

Provisional License or Approval

Regulatory Function:

Flexibility for Applicants, Speeding-up of Activities

Problem:

Applicants for licenses or approvals often have to wait for a long time. Whilst the time might be needed for the proper examination of the application, it might be disproportionate to block the applicant for the entire period.

Solution(s):

Provide for the possibility of provisional licences or approvals or link them automatically to a certain deadline.

Reference(s):

Ghana – Banks and Special Deposit Act, 2016, Section 10.

Chile — Decreto con Fuerza de Ley No. 3/1997 (Ley General de Bancos), Title II (Constitución de los Bancos), Articles 27 and 32: three-stage authorisation including express "Autorización Provisional".

Note(s):

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Temporary "Safe Harbours" or "Sandboxes"

Regulatory Function:

Risk-Managed Pilots

Problem:

Legal uncertainty deters new business models and technologies.

Solution(s):

Designate safe harbour periods or regimes protecting participants from authorisation procedures contingent on compliance with basic process and reporting requirements.

Reference(s):

Australia – Enhanced Regulatory Sandbox introduced by the Treasury Laws Amendment (2018 Measures No. 2) Bill 2019: Corporations Act 2001, sections 926B and 1020B; Corporations (FinTech Sandbox Australian Financial Services Licence Exemption) Regulations 2020; National Consumer Credit Protection (FinTech Sandbox Australian Credit Licence Exemption) Regulations 2020: provides temporary exemption from Australian Financial Services Licence (AFSL) and Australian Credit Licence (ACL) requirements for up to 24 months to enable testing of innovative financial services and credit activities, subject to eligibility criteria (innovation test, net public benefit test), exposure limits ($10,000 individual/$5 million aggregate), notification to ASIC, and ongoing compliance and reporting requirements, thereby creating a risk-managed pilot framework that protects participants from full authorisation procedures during testing.

Argentina – Resolución General Comisión Nacional de Valores 1069/2025, Sección IX: establishes regulatory sandbox ("Sandbox Regulatorio") for tokenisation of securities, providing temporary controlled testing environment valid until 21 August 2026, enabling digital representation of securities under supervised conditions without case-by-case authorisation, with CNV empowered to evaluate and adjust the regime upon expiry, thereby creating time-limited safe harbour for innovative securities tokenisation technologies subject to CNV supervision and risk mitigation measures.

Note(s):

See also this article on the design of regulatory sandboxes.

Approval and Oversight of Entrusted/Authorised Economic Actors

Regulatory Function:

Facilitating Secure and Compliant Trade

Problem:

Businesses with a strong compliance record should benefit from streamlined controls and lower administrative burdens.

Solution(s):

Establishment of Entrusted / Authorised Economic Actor status with formal approval, audits, and periodic review or agreement.

Reference(s):

Australia – Customs Act 1901, Part XA (sections 176–179A) inserted by Customs Amendment (Australian Trusted Trader Programme) Act 2015: establishes Australian Trusted Trader (ATT) Programme enabling the Comptroller-General of Customs to enter into trusted trader agreements with entities that satisfy qualification criteria (including two years trading history, secure supply chain, high compliance levels), subject to documentary assessment and physical validation of operations, conferring trusted trader status and trade facilitation benefits (duty deferral, account manager, FTA certification exemptions), with ongoing oversight through agreement variation, suspension or termination for failure to maintain criteria or breach of conditions.

Argentina – Resolución General AFIP N° 5.107 and Resolución General AFIP N° 5.504/2024: implement Programa Operador Económico Autorizado (OEA) enabling operators meeting established requirements to access significant benefits optimising foreign trade operations management and contributing to international logistics chain security, with systematic presentation processes,

customs informatics/documentary registries, and physical-systematic, remote and selective consolidation procedures for OEA operations.

Note(s):

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Simplified Procedures for Custom, or Heritage Products or Services

Regulatory Function:

Proportionality and Burden Reduction

Problem:

Complex standard compliance is excessive for minor or unique cases.

Solution(s):

Allow for "Specific Technical Documentation" and simplified procedure as an alternative to full conformity assessment in justified cases.

Reference(s):

Canada – Medical Devices Regulations, SOR/98-282, Part 2: lower procedural obligations for custom-made devices (manufactured according to health care professional's written directions giving design characteristics, for sole use of a particular patient or to meet practitioner's special needs).

Brazil – ANVISA Resolução da Diretoria Colegiada (RDC) Nº 305/2019 (24 September 2019): establishes derogation from standard registration/listing requirements for custom-made medical devices (dispositivos médicos sob medida) manufactured exclusively for a particular individual according to qualified health professional's prescription, substituting full registration with simplified two-step process: (i) one-time consent (anuência) per manufacturing facility valid for all future custom devices, and (ii) notification for each Class III/IV device

without awaiting ANVISA approval before manufacture/import, with Classes I/II requiring only initial consent, thereby exempting custom-made devices from pre-market authorisation while maintaining safety oversight through professional prescription, informed consent, and manufacturer responsibility.

Note(s):

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Fast-Track or Simplified Procedures for Minor Cases

Regulatory Function:

Administrative Efficiency and Flexibility

Problem:

Resource-intensive procedures hinder low-impact operations.

Solution(s):

Provision of fast-track or summary procedures (short deadlines, reduced documentation).

Reference(s):

Australia (NSW) – State Environmental Planning Policy (Exempt and Complying Development Codes) 2008; Environmental Planning and Assessment Regulation 2000: establish fast-track pathways for minor and low-risk building works.

Note(s):

-

Fast-Track or Simplified Procedures for Urgent or Cases

Regulatory Function:

Administrative Efficiency and Flexibility

Problem:

Resource-intensive procedures hinder urgent operations.

Solution(s):

Provision of fast-track, emergency, or summary procedures (short deadlines, reduced documentation).

Reference(s):

Australia – Therapeutic Goods Act 1989, Section 23AA; TGA Provisional Approval Pathway: provides expedited registration for prescription medicines treating serious, life-threatening or severely debilitating conditions with unmet clinical need and promising early evidence of major therapeutic advance, allowing provisional approval based on reduced clinical data requirements (incomplete dossier with promising evidence rather than full clinical trial data), contingent on sponsor submitting comprehensive clinical data during provisional registration period, thereby facilitating urgent access where potential benefit outweighs risks of incomplete data.

Brazil – ANVISA Resolução da Diretoria Colegiada (RDC) Nº 1.001/2025: establishes priority classification for medicine registration petitions addressing neglected, emerging or reemerging diseases, public health emergencies, or serious debilitating conditions where no therapeutic alternative is available or medicine presents significant improvement in safety/efficacy/adherence, with Ministry of Health empowered to request priority analysis of vaccine registrations to meet public health programs, thereby providing expedited review pathway for urgent and high-impact medicines.

Note(s):

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"Green Channels" (Automated Regulatory Processing) for Low-Risk Activities

Regulatory Function:

Administrative Efficiency

Problem:

Low-risk operators face unnecessary procedural burdens.

Solution(s):

Permit digital fast-tracking or green channels with spot verification for low-risk cases.

Reference(s):

South Africa – Customs and Excise Act 1964; Amendment of Rules (DAR81): establish red and green channel system with green channel providing automated clearance for low-risk travelers (with nothing to declare or within duty-free allowances) who are deemed to have declared goods by entering green channel; supported by electronic clearance system enabling Single Administrative Document submission through Electronic Data Interchange (EDI) with digital signatures and eFiling platform, subject to spot verification checks to maintain compliance while facilitating low-risk traffic flow.

Bolivia – Reglamento a la Ley General de Aduanas (RLGA), Article 106: establishes selective or random channel assignment system for customs clearance, with canal verde (green channel) providing authorisation of immediate automatic merchandise release (levante automático) without physical inspection or documentary review once IT system assigns green channel, enabling direct

progression to final release step, thereby providing digital green channel for low-risk imports through fully automated processing.

Note(s):

The second reference distinguishes not only between a green and a red channel, but also provides a yellow channel with accelerated documentary control in-between.

Authorisation for New Economic Operators

Regulatory Function:

Inclusion and Clarification

Problem:

Regulatory frameworks must keep pace with new business models or roles—e.g., 3D-printing service providers, digital-only intermediaries.

Solution(s):

Define in law the obligations and rights of novel actors and assign their treatment/obligations and authorisation procedure to one or several existing categories of actors or set up new obligations and procedures.

Reference(s):

Ghana – Payment Systems and Services Act, 2019 (Act 987): establishes five distinct licensing categories for new economic operators including Dedicated Electronic Money Issuers (DEMIs, reserved for Ghanaian entities) authorised for wallet management and mobile money services, three tiers of Payment Service Providers (Enhanced, Standard, Medium) with graduated permissible activities from full payment infrastructure to entry-level services, and Payment and Financial Technology Service Providers (PFTSPs) for digital product development and KYC/fraud management, with sixth category Virtual Asset

Service Providers (VASPs) under development for crypto services, providing comprehensive definitions of agent, acquirer, payment gateway, switching, routing, and liability shift to clarify obligations and rights of novel fintech actors.
Chile – Ley Nº 21.521 (Ley Fintech), published January 2023: establishes first formal legal framework regulating fintech industry, defining seven new categories of financial service providers (Investment Advisory, Credit Advisory, Crowdfunding Platforms, Alternative Trading Systems, Order Routing, Financial Instrument Intermediation, Financial Instrument Custody) supervised by Comisión para el Mercado Financiero (CMF), introducing specific concepts of regulated financial instruments and crypto-assets/virtual financial assets, requiring entities to register in Registro de Prestadores de Servicios Financieros with CMF and obtain specific authorisation for each service (registration alone insufficient), with general requirements/principles in law and specific licensing requirements established by CMF through administrative norms enabling dynamic regulatory adaptation addressing emerging business models, technologies, or risks without legislative reform.

Note(s):

Avoids regulatory "dark zones".

Higher Level Decision Power for High-Risk Sectors/Services/Products

Regulatory Function:

Uniform High-Level Risk Control

Problem:

Devolved enforcement may be inadequate in high-risk or critical areas.

Solution(s):

Central / higher level authority given overriding or direct regulatory/supervisory powers for specific cases.

Reference(s):

Australia (Queensland, Victoria, South Australia) – Planning Acts establishing Ministerial call-in powers: delegate development application assessment and approval to local councils as consent authorities, while reserving to State Minister for Planning the power to "call in" certain applications in exceptional circumstances where state economic or environmental interests are involved, with Minister (or Minister-appointed State Planning Commission) assuming role of assessment manager and consent authority for called-in applications, thereby enabling state-level decision-making for high-impact or problematic cases while maintaining local assessment for routine development.

Brazil – Lei Federal Nº 9.782/1999, Article 7, §1 and §2: Article 7 §1 authorises ANVISA to delegate to States, Federal District and Municipalities execution of health surveillance attributions, expressly excepting nine high-risk functions including Item IX (granting product registrations), Item VIII (consenting to import/export of products), Item XV (prohibiting manufacture/import/distribution/ commercialization in case of violation or imminent health risk), and Item XVI (canceling company operating authorisations in case of violation or imminent risk), thereby establishing delegated licensing/authorisation system for routine health surveillance while reserving to federal authority the core high-risk functions of product registration, import/export consent, and emergency prohibition/cancellation powers for imminent health risks.

Article 7 §2 gives control and intervention rights to ANVISA even where competences have been devolved.

Note(s):

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Comparative Assessments in View of Goals

Regulatory Function:

Optimising Regulatory Goals

Problem:

Some policy goals merit being pursued in the best possible way. Setting a benchmark will mostly lag behind the optimal solution.

Solution(s):

Create a legal base for authorising only the best or least harmful products, substances, services, processes or actors.

Reference(s):

Canada – Certain Products Containing Toxic Substances Regulations, SOR/2025-36, Sections 3(1)(c) and 4(2)(a): require permit applications to include evidence with supporting documents that it is not technically or economically feasible to use alternative or substitute achieving similar result with less harmful effect on environment or human health (Section 3(1)(c)), and condition permit issuance on applicant having established that no such less harmful alternative is technically or economically feasible (Section 4(2)(a)), thereby mandating comparative assessment of existing safer alternatives as procedural step in authorisation decision, with authorisation refused where less harmful alternative exists and is feasible.

Note(s):

- This approach is particularly relevant for environmental and health aspects.
- The comparative assessment can also be integrated into ex post control measures, see the separate entry "Ban Based on Comparison" in Chapter K.
- Moreover, both can be matched by an obligation to optimise, incumbent on actors, e.g. to apply the best available option or technique or the obligation to reduce risks as much as possible.

Clear Sampling and Acceptability Criteria

Regulatory Function:

Compliance Ensurance, Legal Certainty, Fairness

Problem:

Without precise rules authorities apply different benchmarks for sampling and acceptability of test results.

Solution(s):

Establish precise rules on the number of samples to be taken, frequency of sampling and limits of tolerated non-conformity.

Reference(s):

Argentina – Resolución SENASA N° 228/2021, Section 6: specifies that one sample has to be taken and the presence of one living insect triggers the rejection of the application / licence.

Note(s):

Also relevant for certification by (private) control bodies and ex post controls, thus outside licensing and certification. See: United Kingdom – The Water Supply (Water Quality) Regulations 2016 (SI 2016/614), Schedules 3 and 4: Establish precise rules on the standard sampling frequency per year (e.g., based on population served) and the specific acceptability criteria (parametric values) that must be met to ensure compliance with water quality standards.

Voluntary Agreements as Compliance Tools

Regulatory Function:

Alternative Pathways to Compliance / (Partial) Replacement of Authorisation Procedures

Problem:

Not all regulatory objectives are efficiently achieved through classic mandatory rules to be examined in authorisation procedures.

Solution(s):

Allow voluntary agreements (e.g., self-regulation, codes of conduct) to be recognised as evidence of compliance if they meet set standards and are monitored. Recognise the fulfilment of the voluntary agreement as a (partial) replacement of an authorisation procedure.

Reference(s):

Australia – Corporations Act 2001, Sections 1101A to 1101AD: Section 1101A authorizes Australian Securities and Investments Commission (ASIC) to approve by legislative instrument a code of conduct relating to any aspect of activities of Australian financial services licensees, authorised representatives or issuers of financial products upon application (subsection (1)), with ASIC empowered to identify provisions as enforceable code provisions if appropriate (subsection (2)), and approval contingent on ASIC satisfaction of prescribed matters (subsection (3)), with "approved code of conduct" defined as code approved by ASIC under section 1101A, thereby establishing voluntary industry self-regulation framework where regulated entities develop codes and apply for governmental approval, with ASIC serving as independent overseer verifying persons are bound by codes.

Colombia – Ley 964 de 2005, Articles 24-28; Decreto 1565 de 2006 (not in force anymore): establish self-regulatory organizations (Organismos de Autorregulación) in securities market with function to establish rules of conduct and operational rules for members and ensure disciplinary mechanisms, requiring regulations of self-regulatory organisations and all modifications to be previously authorised by Superintendencia Financiera de Colombia prior to entry into force.

Note(s):

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Voluntary Conformity Procedure as Compliance Enhancement

Regulatory Function:

Compliance Ensurance

Problem:

Actors sometimes do not know how to ensure compliance.

Solution(s):

Offer a voluntary conformity procedure.

Reference(s):

Canada – Transport Canada Small Vessel Compliance Program (SVCP), established under the authority of the Canada Shipping Act 2001 (S.C. 2001, c. 26), Sections 10 and 10.1: the Act empowers the Minister to establish inspection and certification schemes for vessels, and under this authority Transport Canada has created the SVCP as a voluntary compliance programme under which operators of small commercial vessels submit to periodic third-party inspections against regulatory requirements and, upon satisfactory completion, receive a compliance decal and are entered in a compliance register; participation in the SVCP is taken into account by Transport Canada inspectors as evidence of compliance in enforcement prioritisation, explicitly reducing the frequency and intensity of mandatory inspection interventions for enrolled vessels and thereby institutionalising voluntary certification as a recognised compliance enhancement tool that lowers regulatory burden on compliant operators.

Brazil – INMETRO Regulatory Model (2022), Sections 7.4 and 7.6; Brazilian Conformity Assessment System: establish conformity assessment system divided into compulsory certification (products must carry INMETRO logo before market sale) and voluntary certification (products in mandatory list could be tested voluntarily), with INMETRO Regulatory Model requiring market surveillance authorities to "take into account voluntary conformity assessment procedures" (by reduced sampling or control intensity).

Note(s):

It is also possible to open the door for the voluntary application of a stricter conformity assessment procedure, providing better market opportunities.

Priority Procedure for Sustainable or Strategic Products or Services

Regulatory Function:

Innovation & Strategic Autonomy

Problem:

Critical or green innovations can be blocked by administrative delays.

Solution(s):

Fast-track or elevate priority for sustainable, strategic, or green applications in administrative procedures.

Reference(s):

Canada – Patent Rules, Section 28(1)(b): authorise expedited patent examination for applications relating to technology whose commercialisation would "conserve the natural environment and resources" or "help to resolve or mitigate environmental impacts," requiring applicants to file statement attesting to

environmental benefit when requesting examination, with admitted applications examined approximately 12 months after examination request (compared to standard timeline).

Canada – Building Canada Act (2025): create a new classification system identifying projects of "national interest" with mechanisms to fast-track approval, particularly focused on streamlining permitting procedures for critical mineral projects, energy infrastructure, and developments deemed essential to Canada's economic security and clean energy transition.

Colombia – Decreto 1020/2024; Decreto 2767/2012, Article 1; Ley 1483/2011: create Comisión Intersectorial de Proyectos Estratégicos (CIPE - Intersectoral Commission for Strategic Projects) to orient functions of public entities participating in structuring strategic projects, requiring investment projects exceeding government period to be previously declared of strategic importance by Government Councils of territorial entities (Decreto 2767/2012, Article 1); with infrastructure, energy and communications projects required to include definition of priority works and detailed engineering, thereby establishing institutional framework for coordination and prioritisation of strategic projects including energy infrastructure with strategic importance declaration enabling expedited multi-period authorisation.

Note(s):

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Transfer of Licence or derived Rights

Regulatory Function:

Administrative Burden Reduction, Protection of Rights

Problem:

It is an unnecessary burden to undertake a full new assessment when certain activities or rights are transferred from one person to the other.

Solution(s):

Provide for a reduced authority verification in case of transfer of a licence or of certain rights derived from the licence.

Reference(s):

Rwanda – Law Governing Biological Diversity, 2021, Section 43.

Zambia – Agricultural Credits and Warehouse Receipts Act, 2026, Section 16.

Solomon Islands – Special Economic Zones Act 2025, Sections 31 and 32.

Kenya – Environmental (Impact Assessment and Audit) Regulations, 2003 (LN 101/2003), Regulation 26.

Chile – Ley No. 18.892/1989 (Ley General de Pesca y Acuicultura), Article 55 N.

Note(s):

- See also Division 4.3 of Australia's Therapeutic Goods (Medical Devices) Regulations 2002 (Cth). It refers to certificates issued by conformity assessment bodies, but provides granular rules that could be useful in a licensing context as well.

- See also Australia — Therapeutic Goods Regulations 1990, Regulation 10F.

Death, Insolvency or Winding-up of Licensee: Protection of Rights and Oversight

Regulatory Function:

Continuity of Market Oversight, Protection of Rights

Problem:

Licensed natural persons can die, licensed legal persons can cease to exist, and both can fall into insolvency and subsequent administration. However, their rights might need to be preserved.

Solution(s):

Provide a procedure ensuring the continuity of rights and oversight.

Reference(s):

Australia — Therapeutic Goods Regulations 1990, Regulation 10F.

Note(s):

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Change of Name of Licensee: Protection of Rights and Oversight

Regulatory Function:

Continuity of Market Oversight, Protection of Rights

Problem:

Licensed natural or legal persons can change names.

Solution(s):

Provide a procedure ensuring the continuity of rights and oversight.

Reference(s):

Australia — Therapeutic Goods Regulations 1990, Regulation 10FA.

Note(s):

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Publication of Licences

Regulatory Function:

Transparency and Compliance

Problem:

It is sometimes difficult for enforcement authorities, e.g. ordinary police, to know whether a certain actor has obtained a licence or not.

Solution(s):

Publish licences.

Reference(s):

Rwanda – Law Governing Biological Diversity, 2021, Section 24.

Brazil – Lei No. 6.938/1981 (Política Nacional do Meio Ambiente), Art. 10 § 1; Art. 19, Resolução CONAMA No. 237/1997, Article 10(VIII).

Note(s):

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Digital "Credential Wallets" for Operator/Staff Approval/Certification

Regulatory Function:

Streamlined Credential Verification

Problem:

Traditional paper or isolated digital certificates impede mobility and trust.

Solution(s):

Mandate or permit use of verifiable digital wallets for staff/operator qualifications.

Reference(s):

India – Information Technology (Preservation and Retention of Information by Intermediaries Providing Digital Locker Facilities) Rules 2016, with additional Rule 9A (notified on February 8, 2017, G.S.R. 711(E)): deem issued documents in DigiLocker system to be at par with original physical documents, with Rule 9A(1) enabling issuers to issue and requesters to accept digitally signed certificates or documents shared from subscribers' Digital Locker accounts at par with physical documents, and Rule 9A(2) deeming documents issued by issuer and accessed by requester through URI as shared directly in electronic form, enabling digital storage of identity documents (Aadhaar, Driving License, PAN, Passport), academic credentials (degrees, diplomas), and professional certificates (professional certificates, skill certificates, employment documents) with regulatory recognition through Ministry of Finance PMLA Guidelines and RBI/SEBI Master KYC Circular accepting DigiLocker e-Docs as valid Officially Valid Documents, thereby establishing digital public infrastructure credential wallet with legal equivalence to physical documents under Information Technology Act 2000 framework.

Note(s):

In Latin America, we did not find a proper wallet, but just laws providing for the validity of electronic documents. See e.g.: Argentina – Decreto 744/2019: enables use of digital DNI (Documento Nacional de Identidad) throughout national territory through Decreto 744/2019, with virtual credential for smart mobile devices via Mi Argentina app considered for all effects National Identity Document having full identificatory value in all public and private acts under Law 17.671 (except voting and foreign travel), complementing but not replacing physical DNI with same legal validity.

Also see the following Chapter E, which contains elements suitable for authorisation procedures.

E. Certification by Private Conformity Assessment Bodies

Also see the previous Chapter D, which contains elements suitable for certification by private conformity assessment bodies ('certification bodies').

Third-Party (Conformity) Assessment System

Regulatory Function:

Assurance of Independence and Credibility

Problem:

Self-certification may not engender trust or ensure safety.

Solution(s):

Require third-party conformity assessment by notified/accredited certification bodies for defined products, services or risks.

Reference(s):

United Kingdom — Medical Devices Regulations 2002 (SI 2002/618, as amended), regs. 45–48. Regs. 45–48 of the Medical Devices Regulations 2002 establish the statutory requirement for manufacturers of Class IIa, IIb, III devices to obtain a conformity assessment certificate from an Approved Body designated by the Agency MHRA before placing a UKCA-marked device on the GB market.

India — Bureau of Indian Standards Act, 2016 (No. 11 of 2016), Sections 13(4), 16–17. BIS (Conformity Assessment) Regulations, 2018, Regs. 3–4, 12-14 and Schedule II (Schemes I, IV, and V).

Mexico — Ley Federal sobre Metrología y Normalización (LFMN), Articles. 3(I), 3(XII), 68, 73 and 74, partly to be combined with sector legislation rendering the application of the system mandatory.

Note(s):

See also the sixth entry of this Chapter "Accreditation for Certification Bodies or Laboratories".

Independence and Impartiality of Certification Bodies

Regulatory Function:

Impartiality

Problem:

Lack of separation of functions may allow conflict of interest.

Solution(s):

Separation or walling off tasks as certification body vs. other business (e.g. as consultancy); prohibition on capital or other contractual links to the company to be certified; prohibition of competition with that company

Reference(s):

India — Bureau of Indian Standards Act, 2016 (No. 11 of 2016):

- Section 9(2)(f): power of BIS to recognise or accredit institutions engaged in conformity certification and inspection;
- Section 13(4): power to recognise testing laboratories for conformity assessment purposes;
- Section 16(2): Central Government may authorise any agency having necessary accreditation to certify and enforce conformity — making NABCB accreditation to ISO/IEC 17065 (including clause 4.2 on

impartiality and separation of tasks) the statutory gateway for third-party agency designation.

Combined with ISO/IEC 17065:2013, clauses 4.2.1–4.2.9 (not verified), and therein in particular:

- Clause 4.2.4: The certification body shall not offer or provide management system consultancy or internal auditing to certification clients
- Clause 4.2.7: The certification body shall ensure activities of separate legal entities with which it has relationships do not compromise impartiality
- Clause 4.2.8: Where a related entity offers consultancy or the certified product, certification body management and decision-making personnel shall not be involved in that entity's activities, and vice versa
- Clause 4.2.9: The certification body's activities shall not be marketed or offered as linked with consultancy activities.

Mexico — Ley Federal sobre Metrología y Normalización (LFMN), Arts. 68–70, read with EMA Accreditation Rules (ISO/IEC 17065:2013).

Brazil — Portaria INMETRO nº 118/2022, Annex A, Sections 2.3 and 2.3.1.

Note(s):

The first two references establish independence criteria via references to an international standard. It might be preferable to establish such criteria in the legislation itself, as partly done in the third and in regulations of the European Union, see the parallel "EU Legislators' Toolbox", Chapter E.

Quality Management System Requirements for Certification Bodies

Regulatory Function:

Stable Performance

Problem:

Assessment bodies may lack internally harmonised procedures and improvement loops.

Solution(s):

Legal requirement for a (certified) quality management system.

Reference(s):

India — Bureau of Indian Standards Act, 2016 (No. 11 of 2016): Sections 9(2)(f) and 16(2), read with NABCB Notification No. 6/5/2017-BIS, NABCB Accreditation Criteria and ISO/IEC 17065:2012, Section 8 (quality management system).

Colombia — Decreto 1074/2015, Article 1.1.3.20., read with ONAC document LN-3.3-01 (Lineamientos para la evaluación de Organismos de Certificación de Productos, Procesos y Servicios, Version 04, August 2024), mandating ISO/IEC 17065:2012, and thus its Section 8 (quality management system).

Note(s):

Both references mandate the quality management system via references to an international standard. It might be preferable to establish such criteria in the legislation itself, as partly done in regulations of the European Union, see the parallel entry in "EU Legislators' Toolbox", Chapter E.

Limiting the Use of Subcontractors and External Staff by Bodies

Regulatory Function:

Transparency and clear Responsibility

Problem:

Uncontrolled outsourcing and use of external consultants may reduce

accountability for certification bodies. Bodies tend to list as "staff" persons who work also for various other bodies, without clear primary loyalty to the certification body. Both phenomena lead to the emergence of 'empty shell' bodies.

Solution(s):

Regulate, require disclosure/registration, and in some cases limit use of subcontractors. Reserve core and decision-making functions to staff employed under labour law.

Reference(s):

India — Bureau of Indian Standards Act, 2016 (No. 11 of 2016): Sections 9(2)(f) and 16(2), read with NABCB Notification No. 6/5/2017-BIS, NABCB Accreditation Criteria and ISO/IEC 17065:2012, Clause 6.3 (Subcontracting). ISO/IEC 17065:2012, Clause 6.3 (not verified) requires that:

- The certification body take full responsibility for all subcontracted work (clause 6.3.1)
- Subcontracting be carried out only to competent bodies/individuals meeting the applicable requirements (clause 6.3.2)
- The client's consent be obtained before any subcontracting (clause 6.3.3)
- The certification body maintain a register of all subcontractors used (clause 6.3.4)
- Certification decisions may not be subcontracted (clause 7.6, read with clause 6.3).

Colombia — Decreto 1074/2015, Article 1.1.3.20., read with ONAC document LN-3.3-01 (Lineamientos para la evaluación de Organismos de Certificación de Productos, Procesos y Servicios, Version 04, August 2024), mandating ISO/IEC 17065:2012, and thus its Section 6.3.

Note(s):

Both references establish independence criteria via references to an international standard. It might be preferable to establish such criteria in the legislation itself, as partly done in regulations of the European Union. See the

partly more granular and more abuse-preventing provisions in Regulation (EU) 2024/3110 (Construction Products), Articles 46(8) and 48 and Regulation (EU) 2017/745 (Medical Devices), Annex VII, Section 3.4.

External Testing Facilities

Regulatory Function:

Ensuring Quality and Reliability of Test Results

Problem:

Tests performed outside the certification body's own laboratory risk loss of traceability, comparability and result quality.

Solution(s):

External test facilities must have calibrated equipment; traceability and quality of measurements must be ensured.

Reference(s):

See the previous entry.

Note(s):

-

Accreditation for Certification Bodies or Laboratories

Regulatory Function:

Quality of Assessors

Problem:

Divergence in the reliability of notified bodies undermines outcomes. States' authorities are not necessarily good at checking the quality systems of bodies.

Solution(s):

All certification bodies should be accredited against harmonised requirements (not standards).

Reference(s):

United Kingdom — Medical Devices Regulations 2002 (SI 2002/618, as amended), Regulation 46, read with the Accreditation Regulations 2009 (SI 2009/3155), Regulation 3. Reg. 46 sets out the mandatory designation criteria, requiring that candidate Approved Bodies must first obtain UKAS accreditation (the UK national accreditation body under reg. 3 of SI 2009/3155) to the relevant ISO/IEC 17000-series standard before the MHRA may designate them, after which the MHRA carries out its own assessment and formally designates the body by administrative instrument.

Mexico — Ley Federal sobre Metrología y Normalización (LFMN), Arts. 3(I), 3(XII), 68, 73 and 74.

Note(s):

- The UK system provides for a two level designation system of conformity assessment bodies: first, the candidate bodies need to be assessed by the national accreditation body UKAS; second, the agency MHRA decides on the designation. These two layers provide for a more comprehensive assessment of the candidate bodies.

- Accreditation bodies mostly outperform authorities or state agencies with regard to the quality management assessment, whilst authorities or state agencies can better assess the technical competence of the candidate conformity assessment bodies, provided that they are technically competent themselves. The highest quality of certification bodies is achieved through

systems in which both accreditation bodies and authorities supervise certification bodies.

- Accreditation is often based on standards rather than applicable legal requirements. Furthermore, accreditation usually relates to a group of legal entities rather than a specific body. Therefore, verification by the relevant authorities is also required.

Documentation for Application as Body

Regulatory Function:

Transparency in Body Notification

Problem:

Without full documentation relating to the precise applicant legal person, assessing notification eligibility is impossible.

Solution(s):

Application must include CVs, contracts, and accreditation documentation corresponding precisely to the legal person applying.

Reference(s):

Canada — DES-CB: Procedure for the Designation of Canadian Certification Bodies (Issue 4, June 2016), Section 5.

Colombia — Decreto 1074/2015, Article 1.1.3.20., read with ONAC, Reglas del Servicio de Acreditación, RAC-3.0-01 (v.12), Section 5.1, and ONAC document LN-3.3-01 (Lineamientos para la evaluación de Organismos de Certificación de Productos, Procesos y Servicios, Version 04, August 2024).

Note(s):

- Promotes professionalisation and prevents 'empty shell' notifications.

- Must evidently match the designation criteria.

On-Site Audits of Bodies and Economic Operators

Regulatory Function:

Depth in Oversight Procedures

Problem:

Paper assessments may not reveal real operational quality.

Solution(s):

Mandate on-site audits, unless the documentation review already establishes non-compliance.

Reference(s):

Singapore — CT 01: Accreditation Process for Certification Bodies and V&V Bodies (01 January 2026), Section 4.4.3.

Colombia — Decreto 1074/2015, Article 1.1.3.20., read with ONAC, Reglas del Servicio de Acreditación, RAC-3.0-01 (v.12), Section 6.4.2, and ONAC document LN-3.3-01 (Lineamientos para la evaluación de Organismos de Certificación de Productos, Procesos y Servicios, Version 04, August 2024).

Note(s):

- Some jurisdictions provide for the possibility of optional preliminary audits, see e.g. Singapore — CT 01: Accreditation Process for Certification Bodies and V&V Bodies (01 January 2026), Section 4.3.

- Regulation (EU) 2017/745 on medical devices takes the concept of on-site audits a step further by mandating so-called 'observed audits', in which notified bodies assess manufacturers under the supervision of the designating/notifying authorities.

Periodic (full) Reassessment of Bodies

Regulatory Function:

Quality Assurance of Conformity/Assessment Bodies

Problem:

Bodies may lose competence or impartiality over time.

Solution(s):

Mandatory periodic review, re-accreditation or re-designation of certification bodies (full assessment).

Reference(s):

Singapore — CT 01: Accreditation Process for Certification Bodies and V&V Bodies (01 January 2026), Section 4.6.2.

Colombia — Decreto 1074/2015, Article 1.1.3.20., read with ONAC, Reglas del Servicio de Acreditación, RAC-3.0-01 (v.12), Section 6.8, and ONAC document LN-3.3-01 (Lineamientos para la evaluación de Organismos de Certificación de Productos, Procesos y Servicios, Version 04, August 2024).

Note(s):

Consider mandating onsite-audits as part of the reassessment.

Ongoing Monitoring and For-Cause-Audits of Bodies

Regulatory Function:

Quality Assurance of Conformity/Assessment Bodies

Problem:

Bodies may lose competence or impartiality over time.

Solution(s):

Mandate ongoing monitoring and For-Cause-Audits, based on:

- Market surveillance data;
- Sampling and scrutiny of certificates for the same category of products / services / processes;
- Information on non-compliance of bodies, or economic actors operating under control of the bodies.

Reference(s):

Singapore — CT 01: Accreditation Process for Certification Bodies and V&V Bodies (01 January 2026), Section 4.6.1.

Colombia — Decreto 1074/2015, Article 1.1.3.20., read with ONAC, Reglas del Servicio de Acreditación, RAC-3.0-01 (v.12), Sections 7.1 (periodic) and 7.3 (for cause), and ONAC document LN-3.3-01 (Lineamientos para la evaluación de Organismos de Certificación de Productos, Procesos y Servicios, Version 04, August 2024).

Note(s):

Should be combined with provisions on periodic (full) reassessment.

Rules for "De-Designation"

Regulatory Function:

Quality Assurance of Certification Bodies

Problem:

Non-performing bodies must be removed to guarantee credibility. Where bodies stop their activities for whatever reason, the validity of certificates and the take-over of continuous monitoring tasks of the body have to be regulated.

Solution(s):

Lay out notification, appeal, and enforcement mechanisms for withdrawing designation. Set out consequences, including for certification and continuous monitoring tasks of notified bodies. Give preference to agreements between the parties, but set up fall-back solutions by intervention of authorities.

Reference(s):

Colombia — Decreto 1074/2015, Article 1.1.3.20., read with ONAC, Reglas del Servicio de Acreditación, RAC-3.0-01 (v.12), Section 12, and ONAC document LN-3.3-01 (Lineamientos para la evaluación de Organismos de Certificación de Productos, Procesos y Servicios, Version 04, August 2024).

Note(s):

See also the next entry which is connected to this.

Transfer and Continuity of Certificates when Bodies' stop Activity

Regulatory Function:

Legal Continuity and Supply Chain Integrity

Problem:

Certifications might be lost when a business is transferred to a new legal entity or simply phased out. At the same time, there can be safety / monitoring loopholes.

Solution(s):

If 100% control passed to another legal person, certificates and test reports remain valid; if not, they remain valid for six-months after de-notification.

Reference(s):

Brazil — Portaria INMETRO nº 118/2022, Section 9.

Note(s):

Please contact us for detailed advice on this ultra-complex issue. The references — including the ones in the parallel EU Legislators' Toolbox — do not provide the full range of measures needed to ensure business continuity and safety.

Confidentiality and Data Handling by Bodies

Regulatory Function:

Protection of Commercial Confidentiality

Problem:

Sensitive business data must be protected without obstructing regulatory clarity.

Solution(s):

Enshrine confidentiality as a rule, with dedicated transparency provisions (see previous and next entry) as exceptions.

Reference(s):

Brazil — Portaria INMETRO nº 118/2022, Anexo A, Section 1.

Mexico — Ley Federal sobre Metrología y Normalización (LFMN), Article 70B-VII.

Note(s):

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Reporting Obligations for Bodies

Regulatory Function:

Transparency and Compliance

Problem:

Authorities need timely, full information to ensure oversight and compliance.

Solution(s):

Oblige certification bodies to report refusals, suspensions, key changes, and to respond to all information requests by authorities.

Reference(s):

Brazil — Portaria INMETRO nº 118/2022, various in Section 13.2.

Note(s):

Includes documentation and confidential information sharing for supervision.

Other Obligations for Bodies

Regulatory Function:

Compliance and System Functioning

Problem:

The certification system can only work well where the conformity assessment bodies make updates and respect certain other generic rules ensuring the reliability of the system. In many jurisdictions, these obligations are not spelt out. This creates legal uncertainty and an uneven playing field.

Solution(s):

Oblige certification bodies to fulfil a range of obligations to keep the certification system running well and fairly.

Reference(s):

Brazil — Portaria INMETRO nº 118/2022, Section 13.2.

Mexico — Ley Federal sobre Metrología y Normalización (LFMN), Articles 70B and 70C.

Note(s):

These collateral obligations are often neglected, whilst being paramount for a well-functioning system.

Bodies to Support Authority Controls

Regulatory Function:

Compliance and System Functioning

Problem:

After certification, surveillance of conformity of marketed products and services is primarily the task of the responsible authority. However, certification bodies might be better placed and partly more competent than authorities. Moreover, authorities might suffer from scarce resources.

Solution(s):

Oblige certification bodies to support authorities, e.g. by undertaking sampling and testing on their behalf.

Reference(s):

Brazil — Portaria INMETRO nº 118/2022, Section 14.

Note(s):

Alternatively or in addition, bodies can be obliged to maintain their own surveillance (sampling and testing) system for certified products or services offered on the market, see the following entry.

Peer Reviews of Bodies

Regulatory Function:

Inter-Body Alignment, Dissemination of Best Practices

Problem:

Fragmentation of assessment approaches/staff skills over time.

Solution(s):

Bodies subjected to peer review by other bodies.

Reference(s):

Canada — Standards Council of Canada Act, R.S.C., 1985, c. S-16: the Act mandates the SCC to accredit conformity assessment bodies, and SCC maintains its accreditation authority through periodic peer evaluations by the IAF and ILAC as a condition of MLA/MRA signatory status (SCC – About accreditation, SCC – Accreditation Program Manual); but no mandatory peer review based on a legal provision.

Australia — National Association of Testing Authorities (NATA) operates under a Memorandum of Understanding with the Australian Commonwealth Government and is peer-evaluated as an ILAC MRA / IAF MLA signatory, ensuring its accreditation system remains equivalent to those of other bodies (APH submission, NATA – Stakeholder Engagement); but no mandatory peer review based on a legal provision.

Mexico — Ley de Infraestructura de la Calidad (2020), Article 70, combined with Inter-American Accreditation Cooperation (IAAC): Article 70 governs mutual recognition agreements. The Inter-American Accreditation Cooperation (IAAC), namely its Multilateral Recognition Arrangement (MLA) procedures require accreditation bodies to be peer-evaluated at set intervals to verify continued compliance with international criteria (see IAAC FAQ, IAAC MLA Policies & Procedures). Mexico's *entidad mexicana de acreditación* (ema) is a signatory.

Note(s):

The peer reviews of these references are peer reviews of accreditation bodies, meaning bodies that assess other conformity assessment bodies or testing laboratories. Evidently, peer review is also meaningful for the (ordinary) conformity assessment bodies or testing laboratories themselves.

Bodies Surveillance (Sampling and Testing) System for Certified Products and Services

Regulatory Function:

Post-Certification Market Integrity

Problem:

Initial certification confirms conformity at a point in time; without an ongoing sampling and market-testing obligation on the certification body itself, non-conformities arising in series production or in the market may remain undetected between scheduled audits.

Solution(s):

Require certification bodies to sample from production and/or the open market, testing.

Reference(s):

Mexico — Ley Federal sobre Metrología y Normalización (LFMN), Articles 101 I. and 103.

Brazil — Portaria INMETRO 148/2022 (household electrical appliances), Section 6.1.2.2.2.2.

Note(s):

See also the repealed version of Section 6.1.2.2.2.2 of the Brazilian reference: alternating factory and market sampling.

Obligations for Certified Economic Actors

Regulatory Function:

Compliance and System Functioning

Problem:

The certification system can only work well where the certified actors make updates, inform the body and authorities and respect certain other rules. In many jurisdictions, these obligations are not spelt out. This creates legal uncertainty and an uneven playing field.

Solution(s):

Oblige certified economic actors to fulfil a range of obligations to keep the certification system running well and fairly.

Reference(s):

India — Bureau of Indian Standards Act, 2016 (No. 11 of 2016): Section 18.

Brazil — Portaria INMETRO nº 118/2022, Sections 13.1 and 14.1/14.2.

Note(s):

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Recognition of Previous Tests, Certification or Authorisation in Modular Assessment

Regulatory Function:

Assessment Efficiency and Avoidance of Redundancy

Problem:

Testing may be unnecessarily repeated for products/modules already reliably tested.

Solution(s):

Allow manufacturers to rely on prior compatible test results for essential components, interim products, characteristics or modules, under specific conditions.

Reference(s):

Australia — National Construction Code 2022 (NCC 2022), adopted by reference under State and Territory building legislation (e.g. section 7, Building Act 1975 (Qld); section 16, Building Act 2000 (Tas)): Clause A5G3 (Evidence of Suitability).

Brazil — Portaria INMETRO nº 118/2022, Section 6.2.3.2 onwards: setting out what needs to be verified even where there is a certificate that can be built-on.

Note(s):

Necessary to ensure that the 2nd assessment body is informed when the 1st assessment body withdraws or limits the certificate or test report.

For other aspects falling under this Chapter, we recommend:

1. The references provided by our parallel EU Legislators' Toolbox in its Chapter E;
2. The Brazilian Portaria INMETRO nº 118/2022.

These references close at least partly the many regulatory loopholes created by mere references to the international standardisation (ISO/IEC) and accreditation (IAF) systems.

F. International Matters

"Extraterritorial" Scope Covering Companies abroad Targeting the National Market

Regulatory Function:

Enforcement in the Digital Age

Problem:

Foreign providers can evade regulation despite substantial national impact.

Solution(s):

Explicitly extend law to non-national actors offering services or selling in the national market.

Reference(s):

Australia – Competition and Consumer Act 2010, Sections 4N and 5: extends application of the Act to conduct engaged in outside Australia by corporations incorporated or carrying on business within Australia, thereby capturing foreign corporations with Australian business presence that engage in conduct abroad affecting Australian consumers or competition, establishing extraterritorial reach even for contracts formed abroad with non-Australian citizens where foreign corporation carries on business in Australia.

Brazil – Lei Geral de Proteção de Dados (LGPD), Lei nº 13.709 (14 August 2018), Articles 3 and 4: establishes extraterritorial application to data processing operations that (i) aim to offer or supply goods and services to people located in Brazil; (ii) process personal data of people located in Brazil; or (iii) process personal data collected in Brazilian territory, with Article 3(§1) specifying that data

are considered collected in national territory when the data subject is located there at the moment of collection.

Note(s):

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Usability of Foreign Investigations

Regulatory Function:

Efficiency and Cross-border Enforcement

Problem:

Where foreign agents or administrations act on behalf of the administration in charge, the usability of their findings might be legally questionable.

Solution(s):

Clarify that respective reports and testimonials are usable as evidence.

Reference(s):

Sri Lanka – Proceeds of Crime Act 5/2025, Section 65(10): reports of foreign officers can be used as if they were domestic reports.

Colombia, Ley 906 de 2004 (Código de Procedimiento Penal), Articles 427 and 429A.

Brazil – Lei nº 9.782, de 26 de janeiro de 1999 (Establishes the National Health Surveillance System), Article 7, paragraph 7 added by Lei nº 13.097/2015: explicitly empowers ANVISA to use confidential information about inspections received within the framework of agreements or arrangements with health surveillance authorities of other countries (*utilizar de informações confidenciais sobre inspeções recebidas no âmbito de acordos ou convênios com autoridade sanitária de outros países*), and further to authorise inspections and audits of manufacturing plants by nationally or internationally accredited institutions,

thereby creating a direct statutory basis for receiving and using foreign regulatory database and inspection information under confidentiality safeguards.

Note(s):

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Inspections and Enforcement outside the National Territory

Regulatory Function:

Global Supply Chain Control

Problem:

Product ingredients, parts, or data processed or services provided outside the national territory require direct oversight for safety and compliance.

Solution(s):

Grant national bodies or authorities explicit legal powers to audit or inspect facilities/information outside the country.

Reference(s):

Bahamas – Air Navigation Services Act 2021, Section 6: authorises the delegation of tasks, to be executed abroad, apparently to natural and legal persons of the same and other jurisdictions.

Argentina – ANMAT Disposición 7998/2025 (27 October 2025): establishes procedures for certifying Good Manufacturing Practices also at foreign pharmaceutical plants (Article 4 and Annex II), granting Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT) authority to evaluate foreign facilities through documentary assessment, virtual inspections, or on-site inspections using risk-based tiered system, with certificates verified through

official digital platform Visor GEDO, replacing previous mandatory on-site inspection requirement with Good Reliance Practices model recognising trusted foreign regulatory authorities' certifications.

Note(s):

Under international public law, the activities of states on the territory of another state need to be authorised by the latter. The same applies to inspection and enforcement activities by national regulatory authorities in foreign jurisdictions.

Reporting Duties for Third-Country Operators

Regulatory Function:

Level Playing Field Across Borders

Problem:

Non-national actors otherwise evade reporting requirements by operating solely abroad.

Solution(s):

Mandate third-country operators addressing the national market to appoint nationally-based representatives for reporting/communication.

Reference(s):

South Africa – Protection of Personal Information Act (POPIA), Act 4 of 2013, Section 55 read with Information Regulator guidance on information officers: requires responsible parties (data controllers) established outside South Africa but processing personal information of South African data subjects to appoint an authorised representative within South Africa, who acts as point of contact for the Information Regulator and serves as conduit between the Regulator and the information officer of the responsible party, with all registered information officers required to be based in South Africa.

Brazil – Lei Geral de Proteção de Dados (LGPD), Lei nº 13.709 (14 August 2018), Article 61: requires foreign companies that process personal data of individuals in Brazil to appoint a Brazilian legal representative (DPO or local agent).

Note(s):

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Access to Databases for Foreign Partners

Regulatory Function:

International Regulatory Engagement

Problem:

Trusted foreign countries / partners may need access to facilitate mutual regulatory oversight.

Solution(s):

Grant conditional access to regulatory information systems, with strict safeguards (confidentiality, data protection, engagement).

Reference(s):

Australia / Canada / Singapore / UK / Switzerland – Access Consortium work-sharing framework for medicines (TGA, Health Canada, HSA Singapore, Swissmedic, UK MHRA): coordinated electronic review of marketing applications using shared regulatory reports and data, under confidentiality and data-protection safeguards and independent national decisions.

Note(s):

- As formal agreements are cumbersome to agree and to administer, we

recommend establishing the power to provide access unilaterally and to use this power where reciprocity, confidentiality and data protection are ensured.
- See also the following entry.

International Data Sharing (General)

Regulatory Function:
Global Data Collaboration

Problem:
Lack of framework for data sharing with third countries damages public policy and cross-border users.

Solution(s):
Legal basis for sharing data internationally, allowing access.

Reference(s):
Australia – Therapeutic Goods Act 1989, Section 61(4) to (5): authorises the Secretary to release "therapeutic goods information" to a national regulatory authority of another country and to an international organisation where there are cooperative arrangements on assessment or regulation of therapeutic goods, including information on advisory committee recommendations, conditions attached to supply, and information on Australian conformity assessment bodies and related determinations.
Zimbabwe – Insurance and Pensions Commission Amendment Act, 2026, Section 12.
Brazil – ANVISA–FDA Confidentiality Commitments: authorise bilateral exchange of non-public regulatory information, with strict obligations to protect confidentiality, limit onward disclosure, and notify of any compelled disclosure,

thus enabling database-level access for cooperative oversight; however, we did not find any statutory provision backing this practice from the Brazilian side.

Note(s):

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Enforcement on behalf of Other Countries

Regulatory Function:

Mutual Enforcement and Regulatory Diplomacy, indirect Support of Own Enforcement abroad

Problem:

Enforcement synergies with aligned third countries are hampered by lack of legal basis.

Solution(s):

Legally permit authorities to support third countries or even to use their enforcement powers on behalf of third countries, contingent on mutual support agreements or de facto reciprocity. Consider establishing rule of law requirements.

Reference(s):

Canada – Competition Act (R.S.C. 1985, c. C-34), Section 74.012 "Assisting foreign states": empowers the Commissioner of Competition, for the purpose of assisting an investigation or proceeding under the competition or consumer laws of a foreign state or of an international organisation, to conduct any investigation the Commissioner considers necessary using all the investigatory powers available under the Act as if the matter were domestic, and to communicate the resulting information to the foreign state or organisation, provided that body gives

written undertakings on use, confidentiality, and comparable assistance, thereby creating an explicit legal basis to deploy Canadian enforcement powers on behalf of trusted foreign partners subject to reciprocity and safeguards.

Eswatini – Suppression of Terrorism Act, 2008, Sections 35 and 36: easier cross-border support where both states adhere to relevant conventions or agreements.

Brazil – Código de Processo Civil (Law No. 13.105/2015), Articles 26-30: authorises Brazilian authorities and courts, upon request from foreign judicial authorities, to provide direct assistance in the form of obtaining and transmitting evidence, information on proceedings, and other procedural acts that do not require prior recognition of a foreign judgment, so long as the requested measures are compatible with Brazilian law and public order; this mechanism enables Brazilian institutions to support foreign civil and commercial enforcement by performing procedural acts and sharing case information on behalf of foreign courts without full exequatur, while preserving jurisdictional limits and due process guarantees.

Note(s):

- Article 26 V §1 of the Brazilian reference refers to the de facto reciprocity of support, supplementing the cases where formal agreements exist. This seems to be a commendable practice.
- Tanzania – Arbitration Act, 2020, Section 78 even provides for the recognition of foreign arbitral awards.

Risk Classification of Third Countries

Regulatory Function:

Unequal Non-compliance Risks

Problem:

Other states and their actors are not equally performing and trustworthy.

Solution(s):

Classify states.

Reference(s):

Canada – Proceeds of Crime (Money Laundering) and Terrorist Financing Act (PCMLTFA) Part 1.1 Section 11.49, and FINTRAC advisories on high-risk jurisdictions: under the federal AML/CFT regime, Canada applies enhanced due diligence and reporting expectations for transactions involving jurisdictions identified by the Financial Action Task Force (FATF) as "high-risk jurisdictions subject to a call for action" or "jurisdictions under increased monitoring", with FINTRAC issuing public advisories directing reporting entities to treat transactions related to such countries with greater scrutiny; this framework effectively embeds a risk classification of third countries into financial-sector compliance obligations.

Peru – Supreme Decree No. 340-2018-EF (tax havens and non-cooperative jurisdictions), Article 86: issued under Peru's Income Tax Law, this decree approves and periodically updates a "black list" of countries and jurisdictions considered tax havens or non-cooperative for tax purposes, based on criteria such as low or no taxation, lack of exchange of information, and harmful preferential regimes; transactions involving persons or entities resident in listed jurisdictions are subject to stricter rules (e.g. limitations on deductibility, withholding tax adjustments), and the Decree sets conditions for adding or removing jurisdictions from the list, thereby establishing a formal risk classification of third countries.

Note(s):

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Regulatory International Alignment

Regulatory Function:

Global Regulatory Alignment

Problem:

Isolated national standards may impede participation in the global economy.

Solution(s):

Obligation to consult, inform, or align with international bodies (e.g., WHO, Codex, ISO, UNECE) or informal alignment bodies (e.g. International Medical Devices Regulatory Forum).

Reference(s):

Australia – Food Standards Australia New Zealand Act 1991, Section 18(2)(b): requires Food Standards Australia New Zealand, in developing or reviewing food regulatory measures and variations of those measures, to have regard to the promotion of consistency between domestic and international food standards, thereby obliging the authority to take into account relevant Codex Alimentarius and other international benchmarks when setting national standards.

Peru – Ley Nº 30224, que crea el Sistema Nacional para la Calidad y el Instituto Nacional de Calidad (INACAL) (11 July 2014), Articles 4(a), 19(5) and 20: Article 4(a) establishes as a core principle of the National Quality System the obligation to orient and articulate normalisation, accreditation, metrology and conformity assessment activities in accordance with internationally recognised norms, standards and codes; and Articles 19.5 and 20 require the normalisation body to approve Peruvian Technical Standards "in accordance with international agreements and standards on the matter", thereby creating a comprehensive statutory obligation to integrate international standards (ISO, IEC, Codex, OIML) into domestic technical regulation.

Note(s):

International alignment does not only happen in relation to international standards. See e.g. www.imdrf.org and the regulations adopted under the UNECE 1998 Agreement. Those "Global Technical Regulations" serve solely as patterns for alignment, whereas the regulations under the 1958 Agreement are binding international public law.

Recognition of International Test Reports, Certificates or Approvals

Regulatory Function:

Burden Reduction, Cheaper Production / Services

Problem:

Industry produces for the world market, but is burdened by test reports, certificate and approval requirements of many different jurisdictions. Products and services become more expensive than necessary.

Solution(s):

Recognition of test reports, certificates or approvals where these are issued in accordance with international agreements or even informal international cooperation that your jurisdiction has adhered to (e.g. UNECE or OECD).

Reference(s):

Australia – Road Vehicle Standards Rules 2019 (look for "1958 Agreement"): the Act provides for the recognition of type approvals granted under the UNECE 1958 Agreement concerning the Adoption of Uniform Technical Prescriptions for Wheeled Vehicles. A type approval or test report granted by any Contracting Party to the 1958 Agreement (covering EU member states, Japan, South-Korea and other major trading partners) in conformity with the relevant UN Regulation

constitutes valid evidence of compliance with the corresponding Australian Design Rule, thereby allowing international UN type approvals and their underlying test reports to serve as the basis for market access in Australia without full repeat testing, certification or licensing.

Zimbabwe – Environmental Management (Prohibition of Lead in Paint and Coating Materials) Regulations, 2026, Section 4(2) and (3) at page 38 of the electronic file: recognition of test reports of foreign manufacturers with verification obligation.

Mexico — Ley Federal sobre Metrología y Normalización (LFMN), Articles 72, 87A and 87B.

Note(s):

See also the following entry and a reference from MERCOSUR: MERCOSUR/GMC/RES. Nº 14/05, Etapa 4 (Stage 4 of the mutual-recognition procedures for conformity-assessment bodies): evaluation teams shall agree on a joint evaluation procedure that includes joint visits, inspections and audits ("visitas, inspecciones, auditorías cruzadas y conjuntas") of laboratories, inspection bodies and certification bodies, thereby merging assessment procedures across MERCOSUR States Parties to avoid duplication.

Adequacy or Equivalence Decisions

Regulatory Function:

International Data/Service/Goods Transfer

Problem:

Other jurisdictions often recognise approvals or certificates if their own are recognised. De facto mutual recognition - outside cumbersome international agreements - is in the interest of both sides.

Solution(s):

Empower the Government to issue adequacy/equivalence decisions for cross-border flows of products, services and data or foreign authorities assessing products, services and data. Allow formal assessment of foreign regimes for equivalence, often leading to simplified procedures for compliant imports.

Reference(s):

Singapore – Securities and Futures Act 2001 (Cap. 289), Sections 9 and 55: empower the Monetary Authority of Singapore (MAS) to grant approved exchange or recognised market operator status to foreign exchanges and clearing houses whose home regulatory framework is comparable in the degree to which MAS's regulatory objectives — investor protection, fair and orderly markets, and financial stability — are achieved relative to requirements applicable to locally incorporated entities.

Australia – Corporations Act 2001, Section 795B(2) (Financial Markets): empowers ASIC to grant an Australian market licence to a foreign market operator already authorised in its home jurisdiction, dispensing with the standard domestic licensing criteria provided ASIC is satisfied that the foreign operator is subject to sufficiently equivalent regulation in its home country with respect to investor protection and market integrity.

Canada – Safe Food for Canadians Regulations (SOR/2018-108), Part 7 (Sections 169–172), Recognition of Foreign Systems: empowers the Minister, on application by a foreign state, to formally recognise a foreign food inspection system for meat products and live or raw shellfish where CFIA assessment demonstrates that the system provides at least the same level of protection as the Safe Food for Canadians Act and its Regulations.

New Zealand – Medicines Amendment Act 2025 Section 7, inserting a new Section 22B into the Medicines Act 1981: empowers the Minister of Health to issue a list of recognised overseas regulatory authorities whose approvals trigger an expedited 30-day ministerial approval pathway for medicines in New Zealand without repeating full evaluation, provided the overseas regulator operates a

regulatory framework similar to New Zealand's, uses international guidelines consistent with New Zealand's approach, and maintains a formal cooperation framework with the Director-General of Health.

Argentina – Resolución SENASA N° 694/2024, Articles 1–2 (27 June 2024): SENASA recognizes equivalencies of technical-grade active substances for plant protection products approved by competent authorities in the United States, Mexico, EU, United Kingdom, Australia, New Zealand, and Brazil, where the substance originates from the same manufacturing establishment and has the same or higher minimum purity, thereby avoiding redundant testing of identical substances.

Note(s):

Ensures trusted cross-border flows while upholding high standards. Easier to manage than international agreements, whilst de facto reciprocity can be requested as a precondition.

Recognition of Foreign Negative or Status related Administrative or Court Decisions

Regulatory Function:

Burden Reduction, Efficiency of Administration and Courts

Problem:

Not only authorisations, but also certain rights-reducing ("negative") foreign administrative acts or court rulings, such as insolvency decisions, divorce, or prohibitions, and status decisions, such as marriage, adoption, merger of legal persons, need to be lengthily duplicated – unless there is a recognition mechanism.

Solution(s):

Establish a mechanism for the recognition of respective foreign decisions, including provisions on the standing of foreign natural or legal persons and authorities in the recognition procedure.

Reference(s):

Malaysia – Cross-border Insolvency Act 2026, Part III.

Chile – Ley N° 20.720 (Ley de Insolvencia y Reemprendimiento), Chapter VIII (Insolvencia Transfronteriza).

Note(s):

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"Passport" as Means for Cross-Border Activities

Regulatory Function:

Fostering the International Market

Problem:

Duplicative national licences obstruct the cross-border supply of products and services.

Solution(s):

Ensure operators authorised in one state can operate in other states on strength of a single registration or approval ("passport" regime).

Reference(s):

Australia – Corporations Act 2001, Chapter 8A (inserted by Corporations Amendment (Asia Region Funds Passport) Act 2018, No. 61 of 2018), Section 1213A et seq.: establishes the Asia Region Funds Passport (ARFP) scheme, under which a managed investment fund registered as an Australian passport

fund, and meeting the common standards of the Memorandum of Cooperation on the Establishment and Implementation of the Asia Region Funds Passport (signed by Australia, Japan, Republic of Korea, New Zealand and Thailand), is entitled to offer interests to retail investors in all other member economies on the strength of its single home-jurisdiction registration without having to meet each host jurisdiction's separate licensing requirements; conversely, foreign passport funds notified to ASIC under Section 1213H may offer interests in Australia on the strength of their home-jurisdiction approval.

Singapore – Securities and Futures Act 2001 (Cap. 289), Part XIII Division 2 (Collective Investment Schemes), Section 287, read with the ASEAN Collective Investment Scheme (CIS) Framework: the SFA empowers MAS to recognise and register as "recognised schemes" collective investment schemes authorised in a home jurisdiction participating in the ASEAN CIS Framework (comprising Singapore, Malaysia, Thailand and the Philippines), allowing a CIS operator approved in its home jurisdiction to offer its fund to retail investors in Singapore through a local distributor on the basis of a single home-jurisdiction authorisation and streamlined notification to MAS, without requiring a full separate Singapore authorisation, thereby implementing a statutory passport mechanism for cross-border fund distribution across the ASEAN region.

Note(s):

In Latin America, we only found the Pacific Alliance Additional Protocol (Protocolo Adicional al Acuerdo Marco de la Alianza del Pacífico), Chapter 11 on Financial Services. Apparently, the four member countries' securities regulators (Chile's CMF, Colombia's SFC, Mexico's CNBV, and Peru's SMV) issue coordinated resolutions exempting investment funds and securities registered in any of the four countries from the obligation to separately register in the other three members' public registries. However, we did not find any implementing decisions, and the mechanism does not seem to fully coincide with the passport concept either.

G. Obligations of (Economic) Actors

"State of the Art" or "Best Available Technique" as Legal Benchmark

Regulatory Function:

Ensuring Up-to-Date Performance and Safety

Problem:

Legal standards can become outdated or may not reflect the latest technological or safety advances.

Solution(s):

Define "state of the art" or "best available technique" as a substantive legal benchmark, with guidance on how this is to be regularly assessed and referenced.

Reference(s):

Australia (NSW) – Protection of the Environment Operations Act 1997 (NSW), Section 78(4A) and Schedule 1, Sections 31(2)(g).

New Zealand – Resource Management Act 1991, Section 2 (Interpretation), definition of "best practicable option":

Note(s):

"Best available techniques" is more stringent than "state of the art". See for more details our Handbook 'How to Regulate?', Sections 3.3.1, 8.13 and 8.14.

Power to Adopt / Adapt Technical / Legal Requirements at Government Level

Regulatory Function:

Technical Detail and Adaptive Implementation

Problem:

Primary law cannot anticipate all future details or change.

Solution(s):

Empowerment for the Government to adopt and adapt technical regulation.

Reference(s):

United Kingdom – Health and Safety at Work etc. Act 1974, Section 15: Empowers the Secretary of State to make health and safety regulations, providing a comprehensive delegated power to adopt, amend, and continuously adapt technical requirements and standards as risks and technologies evolve, without the need for primary legislation.

Mexico – Ley General de Salud, Artículo 13(A)(I): Empowers the Secretaría de Salud to issue, modify, and revoke Normas Oficiales Mexicanas (NOMs), which serve as the primary binding legal instrument to adopt and continuously adapt detailed technical, health, and safety requirements as science and technology advance.

Note(s):

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Dynamic Link/Reference to Future Innovations

Regulatory Function:

Automated Future-Proofing

Problem:

Statutory reference to technical standards or protocols is quickly outdated.

Solution(s):

Allow "dynamic referencing" so that references always point to the latest version of a standard or protocol adopted under defined international schemes.

Reference(s):

Australia – Acts Interpretation Act 1901 (Cth), Part 4 Sections 10 and 10a.

Canada – Incorporation by Reference in Regulations Act, S.C. 2015, c. 33, Sections 18.1–18.6 (inserted into the Statutory Instruments Act, R.S.C. 1985, c. S-22): Section 18.1(1) provides that the power to make a regulation includes the power to incorporate in it by reference a document either as it exists on a particular date (static) or as amended from time to time (ambulatory); ambulatory incorporation by reference — also expressly described as referring to the "latest edition" or "most recent edition" of a document — means that any subsequent update to the referenced standard, protocol, or technical document automatically takes effect in the regulation without need for formal regulatory amendment; Section 18.3 ensures public accessibility of incorporated documents, and Section 18.4 prohibits ambulatory incorporation in a manner that gives a person an exclusive power to amend the regulation's substantive effect.

Note(s):

Distinct from static reference clauses. Check legality in your jurisdiction. In quite some jurisdictions, dynamic references are legally only permitted where acts referred to (or the accession thereto) are under the legal control of the same or a higher institution.

"Retirement" of Outdated Technical Norms

Regulatory Function:

Regulatory Hygiene and Simplification

Problem:

Obsolete or excessively complex norms create hidden barriers.

Solution(s):

Mandate periodic review, sunset or simplification, and open procedure for "retiring" old standards.

Reference(s):

Queensland (Australia) – Statutory Instruments Act 1992 (Qld), Section 54 (expiry of subordinate legislation): Section 54 provides that a statutory instrument (including technical product, safety, and environmental regulations) automatically expires on 1 September first occurring after the tenth anniversary of the day it was made, unless action is taken to preserve it; where an agency wishes to remake the instrument, it must conduct a "sunset review" assessing its continuing necessity, effectiveness, and efficiency, with public consultation, before the replacement can be made — thereby institutionalising a mandatory and periodic "retirement" procedure for outdated technical norms at the sub-national level, and creating an open procedure under which obsolete subordinate legislation is removed automatically absent positive justification for its continuation.

Colombia – Ley 2085 de 2021 (por la cual se adopta la figura de la depuración normativa): Article 1 establishes "depuración normativa" as a permanent instrument of the Colombian legal order, defined in Article 2 as allowing declarations of loss of validity and express derogation of legal and regulatory norms affected by "obsolescencia" — defined as norms which, in light of current social, economic, cultural, political, and historical reality, are no longer adequate — as well as norms that contravene the current constitutional order, have fulfilled

their purpose, or were adopted on a temporary basis; the Law empowers the national administration, departmental assemblies, and municipal councils in their respective spheres to use this mechanism on an ongoing basis to identify and retire obsolete norms, and formalises the process for publishing and recording retired norms in the official legal information system SUIN-JURISCOL, thereby creating a statutory framework for systematic regulatory hygiene and the retirement of outdated technical and general norms.

Note(s):

Whilst the two references deal with a generic, cross-sector clean-up or obsolescence, there can also be a need for a sector-specific clean-up.

Reference/Alignment with International Standards

Regulatory Function:

International Interoperability and Best Practice

Problem:

Unnecessary divergence from widely-accepted international standards increases barriers and costs.

Solution(s):

Mandate or facilitate the use of international standards where compatible (e.g., ISO, IEC).

Reference(s):

South Africa – Standards Act, No. 8 of 2008, Section 23(2)(a)(i) and (iii): the national norm developed and maintained by the South African Bureau of Standards (SABS) for the development of South African National Standards must detail a process that ensures, as far as possible, that (i) the latest technological

developments are considered and (iii) South African National Standards are harmonised with international standards, if applicable.

Trinidad and Tobago – Standards Act (Chap. 82:03), Section 16(5): where the Trinidad and Tobago Bureau of Standards (TTBS) finds it impracticable to formulate its own specification, it may adopt another specification formulated elsewhere as a national standard.

Kenya – Environmental (Impact Assessment and Audit) Regulations, 2003 (LN 101/2003), Regulation 32: International standards are to be applied where there are no national standards.

Costa Rica – Reglamento para elaborar Reglamentos Técnicos, Decreto Ejecutivo No. 19079-MEIC, Article 8, with dynamic reference to a guidance document. Section 1.2.3.1. of the attached guidance document indicates which standards to be considered as reference.

Note(s):

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Government to make Standards Mandatory

Regulatory Function:

Standardisation and Equal Application of Requirements

Problem:

It is difficult to establish regulation for all technical details. At the same time, the application of generic law varies widely.

Solution(s):

One way to strike a balance is to make standards – elaborated by standardisation bodies or other institutions – mandatory. This can be achieved through a reference to a specific version of a standard in secondary legislation.

However, this approach requires the secondary legislation to be updated periodically, which is inconvenient due to the immense administrative burden it entails. An alternative is to empower the Government to make standards mandatory.

Reference(s):

Uganda – Uganda National Bureau of Standards Act (Cap. 327), Sections 8 and 18.

Colombia – Decreto 2269 de 1993 (por el cual se organiza el Sistema Nacional de Normalización, Certificación y Metrología), Article 2(d) and Article 6.

Note(s):

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Presumption of Conformity for Standards and Government Specifications

Regulatory Function:

Standardisation, Legal Certainty and Equal Application of Requirements

Problem:

It is difficult to establish regulation for all technical details. At the same time, the application of generic law creates legal uncertainty and varies widely. Operators need legal certainty on how they can be on the safe side with regard to compliance.

Solution(s):

Empower the Government to:

a) Issue detailed mandates to Standardisation Organisations, setting out the

basic principles, but also the technical reference points;
b) Control and correct submitted standards, also legally;
c) Provide a presumption of conformity with certain, precisely defined legal requirements by means of citation of the standards in the Official Journal;
d) Adopt government technical specifications if the Standardisation Organisations do not provide citable standards.

Reference(s):
UK – Electrical Equipment (Safety) Regulations 2016 (SI 2016/1101), Regulation 36(1) and (2): Regulation 36(1) provides that electrical equipment which is in conformity with a designated standard (or part thereof) the reference to which has been published in the Official Journal of Great Britain is presumed to be in conformity with the principal elements of the safety objectives covered by that standard; Regulation 36(2) makes this presumption rebuttable, thereby establishing a formal, statutory and judicially enforceable presumption of conformity linked to government publication of standard references — directly implementing solutions (c) and (d): citation of standards in an official publication creates compliance certainty, with government technical specifications available as fallback where designated standards are absent.
Brazil – Lei nº 9.933, de 20 de dezembro de 1999 (dispõe sobre as competências do CONMETRO e do INMETRO), Article 2, as operationalised through the INMETRO Regulatory Model (Sections 7.1 and 7.5): the INMETRO Regulatory Model, issued under these powers, mandates that technical regulations must be drafted in a non-prescriptive manner around essential requirements, that INMETRO must "identify and publish the list of technical standards and other normative documents that confer presumption of conformity to technical regulations", that compliance with those listed standards triggers the presumption of conformity with the essential requirements, and that suppliers who do not follow the identified standards may demonstrate compliance by other means but bear the burden of proof.

Note(s):

- As standardisation by independent standardisation bodies does not always work, we recommend creating also a power for the government to step in with its own technical specifications.
- See also: New Zealand – Building Act 2004; Building Code; Acceptable Solutions; Verification Methods: establish non-mandatory compliance pathways through Acceptable Solutions (specific step-by-step construction methods for commonly used materials/systems) and Verification Methods (tests or calculation methods) that, if followed, must be accepted by Building Consent Authorities as evidence of compliance with Building Code and are deemed to comply, providing legally privileged alternative pathway to individual performance demonstration while remaining voluntary, with applicants retaining option to use alternative solutions or reference Acceptable Solutions/Verification Methods in part.

Standards or Government Specifications to be Followed by Default

Regulatory Function:

Standardisation, Legal Certainty and Equal Application of Requirements

Problem:

It is difficult to establish regulation for all technical details. At the same time, the application of generic law creates legal uncertainty and varies widely. In some areas, technical specifications should be followed except in atypical cases.

Solution(s):

Empower the Government to render the standards mandatory by default or to adopt its own technical specifications that are mandatory by default, while permitting exceptions for atypical cases or when justified by the operator.

Reference(s):

United Kingdom – Building Act 1984, sections 1 and 8; Building Regulations 2010, Regulation 11: Binding building regulations apply by default. A requirement may be relaxed or dispensed with only through a case-specific determination that its operation would be unreasonable in relation to the particular work or case, and the relaxation power is unavailable for specified requirements.

South Africa – National Building Regulations and Building Standards Act 103 of 1977, Sections 17 and 18: National building regulations establish the default technical requirements. A local authority may grant an exemption only where application would be unreasonable in the particular case and exemption would not prejudice the public interest.

Colombia – Ley 400 de 1997, Articles 8–11: Prescribed seismic-design and construction requirements form the mandatory baseline. Different materials, methods of analysis or design, or construction methods require technical substantiation and prior authorisation under the statutory alternative-method procedure.

Note(s):

- These references allow deviating from the default rules only subject to prior authorisation. However, it is also possible to allow deviating just where there are good reasons to deviate from the default rules. That approach has been traditionally chosen in the European Union law on in vitro diagnostic medical devices, and recently even for some ordinary medical devices, see Regulation (EU) 2017/745, Article 9(3).

- This approach can be combined with the presumption of conformity described in the previous entry. Of course, it is also possible to provide only for standards or only for Government specifications. However, the combination suggested here provides the utmost flexibility and a fallback in case standardisation does not work for one reason or another.

Obligations Tiered by Risk / Value / Volume

Regulatory Function:

Proportionate Burden and Risk Management

Problem:

Uniform due diligence or other obligations can impose excessive burdens.

Solution(s):

Structure requirements with intensity/complexity fitting the scale of risk or the operator's market volume.

Reference(s):

India – Reserve Bank of India (Non-Banking Financial Company – Scale Based Regulation) Directions, 2023, issued under Section 45-IA of the Reserve Bank of India Act, 1934, Paragraph 2.1: Paragraph 2.1 mandates a four-tier regulatory architecture for all Non-Banking Financial Companies (NBFCs), classifying them into Base Layer (NBFC-BL, asset size below INR 1,000 crore), Middle Layer (NBFC-ML, asset size INR 1,000 crore and above), Upper Layer (NBFC-UL, specifically identified by the RBI as posing heightened systemic risk), and Top Layer (NBFC-TL, reserved for entities shifted up from the Upper Layer where substantial systemic risk increase is determined); each ascending layer carries a cumulative and progressively more intensive set of obligations.

Costa Rica – Reglamento para la prevención, preparación y respuesta ante accidentes químicos (N° 44741-S-MAG) (2024), in particular Article 6.

Colombia – INVIMA Decreto 4725 de 2005, Articles 5, 16 and 17: Article 5 establishes four mandatory risk classes — Clase I (bajo riesgo), Clase IIa (riesgo moderado), Clase IIb (alto riesgo) and Clase III (muy alto riesgo) — and Articles 16–17 directly tie the intensity of pre-market regulatory obligations to the assigned class.

Note(s):

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Catalogue of Detailed Obligations for Economic Operators

Regulatory Function:

Role-Specific Clarity and Responsibility

Problem:

Legal uncertainty can result when roles in the supply chain are ill-defined. Moreover, state enforcement is not sufficient in many instances if there is no support by economic operators with regard to compliance.

Solution(s):

All relevant economic operator categories' obligations and relationships are precisely detailed. This should include mutual control of and by economic operators for certain formal compliance aspects.

Reference(s):

Singapore – Health Products Act 2007 Part 8, and Health Products (Medical Devices) Regulations 2010: The Acts define and separately license each supply chain actor and establish common and specific obligations.

Mexico – Reglamento de Insumos para la Salud (DOF 23.12.1999, last amended 2014), Título Quarto, Título Quinto.

Note(s):

Helps guarantee traceability and compliance throughout the chain.

Outsourcing of Obligations: Limits and Conditions

Regulatory Function:

Compliance

Problem:

Some actors outsource compliance tasks and thereby lose control.

Solution(s):

Establish limits and conditions for the outsourcing of compliance obligations.

Reference(s):

Australia – APRA Prudential Standard CPS 231 Outsourcing, Sections 23 onwards, issued under the Banking Act 1959 and Insurance Act 1973, requires APRA-regulated institutions to maintain a Board-approved outsourcing policy, mandates that ultimate Board responsibility for any outsourced material business activity remains with the institution and cannot be transferred to the service provider, prescribes mandatory content for all outsourcing agreements covering monitoring rights, and establishes sub-contracting limits, data access, business continuity and exit arrangements.

Mexico – Ley de Instituciones de Crédito (LIC), Articles 46 Bis 1 and 46 Bis 2: Article 46 Bis 1 of the LIC requires credit institutions to notify the CNBV at least 30 days before entering into outsourcing agreements for operational processes or database administration, and prohibits outsourcing of activities that would result in the institution losing direct control over its compliance obligations or that would impede the CNBV's supervisory access. Article 46 Bis 2 sets up further limits.

Note(s):

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Responsibility Organisations of Economic Actors

Regulatory Function:

Compliance

Problem:

It is sometimes difficult for a single economic operator to fulfil certain legal obligations alone, on its own.

Solution(s):

Permit or mandate the creation of "responsibility organisations" that take over the obligations of a pool of economic operators.

Reference(s):

Australia – Product Stewardship Act 2011 (No. 76, 2011), Part 3, Sections 18–35: Section 18 mandates that every "liable party" — defined in Section 19 as a manufacturer, importer or first supplier of a class of products specified in the regulations — must be a member of an "approved co-regulatory arrangement" for that class of products; Section 20 defines the approved co-regulatory arrangement as an organisation accredited by the Minister that administers the collective compliance scheme on behalf of all its member liable parties, discharging the statutory stewardship outcomes in place of individual compliance.

Chile – Ley nº 20.920, Marco para la Gestión de Residuos, Responsabilidad Extendida del Productor y Fomento al Reciclaje (DOF 1.6.2016), Title III, Articles 9–27: establishes the Extended Producer Responsibility (REP) regime, under which producers of "productos prioritarios" (priority products specified by supreme decree) are collectively responsible for financing and organising the management of the waste generated by those products; permits — and the implementing supreme decrees in practice require — producers to discharge their obligations either individually or by joining a "sistema colectivo de gestión" (collective management system), which is a legal entity constituted exclusively by

producers that acts as the responsibility organisation taking over the operational and financial obligations of its member pool; requires the collective system to obtain Ministerial approval for its "plan de gestión".

Note(s):

See also the following entry.

Guarantee for Fulfilment of Obligations

Regulatory Function:

Compliance

Problem:

Some functions are systemically important. Failure to fulfil obligations, e.g. following insolvency, might cause important damage.

Solution(s):

Require a performance guarantee, including in case of insolvency, e.g. as part of an authorisation or certification.

Reference(s):

Australia (Victoria) – Environment Protection Act 2017 (Vic), Sections 219–234, and Environment Protection Regulations 2021, Sections 167 and 168: exemplary detailed provisions covering all modalities of financial assurances.

Chile – Ley nº 20.551, Regula el Cierre de Faenas e Instalaciones Mineras (DOF 11.11.2011), Articles 6, 50–58, as operationalised by the SERNAGEOMIN Guía Metodológica para la Constitución y Disposición de la Garantía Financiera (2020): Article 6 requires every mining operator to submit a closure plan — approved by SERNAGEOMIN — that must include a *garantía financiera* (financial guarantee) covering the full estimated present value of the costs of

implementing all closure and post-closure measures by virtue of Article 50 onwards.

Note(s):
See also the previous entry which constitutes a case where such a guarantee might be suitable.

Withdrawal, Recall, and Corrective Action

Regulatory Function:
Public Safety and Market Order

Problem:
Non-compliant or dangerous products or services must be rapidly controlled, removed or corrected.

Solution(s):
Obligation for rapid market withdrawal, recall, or other corrective measures—triggered by defined risks.

Reference(s):
Rwanda – Regulations Governing Recall, Treatment and Disposal of Unfit Products, Articles 6–22: Articles 7–9 prescribe a three-tier recall classification — Class I (immediate risk of serious adverse health consequences or death), Class II (remote probability of serious adverse health consequences), and Class III (unlikely to cause adverse health consequences) — with the urgency and scope of required corrective action calibrated to the assigned class; Article 12 empowers Rwanda FDA to independently initiate a recall on its own motion where the registration holder or importer fails to act upon becoming aware of a non-compliant or unsafe product; Article 15 requires the responsible party to submit progress reports to Rwanda FDA every 72 hours during an active Class I

recall; and Article 18 requires the responsible party to identify the root cause of the recalled product's non-conformity and submit a documented Corrective and Preventive Action (CAPA) plan to Rwanda FDA — combining mandatory operator-triggered recall obligations with a regulator override power and a post-recall corrective action requirement in a unified, risk-tiered statutory framework.

Argentina – Resolución de la Secretaría de Comercio nº 808-E/2017, which incorporates into Argentine law the MERCOSUR GMC Resolution nº 4/2017 on alert and withdrawal procedures, Annex Articles 1–8: the MERCOSUR Annex establishes the full procedural framework.

Note(s):

See also our "List of Powers and Obligations", which includes several hundred empowerments useful for enforcement.

Obligations for Brokers and Platform Operators

Regulatory Function:

Adapting Rules to the Digital/Supply Chain Shift

Problem:

Platforms, brokers or other intermediaries exploit loopholes as neither conventional retailers nor manufacturers. Classic economic operators can hide behind platforms, brokers or other intermediaries so that authorities cannot get hold of them.

Solution(s):

Expressly define platform operators, online marketplaces, brokers and other intermediaries as regulated economic operators distinct from manufacturers, importers and sellers. Allocate direct obligations according to the functions each

intermediary performs, including duties to verify and retain the identity and contact details of third-party traders; disclose the identity of the actual seller and the platform's own contractual role; provide transaction, price and complaint information; preserve relevant records; cooperate with authorities; and ensure that sellers cannot remain commercially active while legally or practically unreachable. Establish liability appropriate to the platform's control, knowledge, representations and participation in the transaction, without treating liability as a substitute for ex ante governance and traceability duties.

Reference(s):

India – Consumer Protection (E-Commerce) Rules, 2020, Rules 4–6, issued under Section 101(1)(zg) of the Consumer Protection Act, 2019: Rule 4 defines "marketplace e-commerce entities" as a distinct operator category — the platform intermediary facilitating transactions between third-party sellers and buyers — and separately defines "inventory e-commerce entities" that directly sell their own goods; Rule 5 imposes on marketplace e-commerce entities a specific catalogue of obligations including: (i) obtaining a written undertaking from every seller on the platform that their product descriptions, images, and claims are accurate and do not infringe third-party rights; (ii) disclosing to the consumer, upon purchase, the identity, address, and contact details of the seller; (iii) providing a ticket number for each complaint enabling traceability; (iv) establishing and publishing a clear grievance redressal mechanism with a Grievance Officer who must acknowledge complaints within 48 hours and resolve them within one month; and (v) ensuring that the platform does not manipulate search results or rankings to give unfair advantage to related parties; Rule 6 separately defines and imposes obligations on sellers on marketplace platforms, requiring them to display country of origin, all mandatory statutory notices, and full price breakdowns — thereby establishing a role-differentiated, explicitly statutory framework of intermediary and seller obligations.

Chile – Decreto Supremo Nº 6 de 2021, Reglamento de Comercio Electrónico, Articles 1–14: The Regulation expressly defines electronic-commerce platform

operators separately from third-party sellers and subjects them to direct, role-specific duties. These include disclosure of the seller's identity and contact details, clarification of whether the platform or a third party is making the offer, explanation of the platform operator's role and assumed contractual obligations, and requirements concerning price, availability, delivery, withdrawal rights, contractual terms and transaction confirmation. The framework consequently allocates obligations according to the functions performed by the platform and seller rather than allowing intermediary status to create a regulatory gap.
Colombia – Ley 1480 de 2011 (Estatuto del Consumidor), Article 53: The statute places direct traceability duties on operators of electronic contact portals: they must obtain and retain sufficient identifying and locating information from every offeror, disclose that information to an affected purchaser for purposes of a claim, and supply it to competent authorities upon request. This prevents conventional suppliers from becoming unreachable by operating through a marketplace or other electronic intermediary.

Note(s):

See also our model law on Cross-border internet activities and virtual worlds.

E-Commerce and Digital Market-Specific Provisions

Regulatory Function:

Digital-Readiness and Effective Enforcement

Problem:

Online market structures evade enforcement under traditionally formulated laws.

Solution(s):

Set obligations and liabilities specifically tailored to online marketplaces, interfaces, and digital intermediaries.

Reference(s):

South Africa – Electronic Communications and Transactions Act 25 of 2002 (ECT Act), very comprehensive; just a selection here: Section 43 imposes on any supplier offering goods or services for sale through a website or other electronic interface a mandatory pre-contractual disclosure obligation requiring the supplier to make available to consumers, in a manner that is accessible, the supplier's full legal name, physical address (not merely a PO box), telephone and fax numbers, website address, and e-mail address — specifically to ensure that consumers can locate and pursue the supplier through offline channels and that enforcement authorities can identify them; Section 44 imposes a statutory cooling-off right of seven days in all direct marketing transactions concluded electronically, exercisable against the online seller directly; Section 45 prohibits unsolicited commercial communications by online sellers; and Section 46 requires online sellers to execute orders within 30 days unless otherwise agreed, and to repay consumers within 30 days of cancellation — creating an e-commerce-specific compliance framework for online sellers that operates independently of the general Consumer Protection Act and is specifically calibrated to the enforcement gaps created by online supply of goods and services.

Kenya – Consumer Protection (General) Regulations, 2025: The Regulations impose on any supplier conducting e-commerce — defined as the supply of goods or services through digital means or an online interface — specific obligations including: (i) disclosure of the supplier's full legal identity, physical address, and contact details on every transactional webpage; (ii) clear display of the total price of goods inclusive of all taxes and delivery charges before the consumer is committed to the transaction; (iii) provision of a mechanism for the consumer to review, correct, and confirm the transaction before it is concluded; (iv) provision of an electronic acknowledgement of the order within a prescribed period; (v) maintenance of accessible records of all e-commerce transactions for a minimum period; and (vi) ensuring that the digital description and presentation of the product contains all information that would be required on a physical label,

including safety and health warnings where applicable — thereby specifically addressing the enforcement gap created when online sellers present inadequate product information or conceal their identity behind digital interfaces.new.

Brazil – Decreto nº 7.962, de 15 de março de 2013 (regulamenta o Código de Defesa do Consumidor no comércio eletrônico), Articles 2–6: Article 2 requires every online supplier (fornecedor que realiza o comércio eletrônico) to display prominently on every page of the website: (i) its corporate name and CNPJ registration number; (ii) its physical address for all legal purposes; (iii) telephone and e-mail contact for consumer service; and (iv) in the case of a foreign supplier operating in Brazil, the address and identity of its legal representative in Brazil — thereby closing the enforcement gap created by digital anonymity; Article 3 imposes pre-contractual disclosure obligations on online sellers including complete product information, total price breakdown, and delivery terms; Article 4 requires online sellers to provide an immediate electronic order confirmation and a summary of the purchase terms; Article 5 obliges the online seller to provide at least one customer service channel accessible through the same digital medium used for the sale; and Article 6 extends the statutory right of withdrawal (direito de arrependimento) of Article 49 of the CDC to all online purchases and requires the online seller to provide a toll-free mechanism for its exercise — establishing in primary regulatory law a comprehensive set of digitally-specific seller obligations focused precisely on the enforcement problems arising from online anonymity and information asymmetry.

Note(s):

Should be combined with international cooperation so as to ensure enforcement abroad. See also our model law on Cross-border internet activities and virtual worlds.

Coverage of New / Atypical Economic Operators

Regulatory Function:

Adapting Regulation to new Forms of Operation

Problem:

The markets produce ever new forms of economic operators, e.g. fulfilment centres and commercial promoters / influencers. Legislation often lags behind.

Solution(s):

Try to learn from other sectors and jurisdictions and also integrate types of economic operators that have emerged in other sectors or jurisdictions.

Establish an open, function-based definition of "economic operator" covering any natural or legal person that, professionally or for commercial benefit, participates directly or indirectly in making a product or service available to consumers. The definition should be expressly non-exhaustive and should include persons who manufacture, import, assemble, alter, package, label, store, fulfil, dispatch, transport, distribute, sell, supply, intermediate, operate an online marketplace, process transactions or commercially promote products or services.

Apply a basic set of obligations to all economic operators according to their functions, control and access to relevant information. These should include duties to: identify themselves and the other responsible operators; retain and disclose supply-chain records; cooperate with regulators; refrain from supplying or promoting products known, or reasonably suspected, to be unlawful or unsafe; preserve traceability; communicate warnings, recalls and corrective measures; avoid misleading commercial communications; and disclose commissions, sponsorships or other commercial relationships where these could affect consumers' understanding of a recommendation.

The law should additionally name important emerging operators—including fulfilment service providers, online marketplaces and remunerated promoters ("influencers")—without making the general definition exhaustive.

Reference(s):

Singapore – Consumer Protection (Fair Trading) Act 2003 (Cap. 52A), Section 2: Section 2 defines "supplier" as any person who, in the course of their business, (a) provides goods or services to consumers, (b) manufactures, assembles or produces goods, (c) promotes the use or purchase of goods or services, or (d) receives or is entitled to receive money or other consideration as a result of the provision of goods or services to consumers — and expressly includes any employee or agent of such a person; this four-limbed, function-based definition is deliberately constructed to capture any economic actor who participates in the supply chain in a commercially significant way, regardless of the formal legal category into which they fall, so that promoters, agents, assemblers and any hybrid operator who does not fit neatly within a traditional category of "manufacturer", "importer" or "retailer" are automatically brought within the statute's obligations; the breadth of limb (c) — covering anyone who "promotes" goods or services — is particularly significant in capturing digital and influencer-based commercial actors whose activities would otherwise fall outside more narrowly drafted legislation.

Peru — Ley No. 29571, Código de Protección y Defensa del Consumidor, Preliminary Title, Article IV(2): The Code uses an expressly illustrative and non-exhaustive definition of "provider," encompassing public or private persons that habitually manufacture, elaborate, manipulate, condition, mix, package, store, prepare, sell or supply products, or provide services of any nature to consumers. The definition therefore attaches obligations to functions performed in the consumer supply chain rather than to a closed catalogue of operator titles. Its express inclusion of storage, handling, conditioning and packaging functions makes it capable of reaching some fulfilment and logistics operators, while its

non-limiting character allows new and hybrid operators to be assessed according to their actual economic activity.

Chile — Ley N° 19.496 de 1997 (Ley sobre Protección de los Derechos de los Consumidores), Articles 1(4) and (5), 28 and 28 B: The statute defines advertising by its commercial purpose and permits it to occur through any suitable means. Its principal misleading-advertising prohibition is directed at whoever induces error or deception through an advertising message, rather than only at formally designated sellers or manufacturers. This medium-neutral and actor-neutral formulation can extend advertising duties to paid influencers, affiliate promoters and other emerging commercial communicators, although it does not make them subject to every obligation imposed on the underlying supplier.

Note(s):

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Reporting/Information on Alignment with Standards

Regulatory Function:

Transparency and Quality Control

Problem:

Users lack information if a certain product or service meets certain standards (e.g. green taxonomy).

Solution(s):

Oblige companies to disclose to what extent they align with certain standards.

Reference(s):

Australia – Treasury Laws Amendment (Financial Market Infrastructure and Other Measures) Act 2024 (No. 87 of 2024), Schedule 4, amending the

Corporations Act 2001, inserting new Chapter 2M, Division 3A (Sustainability Reports), and AASB S2 – Climate-related Disclosures (September 2024): Schedule 4 inserts into the Corporations Act a mandatory requirement for reporting entities meeting prescribed size thresholds — applying from financial years beginning on or after 1 January 2025 for Group 1 entities (consolidated revenue ≥ AUD 500 million, or consolidated gross assets ≥ AUD 1 billion, or ≥ 500 employees), with Groups 2 and 3 phased in from 2026 and 2027 — to prepare, have independently assured, and lodge an annual *sustainability report* as part of their annual reporting obligations; the sustainability report must contain climate-related financial disclosures prepared in accordance with AASB S2, thereby directly mandating disclosure of the entity's alignment with a prescribed sustainability standard; AASB S2 — itself closely aligned with IFRS S2 and the TCFD recommendations, with minimal variations — requires disclosure of governance arrangements, strategy and business model resilience, risk management processes, and quantitative metrics including Scope 1 and 2 greenhouse gas emissions (with Scope 3 from the second reporting year) and climate scenario analysis; the sustainability report is subject to mandatory independent assurance, with assurance requirements also phased in progressively, making the degree of alignment with the AASB S2 standard the mandatory and auditable subject-matter of the statutory disclosure obligation.

Chile – Norma de Carácter General N° 461 de la Comisión para el Mercado Financiero (CMF), issued on 12 November 2021 under Ley nº 18.045 de Mercado de Valores and Ley nº 18.046 sobre Sociedades Anónimas, as amended by the CMF proposals of August 2024 adopting IFRS S1 and S2 (entering into force 2026): NCG 461 was the first regulation in the world to make disclosure of sustainability information in accordance with the TCFD-aligned standards (governance, strategy, risk management, and metrics and targets) mandatory in annual reports for all entities supervised by the CMF — including publicly listed companies, insurance companies, and pension fund administrators; from 2026, following the CMF's August 2024 amendment

proposals, the mandatory baseline standard shifts to NIIF S1 (IFRS S1) and NIIF S2 (IFRS S2) as issued by the International Sustainability Standards Board (ISSB), with a simplified regime for entities with consolidated assets below UF 1,000,000; the requirement expressly includes disclosure of the entity's sustainability-related targets and progress against those targets, the entity's climate-related risks and opportunities, and the entity's governance for managing them — making alignment with ISSB sustainability standards the mandatory, publicly disclosed and CMF-supervised subject-matter of annual reporting.

Note(s):

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Quality Management Systems

Regulatory Function:

Internal Quality Control by Manufacturers or Service Providers

Problem:

Manufacturers' and service providers' processes require reliable internal systems to assure constant compliance.

Solution(s):

Mandate the use of a comprehensive quality management system, be it tailor-made, be it based on an international standard.

Reference(s):

India – Medical Devices Rules, 2017 (GSR 78(E)), Part I, Rules 13, 20, Part II Rule 3(ii) and Fifth Schedule (Quality Management System Requirements): requires every applicant for a manufacturing licence for Class A medical devices to submit an undertaking confirming that the requirements of the Quality Management System as specified in Schedule V have been complied with.

Brazil – ANVISA Resolução da Diretoria Colegiada – RDC nº 665, de 30 de março de 2022, Article 3, XXX, XXXIII §1, Articles 4, 9-11.

Note(s):

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Factory Production or Service Control Requirements

Regulatory Function:

Internal Quality Control by Manufacturers or Service Providers

Problem:

Manufacturers' and service providers' processes require reliable internal systems to assure constant compliance.

Solution(s):

Legal obligation for documented, continuous 'factory production control' (FPC) or 'services control' procedures.

Reference(s):

India — Bureau of Indian Standards Act, 2016 (No. 11 of 2016), Section 17: Section 17(1) prohibits any person from manufacturing, importing, distributing, selling, hiring, leasing, storing or exhibiting for sale any goods notified under Section 16 without a Standard Mark under a valid BIS licence; upon grant of a BIS licence under Section 17, the manufacturer is obligated to comply with the documented *Scheme of Testing and Inspection* (STI) attached to the relevant Indian Standard — the STI constituting the statutory factory production control instrument prescribing documented in-process tests, inspection frequencies, incoming material checks, process parameter monitoring, and corrective action procedures subject to periodic BIS surveillance; failure to maintain the STI procedures results in suspension or cancellation of the BIS licence under Section

17(4), making continuous documented factory production control a legally enforceable precondition of market access.upload.

Mexico – Norma Oficial Mexicana NOM-241-SSA1-2021, Buenas prácticas de fabricación para establecimientos dedicados a la fabricación de dispositivos médicos (DOF, published 2021, mandatory from 2022), Sections 6.1.4, 6.6.6.5.4, 12.14.7 and 13.

Note(s):

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Periodic Sample Testing Obligation

Regulatory Function:

Active Post-Market Surveillance

Problem:

Product failures may emerge only after placement on the market.

Solution(s):

Manufacturers (and sometimes importers/distributors) should be required to perform regular sample testing of products on the market.

Reference(s):

India – Bureau of Indian Standards (Conformity Assessment) Regulations, 2018, Section 19(5) Annexure S, Scheme I Section 3(1)(b).

Mexico – Norma Oficial Mexicana NOM-241-SSA1-2021, Buenas prácticas de fabricación para establecimientos dedicados a la fabricación de dispositivos médicos, Sections 3.51, 3.52, 6.2.5.2.2.4, 6.2.5.2.4.2, 6.2.5.8.3.20, 11.11.4.2.4, 12.2.3, 13.24.1 etc..

Note(s):

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Compliance Checks by Digital Twins or Simulations

Regulatory Function:

Innovation in Testing and Approval

Problem:

Physical testing can be costly, slow, and environmentally burdensome.

Solution(s):

Allow digital twins/simulation data in compliance, provided quality criteria are met.

Reference(s):

Canada — ISED, RSS-102.SAR.SIM, Simulation Procedure for Assessing Specific Absorption Rate (SAR) Compliance in Accordance with RSS-102.

Note(s):

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Operating Records of Service Providers

Regulatory Function:

Traceability and Legal Accountability

Problem:

Service operations can be as safety-critical as goods, but lack equal traceability.

Solution(s):

Service providers maintain full technical dossiers or operating records, parallel to manufacturers.

Reference(s):

Australia — Civil Aviation Safety Regulations 1998, Regulation 42.410 (Retention of copy of maintenance record): requires Australian aviation maintenance service organisations to retain a copy of each maintenance record for 2 years from the date of the certificate of release to service.

Chile — Law No. 20.584 of 2012 (Rights and duties in relation to health care), Article 13: Requires healthcare service providers (*prestadores*) to conserve the clinical record (*ficha clínica*) for a minimum period of 15 years from the date of the last medical consultation.

Note(s):

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Technical Documentation and Event Records Keeping

Regulatory Function:

Traceability, Evidence, and Ex-Post Controls

Problem:

Verification and incident response require robust documentation both on the technical characteristics and particular events.

Solution(s):

Obligation for economic actors to keep specified technical documentation,

typically for at least 10 years. Obligation to keep records on usage for a certain time.

Reference(s):

Australia — Therapeutic Goods Act 1990 (Cth), Section 28(2)(c) and (5)(c) and (ca): Mandatory documentation and record-keeping for medical device manufacturers and sponsors.

Brazil — Lei nº 13.709/2018 (Lei Geral de Proteção de Dados - LGPD), Article 37: Mandatory record-keeping obligations for data controllers regarding processing activities, including documentation retention for incident response and verification.

Note(s):

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Reduced Technical Documentation for Individually Manufactured or Non-Series Products

Regulatory Function:

Proportionality in Assessment Methods

Problem:

Full systematic conformity assessment is excessive for custom or single-use products.

Solution(s):

Allow assessment via Specific Technical Documentation equivalent to formal harmonised requirements.

Reference(s):

Australia — Therapeutic Goods (Medical Devices) Regulations 2002 (Cth),

Regulation 3.10 and Schedule 3, Part 7 (Custom-Made Medical Devices): Establishes a special conformity assessment pathway for custom-made medical devices, permitting compliance through manufacturer documentation and record-keeping requirements rather than the ordinary conformity assessment procedures applicable to standard medical devices.

Brazil — Portaria INMETRO No. 110, de 23 de março de 2022 (Aprova os Requisitos de Avaliação da Conformidade para Componentes Automotivos de Baixo Volume de Importação e de Produção — Consolidado), Article 6 (caput and §§ 1–2), read together with Annex I, Sections 5 and 6.1.4: Establishes a conformity assessment pathway for low-volume automotive components based on a compulsory Supplier's Declaration of Conformity, permitting supplier documentation, historical test reports and equivalent evidence in lieu of mandatory third-party certification.

Note(s):

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Traceability Requirements

Regulatory Function:

Tracking for Safety, Market Order, and Effective Recalls

Problem:

Inadequate traceability hinders rapid response to safety or compliance concerns.

Solution(s):

Impose traceability duties (batch/serial numbers, supply chain linkage, data requirements; customer, supplier and service provider recording). Impose "know-your-customer" rules.

Reference(s):

Australia – Therapeutic Goods Act 1990 (Cth), Section 28(5)(c) and (ca) (with Therapeutic Goods Supply Chain Identification Rules 2024): Mandatory traceability duties for medical devices requiring batch/serial number recording, customer/supplier identification, and supply chain linkage for effective recalls.

Nicaragua – Decreto Presidencial Nº 09-2022 - Reglamento para el Control de las Sustancias que Agotan la Capa de Ozono, Article 39: "Facturas" (billings) to be conserved.

Note(s):

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Digital Identification / Know-Your-Customers Rules

Regulatory Function:

Secure Digital Access and Fraud Prevention

Problem:

Growing fraud, non-compliance and money laundering risk, plus the need for cross-border digital trust.

Solution(s):

Mandate or enable the use of secure digital identity (eID) and harmonised Know-Your-Customers procedures.

Reference(s):

Australia — Anti-Money Laundering and Counter-Terrorism Financing Act 2006 (Cth), Part II, Section 28.

Chile — Resolución Exenta N° 566/2024 (Subsecretaría de Telecomunicaciones), Artículo 2: Obligation of biometric identity verification for

telecommunications companies, establishing minimum requirements for undoubtable identity verification through dactyloscopic or facial biometry.

Note(s):

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Internet Platforms and Brokers to cooperate with Authorities

Regulatory Function:

Supply Chain Traceability and Enforcement

Problem:

Enforcement is weak regarding economic operators offering products and services via internet platforms or brokers.

Solution(s):

Establish specific cooperation obligations for internet platforms and other brokers.

Reference(s):

India — Information Technology Act 2000 (amended 2008), Section 79 (3)(b) + Information Technology (Intermediaries Guidelines) Rules 2021, Rule 3(1)(d): Mandatory cooperation duties imposed on intermediaries towards government authorities.

Brazil — Marco Civil da Internet (Lei Nº 12.965/2014), Article 10 §1 and §2 and Article 13 §3.

Note(s):

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Electronic and Bundled Declaration of Conformity

Regulatory Function:

Burden Reduction

Problem:

Accompanying each individual product with a paper declaration of conformity is cumbersome.

Solution(s):

Permit a declaration of conformity to be created, signed, retained and supplied in electronic form, provided that its authenticity, integrity, continuing accessibility and connection with the relevant product can be established. Permit the product or accompanying documentation to provide a durable electronic link—such as a stable URL, QR code or machine-readable identifier—to the complete declaration. Permit also product types to be bundled for one single declaration of conformity where deviations are minor and unlikely to cause non-conformities. Require a free paper copy on request, especially where the user cannot reasonably access the electronic version.

Reference(s):

New Zealand – Electricity (Safety) Regulations 2010, Regulation 83, read with the Contract and Commercial Law Act 2017, Part 4, Subpart 3, Sections 222-225: According to the first Act, the supplier must make a prescribed supplier declaration of conformity before supplying a declared medium-risk article and provide a copy when requested. Within the scope of the second Act, the declaration need not accompany every individual item, and the general electronic-transactions legislation allows requirements concerning writing, provision and retention of information to be satisfied electronically where its statutory conditions are met.

Brazil – Lei nº 9.933/1999, read with Portaria INMETRO nº 140/2022, Annex II, 1.11. and 6.1.2 ("familha de produtos" / product families) and the applicable

product-specific conformity-assessment requirements: Subject to the applicable grouping rules, one declaration can cover multiple technically equivalent product types.

Note(s):

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Detailed Declaration of Conformity and Performance

Regulatory Function:

Consumer / User Information and Market Transparency

Problem:

Inconsistent or absent declarations obstruct rational choices.

Solution(s):

Require clear, standardised declarations of conformity and performance.

Reference(s):

Australia — Therapeutic Goods (Medical Devices) Regulations 2002 (Cth), Regulation 4.3F: Prescribes mandatory content for conformity assessment certificates, including manufacturer identification, product identification, conformity assessment procedures and certification details, thereby promoting market transparency and functioning as a structured compliance checklist for certification.

Mexico — NOM-CC-12-1992, Criterios Generales Referentes a la Declaración de Conformidad de los Proveedores, Sections 6 and Appendix A: Requires a Supplier's Declaration of Conformity containing prescribed information, including supplier identification, product identification, references to applicable standards, authorised signature and statement of responsibility, and provides a standard declaration model.

Note(s):

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Labels for Product Information

Regulatory Function:

Consumer / User Information and Market Transparency

Problem:

Inconsistent or absent labelling obstructs sustainable choices, safety choices and product traceability.

Solution(s):

Require clear, standardised labels showing sustainability, performance, or regulatory status.

Reference(s):

Australia — Greenhouse and Energy Minimum Standards Act 2012 (Cth), Sections 16 and 26: Authorises mandatory GEMS labelling requirements for regulated products and prohibits supply of products that do not comply with applicable labelling requirements, promoting consumer information, market transparency and energy-performance disclosure.

Chile — Norma Chilena NCh3000.Of2006 – Eficiencia Energética: Refrigeradores, Congeladores y Refrigeradores-Congeladores de Uso Doméstico – Clasificación y Etiquetado, in particular Sections 8 and 9: Requires standardised energy-efficiency labels displaying energy performance classifications, consumption information and prescribed product characteristics to facilitate consumer comparison and informed purchasing decisions.

Note(s):

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Mandatory "Key Characteristics" Indication

Regulatory Function:

User-Friendly Regulatory Disclosure

Problem:

Complex documentation obscures the most important facts.

Solution(s):

Require standardised summary tables of "key characteristics" in technical and user documentation.

Reference(s):

Australia — National Consumer Credit Protection Act 2009 (Cth), sections 133AB - 133AD and 133BC, read with National Consumer Credit Protection Regulations 2010 (Cth), Schedule 5 (Key Facts Sheet — Standard Home Loans) and Schedule 6 (Key Facts Sheet — Credit Card Contracts): mandatory standardised one-page Key Facts Sheet in prescribed table format with prescribed content, required before entry into standard home loan and credit card contracts.

Brazil — Resolução da Diretoria Colegiada ANVISA nº 429, de 8 de outubro de 2020 (Regulamento Técnico sobre Rotulagem Nutricional de Alimentos Embalados), Articles 6–13: mandatory "Tabela de Informação Nutricional" with prescribed rows, dual-column format per-portion and per-100g/100ml, prescribed rounding rules).

Note(s):

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Information for Customers / Consumers / End-Users

Regulatory Function:

Transparency, Consumer Choice, Safety

Problem:

Customers / consumers / end users cannot make informed decisions without access to accurate compliance and safety information.

Solution(s):

A right to request, receive and access all prescribed information, including online, or an obligation of economic actors to provide information proactively.

Reference(s):

Australia — Competition and Consumer Act 2010 (Cth), Schedule 2, Part 3-4 (Information standards), Sections 134–137, and Part 4-4 (Offences relating to information standards), Sections 203–204: Empower the making and declaration of mandatory information standards for goods and services and prohibit the supply, manufacture, or offering of goods and services that do not comply with those standards, thereby obliging suppliers, manufacturers, importers, distributors, hirers and retailers to disclose prescribed information (e.g. care instructions, ingredients, health warnings) to consumers.

Brazil — Código de Defesa do Consumidor (Lei nº 8.078/1990), Article 31: Requires suppliers, in the offer and presentation of products and services, to provide correct, clear, precise and conspicuous information in Portuguese regarding characteristics, quality, quantity, composition, price, warranty, validity period, origin, and risks to consumer health and safety.

Note(s):

- Extends to both pre- and post-purchase, and to complex services.

- The obligation to display key information to customers can be made more precise by mandating their inclusion in the contract; see Argentina — Ley 24.240 (Consumer Protection), Article 10.
- The obligation to display key information to customers can be linked to the right to rescind the contract where the obligation has not been fulfilled; see Argentina — Ley 24.240 (Consumer Protection), Article 10 bis.

Information Accessibility for End Users

Regulatory Function:

Safety

Problem:

End users may not have access to accurate, up-to-date compliance or safety data. These data are easily lost in the distribution or manufacturing chain.

Solution(s):

Obligation for free, user-friendly access to compliance documentation and product status.

Reference(s):

New Zealand — Building Act 2004, Section 362T: Requires a building contractor, upon completion of residential building work, to provide prescribed information and documentation to the client and relevant territorial authority.
Argentina — Ley 24.240 (Consumer Protection), Articles 4 to 6: Requires suppliers to provide consumers, free of charge and in a clear, detailed and accurate manner, with information regarding the essential characteristics of goods and services, the conditions of their commercialization and, where safety is touched upon, a manual.

Note(s):

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Plain Language and Accessibility of Information

Regulatory Function:

Public Usability and Inclusion

Problem:

Complex legal and technical documents exclude non-specialists or people with disabilities.

Solution(s):

Require notices, forms, and digital content to conform to plain language and accessibility requirements.

Reference(s):

Sri Lanka — Microfinance and Credit Regulatory Authority, Act 9 of 2026, Section 48(1)(a).

Brazil — Lei nº 13.146/2015, Estatuto da Pessoa com Deficiência (Brazilian Inclusion Law), Capítulo II: requires that all information and communication systems, including websites and digital platforms, be accessible using universal design principles; applied to public and private sectors, this law establishes accessibility of digital information as a civil right and obliges economic actors and public bodies to ensure that online content and services are perceivable, operable, understandable and robust for persons with disabilities.

Note(s):

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Mandatory Language Requirements

Regulatory Function:

Accessibility for All Citizens

Problem:

Users, authorities, and operators must be able to understand legal and technical information.

Solution(s):

Make translations into required official languages obligatory for all key materials.

Reference(s):

Sri Lanka — Microfinance and Credit Regulatory Authority, Act 9 of 2026, Section 48(1)(b).

Note(s):

Essential, but always to be balanced with capabilities of small and medium enterprises.

Conformity Marking Systems

Regulatory Function:

Market Access and User Assurance

Problem:

Lack of clear badges of conformity impedes free movement and user confidence.

Solution(s):

Institute mandatory conformity labelling/marking for compliant products.

Reference(s):

India — Safety of Household, Commercial and Similar Electrical Appliances (Quality Control) Order, 2025 (S.O. 2232(E), dated 19 May 2025), Clause 2: Requires covered electrical appliances to conform to the applicable Indian Standard and bear the BIS Standard Mark under a valid BIS licence.

Argentina — Resolución Nº 799/1999 de la Secretaría de Industria, Comercio y Minería, Articles 1 and 2: Approves the official conformity marking symbol to be applied to products subject to mandatory certification regimes and requires the symbol to be displayed on each certified product, its packaging or labels.

Note(s):

Conformity marks are to be distinguished from quality marks.

"Batch" and Serial Number Marking

Regulatory Function:

Traceability and Recall Effectiveness

Problem:

Lack of batch/serial numbers makes targeted withdrawal impossible.

Solution(s):

Mandate legible and durable batch, lot or item-level labelling. Alternatively, mandate the affixing of the manufacturing date.

Reference(s):

Australia — Therapeutic Goods (Medical Devices) Regulations 2002 (Cth), Schedule 1 (Essential Principles), Clause 13.3, Item 11: Requires medical devices to be accompanied by the batch code, lot number or serial number of the device as part of the mandatory labelling information.

Colombia — Decreto 4725 de 2005, Chapter VIII (Labelling, Packaging and Inserts), Article 56(d) and (f).

Note(s):

See also the entry "Traceability Requirements" above.

Statutory "Claims Rules"

Regulatory Function:

Fair Comparison and Credibility

Problem:

Unregulated claims mislead consumers.

Solution(s):

Define category-specific rules for e.g. product footprint, eco-labelling, and environmental claims.

Reference(s):

Canada — Competition Act, Section 74.01(1)(b.1)–(b.2): Requires representations concerning the environmental benefits of products, businesses or business activities to be supported by adequate and proper testing or substantiation, establishing statutory rules governing environmental claims.

Colombia — Decreto 1369, Articles 1–5: establishes the mandatory requirements that all advertising referring to the environmental qualities, characteristics or attributes of products must meet, including that claims must be objective and verifiable, based on recognised technical and scientific procedures, complete, truthful and precise, must specify whether the attribute pertains to the product itself or its packaging, and must enable consumers to determine clearly in what the environmental benefit consists.

Note(s):

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Ban on Misleading Claims and Marketing Practices

Regulatory Function:

Consumer/Market Protection and Safety

Problem:

Misleading environmental, safety or compliance claims distort competition and lower the average level of safety.

Solution(s):

Statutory ban on misleading claims; clarification of permitted/unpermitted terms and verification requirements.

Reference(s):

Canada — Competition Act (RSC 1985, c. C-34), section 74.01(1)(b.1) and (b.2): Establishes reviewable deceptive marketing practices by prohibiting environmental and climate-related representations unless supported by adequate and proper testing or substantiation, thereby creating statutory controls against misleading environmental claims.

Colombia — Decreto 1369 de 2014, Articles 1–5: Establishes a statutory regime governing environmental claims in product advertising by requiring that environmental representations be objective, substantiated, truthful, transparent, verifiable, scientifically supported, and specific as to the environmental benefit claimed.

Note(s):

Many consumer protection laws contain the prohibition of "misleading claims" or "deceptive wording". However, without definition of that term, the practice of authorities and courts may vary widely. Therefore, we recommend using wording that specifies what is "misleading" or "deceptive".

Obligation to Provide Samples or to Grant Access

Regulatory Function:

Facilitating Oversight and Safety Checks

Problem:

Lack of access to products and services or their documentation hinders investigation and enforcement.

Solution(s):

Operators must provide samples or grant access to products or services upon request by competent authorities, for free or at cost.

Reference(s):

Canada — Food and Drugs Act (RSC 1985, c. F-27), sections 22.1 and 23: Authorizes inspectors to order persons to provide documents, information or samples for compliance verification, and to enter places, examine articles and records, access electronic systems and data, test products, take samples, seize articles, and require reasonable assistance from persons in charge.

Peru — Decreto Supremo Nº 007-98-SA, Reglamento sobre Vigilancia y Control Sanitario de Alimentos y Bebidas (Food and Beverages), Artículos 66 and 67: establishes the sanitary surveillance system for food and beverages and empowers competent authorities to carry out inspections, take samples, and conduct laboratory analyses across the production, manufacturing, storage, transport, commercialisation and export chain; food business operators must permit access to premises and products and submit to sampling and testing, with non-cooperation constituting an infringement subject to sanctions.

Note(s):

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Contact Details for Accidents/Incidents/Safety Issues

Regulatory Function:

Rapid Risk Detection and Stakeholder Engagement

Problem:

Authorities and other users/affected persons lack a simple channel to report safety problems.

Solution(s):

Mandatory 24/7 contact interface (e.g., hotline or portal) for the public and authorities to report safety incidents and complaints.

Reference(s):

United Kingdom — Telecommunications Infrastructure (Security Requirements for Relevant Connectable Products) Regulations 2023, Schedule 1, Section 2.(2)(a): Mandates that manufacturers of connectable products must publish at least one point of contact to allow any person to report security issues or safety vulnerabilities.

Brazil — Decreto nº 11.034/2022 (Lei do SAC, Consumer Care Law), in particular Article 4: Mandates the provision of accessible contact channels (including 24-hour service channels for urgent safety incidents) to report defects and ensure rapid risk mitigation.

Note(s):

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Transparency on Rules and Procedures

Regulatory Function:

Compliance and Protection of the Interests of Clients

Problem:

The operations of economic operators are often opaque.

Solution(s):

Impose a duty to publish internal rules and procedures.

Reference(s):

Australia — Corporations Act 2001 (Cth), Section 912A(1)(g) and Section 1017G(1): Section 912A(1)(g) imposes a direct legal duty on all Australian financial services licensees to have adequate internal dispute resolution (IDR) procedures and to make these rules and procedures publicly available to clients. Section 1017G(1) mandates the publication and provision of a Financial Services Guide (FSG) to clients, which must clearly outline the entity's internal rules, operational procedures, and how complaints are handled.

Mexico — Ley para la Transparencia y Ordenamiento de los Servicios Financieros, Article 9: Mandates publication of operational rules for loans.

Note(s):

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Complaints Handling and Recording

Regulatory Function:

Responsiveness to Market Information, Safety, Compliance

Problem:

Complaints may be ignored or inadequately processed, risking persistent harms.

Solution(s):

All relevant economic actors must have explicit systems to receive, evaluate, and document complaints, including obligations to act where necessary.

Reference(s):

Bangladesh — Energy Regulatory Commission Act, 2003 (Act No. 13 of 2003), Section 54.

Brazil — Decreto nº 11.034/2022 (Lei do SAC, Consumer Care Law), in particular Article 8.

Argentina — Ley 24.240 (Consumer Protection), Article 27.

Note(s):

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Right to Terminate Contract

Regulatory Function:

Legal Protection, Legal Certainty and Incentivising Compliance

Problem:

Where obligations of operators are not fulfilled or where rights of clients are not respected, the clients have difficulties in defending their interests. Moreover, a legal limbo may emerge.

Solution(s):

Give clients the right to terminate (or withdraw from) contracts both in case of violation of pre-contractual and post-contractual obligations or rights.

Reference(s):

Australia – Competition and Consumer Act 2010 (Cth), Schedule 2 (Australian Consumer Law), Sections 76–82 (especially Section 82(3)) for unsolicited consumer agreements without fulfilment of pre-contractual obligations and Sections 267 and 269–270 for post-contractual failures

Argentina — Ley 24.240 (Consumer Protection), Articles 10 bis and 34.

Note(s):

The right to terminate the contract is also needed in case of distance sales, see Article 34 of the Argentinian reference and Directive 2011/83/EU, Articles 9–14.

Cyber Incident or Security Breach Notification

Regulatory Function:

Resilience and Prevention

Problem:

Authorities, users and market actors must be able to respond quickly to security failures.

Solution(s):

Mandatory notification of incidents/breaches within specified timeframes.

Reference(s):

Australia — Privacy Act 1988 (Cth), Part IIIC (Notifiable Data Breaches), Sections 26WK–26WL: Requires an entity that becomes aware of an eligible data breach to prepare a prescribed statement, notify the Australian Information Commissioner as soon as practicable, and notify affected individuals (or, where individual notification is impracticable, publish the statement and publicise the breach), thereby establishing a statutory data breach notification regime.

Mexico — Ley Federal de Protección de Datos Personales en Posesión de los Particulares, Article 20: Requires data controllers to notify data subjects immediately of security breaches occurring during any stage of processing that significantly affect their economic or moral rights, enabling them to take measures to protect their interests.

Note(s):

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Information and Audit Obligations proportionate to Operator Size and Risk

Regulatory Function:

Avoiding Unnecessary Burden

Problem:

Uniform obligations may disproportionately hurt smaller operators and low-risk sectors.

Solution(s):

Legally scale requirements by risk profile and size, with published thresholds.

Reference(s):

Singapore — Companies Act 1967 (Cap. 50), Section 205C read with the Thirteenth Schedule: Exempts qualifying small companies from the statutory audit requirement by applying published quantitative thresholds based on annual revenue, total assets and number of employees. Parent and subsidiary companies qualify only if both the company and the corporate group satisfy the statutory size criteria, thereby scaling audit obligations according to operator size.

Brazil — Lei Complementar nº 123/2006, Articles 3 and 27: Article 3 establishes objective annual turnover thresholds defining microenterprises and small enterprises, while Article 27 permits qualifying entities opting for the Simples Nacional regime to adopt simplified accounting for the recording and control of their operations, thereby scaling accounting and information obligations according to operator size.

Colombia — Ley 590 de 2000, Article 2: Defines micro, small and medium-sized enterprises through thresholds based on number of employees and total assets,

thereby establishing the statutory basis for differentiated treatment according to operator size.

Note(s):

See also Articles 11(1), 43, 55, 57(9)(g), and Chapters III and IV in general, Regulation (EU) 2024/1689 (Artificial Intelligence), OJ L, 2024/1689, 12.7.2024. The European Union AI Act is instructive as it crosses size and risk parameters.

Annual Reporting of Operators

Regulatory Function:

Compliance and Transparency

Problem:

Authorities cannot easily know to what extent operators ensure compliance or fulfil policy goals.

Solution(s):

Establish an annual reporting obligation.

Reference(s):

New Zealand — Hazardous Substances (Importers and Manufacturers) Notice 2015 (issued under the Hazardous Substances and New Organisms Act 1996), Clauses 6A–6B: Requires importers and manufacturers of identified hazardous substances to submit annual reports to the Environmental Protection Authority between 1 January and 31 May each year covering all identified substances imported or manufactured during the preceding calendar year. The report must include the operator's identity and prescribed information on each substance, including its name, classification, approval number or group standard, and the quantity imported or manufactured.

Costa Rica — Decreto Ejecutivo N° 44567 -MJP - Reforma Reglamento a la Ley de Asociaciones (2024): detailed reporting obligations for associations.

Note(s):

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"Benchmarking" and "League Table" Publication

Regulatory Function:

Driving Performance and Transparency

Problem:

Without comparative data, users and regulators cannot assess market or regulatory outcomes.

Solution(s):

Obligation for benchmarking and regular "league table" publication of regulated operator or authority performance.

Reference(s):

Australia — National Electricity Rules, Section 11.141.10, Part O Rules 6.27 and 6.27A: Require the Australian Energy Regulator to prepare and publish annual benchmarking reports describing, in plain language, the relative efficiency of distribution and transmission network service providers over a 12-month period.

United Kingdom — Water Industry Act 1991, Section 35E: Mandates the economic regulator (Ofwat) to publish comparative information on the performance of different water companies to ensure customers pay a fair price and to promote efficiency and economy in service provision.

Brazil — Lei nº 11.445/2007 (Diretrizes Nacionais para o Saneamento Básico), Artigo 9º, inciso VI, and Artigo 53: Requires the establishment of performance

indicators and mechanisms for monitoring and comparing the performance of different basic sanitation service providers to ensure regulatory transparency.
Colombia — Ley 142 de 1994 (Régimen de los Servicios Públicos Domiciliarios), Artículo 52: Mandates regulatory commissions (e.g., CRA, CREG) to establish efficiency parameters, comparative models, and indicators to evaluate and publicly report on the performance of public utility providers.

Note(s):
Even where a benchmarking obligation is primarily incumbent on an authority, the operators will have to contribute information to the authority. This is the reason why we display the entry in this Chapter.

Importer/Distributor to Verify and Inform

Regulatory Function:
Ensuring Compliance Throughout the Supply Chain

Problem:
Distributors and importers are often closest to the market but may not ensure products comply with legal requirements.

Solution(s):
Importers and distributors must verify key aspects of product compliance before placing products on the market and must inform authorities of known non-compliances.

Reference(s):
United Kingdom — Product Security and Telecommunications Infrastructure Act 2022, Sections 19 to 25: Mandates that importers and distributors who become aware (or ought to be aware) of a compliance failure must contact the manufacturer, take reasonable steps to prevent the product from being made

available, and notify the enforcement authority and other supply chain actors of the compliance failure and associated risks.

Chile — Decreto Supremo N° 298 de 2006, del Ministerio de Economía** (Reglamento para la certificación de productos eléctricos y de combustibles), Articles 12 and 13.

Note(s):

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Responsible Person for Regulatory Compliance

Regulatory Function:

Enhancing Compliance, Individual Accountability

Problem:

Anonymous corporate actors make enforcement and compliance culture difficult.

Solution(s):

Require the appointment of a named natural person responsible for conformity and regulatory compliance.

Reference(s):

United Kingdom — Financial Services and Markets Act 2000, Sections 59 to 63ZE (Senior Managers and Certification Regime): Mandates that regulated firms must allocate specific regulatory responsibilities (e.g., Compliance Oversight, SMF16) to named, approved natural persons (Senior Managers), ensuring clear, individual accountability for regulatory compliance and culture.

Argentina — Ley Nº 16.463, Article 2: Requires regulated activities involving medicines and medical-use products to be conducted only in authorized establishments and under the technical direction of the corresponding qualified university professional registered with the health authority.

Note(s):

Article 3 of the Argentinian reference renders the responsible person jointly and commonly liable.

Regulatory Compliance Department with High-level Head

Regulatory Function:

Enhancing Compliance

Problem:

Those in charge of compliance do not always have the standing to enforce compliance necessities.

Solution(s):

Mandate the creation of an independent regulatory compliance department with a high-level head ("compliance function").

Reference(s):

United Kingdom — Financial Conduct Authority (FCA) Handbook, Senior Management Arrangements, Systems and Controls (SYSC) 6.1.3 to 6.1.4: Explicitly mandates that a firm must "establish, maintain and oversee on an ongoing basis a compliance function" that operates independently and has the necessary authority, resources, and expertise to monitor and assess compliance, headed by a designated Senior Manager (SMF16).

Brazil — Resolução BCB nº 4.595/2017 (Política de Conformidade), Article 5º: Establishes the mandatory "função de compliance" (compliance function/department), requiring it to be structured to guarantee its independence, and mandates the appointment of a "responsável pela função de compliance"

(head of compliance) with authority and direct reporting lines to the board of directors.

Note(s):

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Governance Requirements for Compliance

Regulatory Function:

Enhancing Compliance

Problem:

Governance structures are not always appropriate to ensure compliance and to address risks.

Solution(s):

Set up governance requirements that ensure compliance and ability to address risks. See the reference for illustration of how such requirements can be cast.

Reference(s):

Australia — APRA Prudential Standard CPS 220 – Risk Management, paragraphs 19–35: Requires institutions regulated by the Australian Prudential Regulatory Authority (APRA) to maintain a risk management framework composed of systems, structures, policies, processes and people to identify, measure, monitor, report and control material risks. The framework must include documented roles and responsibilities, formal reporting structures, a designated risk management function, Board-approved risk appetite statement, risk management strategy, business plan, management information systems, stress testing and regular review processes.

Brazil — Resolução CMN nº 4.968, de 25 de novembro de 2021, Articles 2–8: Requires financial institutions to implement and maintain internal control systems

proportionate to their size, complexity and risk profile. The Resolution establishes a governance framework designed to ensure legal and regulatory compliance, internal controls, risk identification and management, clear allocation of responsibilities, reporting mechanisms, monitoring, annual evaluation, and active oversight by senior management and the board of directors.

Note(s):

See also the previous entry.

Authorised/Legal Representatives: Detailed Obligations, Tasks, and Liability

Regulatory Function:

Accountability in Indirect Representation

Problem:

Manufacturers based abroad often operate through authorised representatives, potentially leading to gaps in liability or unclear roles.

Solution(s):

Define in law the detailed obligations, tasks, and liability of authorised representatives, making them jointly and severally liable alongside the manufacturer for non-compliance.

Reference(s):

United Kingdom — The Medical Devices Regulations 2002 (SI 2002/618), Regulation 7A (II)(a)(ii) (Requirement to appoint a UK responsible person) and Regulation 60 (Status of UK responsible person): Mandates that non-UK manufacturers must appoint a 'UK Responsible Person' (UKRP). Regulation 60 establishes that the UKRP may be proceeded against legally as the person

placing or supplying the device on the market, holding them directly accountable and liable alongside the manufacturer for regulatory non-compliance.

Brazil — ANVISA Resolução RDC nº 751/2022, Articles 13, 14, 27, 55 and 56: Requires foreign manufacturers to authorize a Brazilian applicant to represent and commercialize their medical devices in Brazil. The authorization must expressly identify the legal manufacturer and the Brazilian applicant, confer representative authority, and confirm compliance with Brazilian Good Manufacturing Practice requirements. The Resolution further establishes that the legal and technical representatives of the applicant are responsible for the information and documentation submitted, and that the notification or registration holder must maintain the technical dossier and make it available for inspection by the National Health Surveillance System.

Note(s):

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Change of Authorised/Legal Representative

Regulatory Function:

Continuity of Representation and Market Oversight

Problem:

Changing authorised representatives can interrupt regulatory oversight or documentation availability.

Solution(s):

Require notification to authorities and explicit processes to ensure seamless transfer of obligations and records to the new representative, with clear liability overlap during transition.

Reference(s):

Australia — Therapeutic Goods Regulations 1990, regulations 10F(5): Establishes the framework for inclusion and variation of medical device entries in the Australian Register of Therapeutic Goods (ARTG). This regulation covers authorised representatives, but goes beyond.

Note(s):

See also Article 12, Regulation (EU) 2017/745 (Medical Devices), OJ L 117, 5.5.2017, p. 1–175.

Duties where Product/Service is Modified or Intended Purpose Changed

Regulatory Function:

Continuous Product Compliance

Problem:

Products can lose compliance after market placement if modified or their intended purpose changes post-sale.

Solution(s):

Legally require manufacturers' or service providers' obligations to re-apply when products or services are significantly altered or their use changes, reactivating conformity duties.

Reference(s):

Canada — Medical Devices Regulations (SOR/98-282), Section 1 (definition of "significant change") and Section 34 (Application for a Medical Device Licence Amendment): A manufacturer must apply for an amendment to its medical device licence before implementing a significant change to a Class III or IV medical

device. A "significant change" is defined as any change that could reasonably be expected to affect the safety or effectiveness of the device, including changes to the manufacturing process, quality control procedures, device design, or intended use.

Brazil — ANVISA Resolution RDC No. 751/2022, Articles 4(IV–VII), 15–31 (in English here): The Resolution establishes that any modification to the information contained in the notification or registration of a medical device constitutes an alteration, which is classified according to its regulatory significance as: (i) approval-required alterations, (ii) immediate implementation alterations, or (iii) non-reportable alterations. Alterations with greater sanitary relevance require prior approval by ANVISA before they may take effect, while other relevant alterations must at least be formally notified to the authority. Manufacturers and registration holders are therefore required to submit regulatory changes whenever modifications affect the approved characteristics of the device.

Note(s):

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Economic Actors to be Identified by Labels

Regulatory Function:

Clarity and Traceability in the Supply Chain

Problem:

Authorities and users need to identify responsible parties quickly.

Solution(s):

Legal obligation for labels to include clear data on manufacturer, importer, and relevant compliance contact.

Reference(s):

United Kingdom — The Electrical Equipment (Safety) Regulations 2016 (SI 2016/1101), Regulation 8: Mandates that the name, registered trade name or registered trade mark of the manufacturer, and the postal address at which the manufacturer can be contacted, must be indicated on the product, or where that is not possible, on its packaging or in a document accompanying the product, ensuring clear traceability.

Colombia — Decreto 4725 de 2005 (Reglamento Técnico sobre Dispositivos Médicos), Artículos 54(e) and 55(a).

Note(s):

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Supply Chain Actors to Cooperate for Conformity Assessment Procedures

Regulatory Function:

Compliance

Problem:

Main economic operators often cannot ensure compliance without cooperation of suppliers or upstream service providers.

Solution(s):

Require suppliers to cooperate in conformity assessment, at least by providing information.

Reference(s):

Australia — Work Health and Safety Act 2011 (Cth), Section 22(4): Requires a person who supplies a plant or a substance to provide the recipient with

adequate information about the conditions necessary to ensure its safe use and compliance.

Mexico — Ley de Infraestructura de la Calidad (2020), Article 69.

Note(s):

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Non-discrimination and Equal Access Clauses

Regulatory Function:

Market Fairness/Integrity

Problem:

Favouritism or exclusion based on nationality, location, or other grounds undermines the Single Market.

Solution(s):

Mandate non-discrimination, equal access and proportionality in regulatory measures.

Reference(s):

India (Rajasthan) — Electricity Act 2003, Section 42(2) and Section 2(47): non-discriminatory open access in electricity distribution.

Chile — Ley nº 20.453, de 26 de agosto de 2010: establishes the neutrality principle for consumers and users of the internet.

Note(s):

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"Clean Break" Transfers Following Service or Supplier Change

Regulatory Function:

User Control and Market Switching

Problem:

Technical or contractual lock-in stifles competition and user choice.

Solution(s):

Mandate clear procedures for smooth, transparent transfer or porting of data, funds, or services, with deadlines and non-blocking covenants.

Reference(s):

United Kingdom — Payment Accounts Regulations 2015 (SI 2015/2038), Part 3 (Switching Services), Regulations 14–17: Mandates the provision of a statutory account switching service that facilitates a 'clean break' by automatically transferring funds, standing orders, and direct debits to a new provider, while simultaneously closing the old account. It imposes strict deadlines on the financial institutions to execute the transfer and explicitly allocates liability for any delays or failures, thereby preventing contractual lock-in.

Chile — Ley Nº 21.236 (Ley de Portabilidad Financiera): Establishes a comprehensive statutory framework for the portability of financial services (including credit, mortgages, and accounts). It mandates the transfer of funds and balances from the old provider to the new one upon the user's request, requires the automatic termination of the old contract (clean break), and sets strict, non-blocking deadlines for financial institutions to complete the transfer, explicitly prohibiting old providers from impeding the user's exit.

Note(s):

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Transparency Registers for Market Actors

Regulatory Function:

Market Integrity and Public Confidence

Problem:

Opaque market participants may obscure true interests or relationships.

Solution(s):

Dedicated open registers listing actors, roles and beneficial owners in regulated sectors.

Reference(s):

Australia — Corporations Act 2001 (Cth), Part 6C.2, sections 672A–672F, as amended by the Treasury Laws Amendment (Strengthening Financial Systems and Other Measures) Act 2025 (Cth).

Mexico — Ley del Mercado de Valores, DOF 30 de diciembre de 2005: look for "Registro Nacional de Valores".

Note(s):

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Voluntary Certification/Approval of Parts

Regulatory Function:

Reducing Reporting and Compliance Burden

Problem:

Parts should often be checked as well. Full duplicate testing/approval for assemblies using already-certified parts is wasteful.

Solution(s):

Enable voluntary certification of parts, ideally with a legal mechanism for products to "build-on" that certificate when seeking product-level approval.

Reference(s):

Australia — Electrical Equipment Safety System (EESS), Equipment Safety Rules (ESR), Certificate of Suitability - voluntary certification for Level 1 and Level 2 equipment and components.

Note(s):

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Mandatory Certification/Approval of Key Parts or Ingredients

Regulatory Function:

Ensuring Safety and Environmental Performance at the Subsystem Level

Problem:

Critical component failures may cause systemic hazards.

Solution(s):

Designate "key parts" requiring mandatory certification/approval prior to use in end products.

Reference(s):

Australia — Civil Aviation Safety Regulations 1998 (CASR), Part 21, Subpart K (Regulations 21.305–21.306) — Australian Parts Manufacturer Approval (APMA).

Brazil – Portaria INMETRO nº 301/2011 (Regulamento de Avaliação da Conformidade para Componentes Automotivos), Articles 3 and 4.

Note(s):

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Obligations and Requirements relating to Parts and Components (Distinct from Accessories)

Regulatory Function:

Safety and Functional Integrity of Products

Problem:

Replacement parts, consumables, or components used for repair may bypass regulatory controls.

Solution(s):

Define and regulate "parts" and "components" as distinct categories, with clear legal obligations for conformity and traceability.

Reference(s):

Australia — Civil Aviation Safety Regulations 1998 (CASR), Part 21, Subpart K Regulation 21.303, read with Civil Aviation Regulations 1988 (CAR), Regulation 42W.

Colombia — Decreto 4725/2005 (INVIMA), Article 2: the definition of "medical device" ensures that components and parts (sold separately) are processed as medical devices in their own right; see also the term "dispositivo médico terminado" for finished / ready to use medical devices, implying that earlier stages still fall under the term "medical device"; interpretation confirmed by Circular Externa No. 5000-0001-22: Actualización de lineamientos para importación y registro de dispositivos médicos y partes.

Note(s):

Require full new certification or approval where the installation of parts would lead to substantial change.

Modular or System-Based Conformity Assessment

Regulatory Function:

Reflecting Industry Practice/Flexibility

Problem:

Rigid, item-by-item approaches do not fit "systems", kits or complex products.

Solution(s):

Enable conformity assessment on a modular or system basis.

Reference(s):

Australia – Road Vehicle Standards Rules 2019 (Cth), Part VI and Part III Division 2: type approval evidence requirements based on component and system approvals.

Brazil — Portaria SENATRAN nº 990, 1 de Agosto de 2022 (homologação de veículos e equipamentos veiculares - type approval of vehicles and their equipment).

Note(s):

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Manufacturer to Define/Certify Precise Product Type

Regulatory Function:

Clear Targeting for Market Surveillance and Certification

Problem:

Ambiguous declarations enable evasion and confusion across operators.

Solution(s):

Manufacturers must define a precise "product type" and not use over-broad or fuzzy labels; notified bodies must verify this determination.

Reference(s):

Australia – Therapeutic Goods (Medical Devices) Regulations 2002 (Cth), Schedule 3, Part 2, Section 2.3(3).

Note(s):

Foundation for precision in market recalls and enforcement. Often neglected in product legislation.

Detailed and Logically-Ordered Declaration of Conformity

Regulatory Function:

Enhanced Legal Certainty and Market Clarity

Problem:

Confusing, incomplete, or ill-ordered declarations hinder enforcement and market function.

Solution(s):

Set clear steps: compliance check, then declaration of conformity, then conformity marking, then market placement. Set out precise declaration of conformity content.

Reference(s):

Australia – Therapeutic Goods (Medical Devices) Regulations 2002 (Cth), in particular Schedule 3 Section 1.8.

Argentina — Resolución S.I.C. Nº 237/2024 (Marco General de Evaluación de la Conformidad), click on "Anexo" at the bottom or this parallel publication of the Annex; Section 3.1

Note(s):

The declaration of conformity is a meaningful step regardless of whether there is a third party verification or state licensing.

Life Cycle Assessment (LCA) of Effects

Regulatory Function:

Holistic Longterm Policy

Problem:

Environmental and other impacts can be "offshored" or hidden unless the whole value and use chain is considered.

Solution(s):

Legal requirement for full life-cycle assessment (LCA), e.g. for environmental product declarations or labelling.

Reference(s):

Australia (NSW) — State Environmental Planning Policy (Sustainable Buildings)

2022, Sections 2.1(5), 2.2(1)(c), 3.2(2) and Schedules: the latter deal not only with past ("embodied") CO2 emissions, but also with future emissions linked to the use of the (materials in) buildings.

Note(s):

See also the acts referred to in the parallel entry of the EU Legislators' Toolbox and the delegated or implementing acts adopted on their basis. These acts aim to cover the entire environmental footprint, not just CO2 emissions.

Green / Social Labelling Schemes

Regulatory Function:

Consumer Information and Green Marketing

Problem:

Consumers and professionals lack reliable information e.g. on environmental or social attributes of products/services.

Solution(s):

Establish, regulate, or mandate the use of harmonised environmental/social labelling.

Reference(s):

Australia (Cth) — Water Efficiency Labelling and Standards Act 2005, Sections 33–34.

Brazil — Lei Nº 10.295, de 17 de outubro de 2001 (Lei de Eficiência Energética), Articles 1–4, read with INMETRO Portarias establishing mandatory ENCE labelling per product category.

Note(s):

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Shortage or Discontinuity Notification

Regulatory Function:

Access to Crucial Products or Services

Problem:

Economic operators sometimes stop their activities from one day to the next and thereby cause the collapse of a certain market. In some cases, crucial products or services cannot be accessed anymore. In others, prices jump.

Solution(s):

Oblige economic operators to notify their intention to discontinue their activity in advance so that authorities can react.

Reference(s):

Australia – Therapeutic Goods Act 1989 (Cth), Sections 30EF and 30EG.

Brazil – Resolução da Diretoria Colegiada ANVISA — RDC Nº 18, de 4 de abril de 2014, Articles 2–5.

Note(s):

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Obligation to offer Repairs and Spares

Regulatory Function:

Consumer Protection and Circular Economy

Problem:

Lack of timely approval or access to repair information locks product users into new purchases.

Solution(s):

Impose duties for timely registration/approval of replacement parts and access to repair manuals or even repair.

Reference(s):

UK — Ecodesign for Energy-Related Products and Energy Information (Amendment) (EU Exit) Regulations 2021 (SI 2021/745), Schedule 19 (Electronic Displays) and analogous product-specific schedules, Sections 15 and 16.

Australia (Cth) — Competition and Consumer Amendment (Motor Vehicle Service and Repair Information Sharing Scheme) Act 2021 (C2021A00054).

Colombia — Ley 1480 DE 2011, Article 11, in particular 11(7).

Argentina — Ley 24.240 (Consumer Protection), Article 12.

Note(s):

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Requirements for Supply Chain Due Diligence

Regulatory Function:

Responsible Trade and Upstream Control

Problem:

Lax control allows risks and abuses deep in the supply chain.

Solution(s):

Impose detailed due diligence obligations extending to sub-suppliers and service providers.

Reference(s):

Australia (Cth) — Illegal Logging Prohibition Act 2012, Section 13A, read with Illegal Logging Prohibition Rules 2024, Section 8.

Note(s):

Respective Latin American legislative proposals have not been adopted, according to our knowledge.

End-of-Life "Product Stewardship"

Regulatory Function:

Life-Cycle Environmental Protection

Problem:

Products can cause harm at the end of life if not managed by those best placed to mitigate risks.

Solution(s):

Statutory duty for producers/importers to manage product collection, recycling, or disposal.

Reference(s):

Australia (Cth) — Recycling and Waste Reduction Act 2020 (No. 119 of 2020), Chapter III.

Mauritius — Environment Act, 2024, Section 99.

Chile — Ley Nº 20.920 sobre Marco para la Gestión de Residuos, la Responsabilidad Extendida del Productor y el Fomento al Reciclaje (2016), Articles 9–13.

Note(s):

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"Do No Significant Harm" Clauses

Regulatory Function:

Mainstreaming Sustainability

Problem:

A sector's advances may undermine environmental/social goals elsewhere.

Solution(s):

Prohibit actions likely to cause significant harm to defined social or environmental interests.

Reference(s):

Australia (Cth) – Environment Protection Reform Act 2025, amending the Environment Protection and Biodiversity Conservation Act 1999: look for the key word "unacceptable impact".

Chile – Ley Nº 19.300 sobre Bases Generales del Medio Ambiente (1994), Articles 8, 10 and 11. See the criteria in Article 11 that go beyond the sphere of "environment" as commonly understood.

Note(s):

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Pre-Market Risk Assessment in High-Risk Sectors

Regulatory Function:

Precaution and Responsible Innovation

Problem:

Some products/services are placed on the market without prior assessment of broader impacts.

Solution(s):

Compulsory ex ante (e.g. environmental/social/health/safety/rights) risk assessment for certain categories.

Reference(s):

Australia (Cth) – Environment Protection and Biodiversity Conservation Act 1999, Parts 7 and 8.

Cuba – Ley Nº 150 - Ley del Sistema de los Recursos Naturales y el Medio Ambiente, Título VI, Capítulo V.

Note(s):

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H. Liability of Actors

Liability for Defective or Non-compliant Products or Services

Regulatory Function:

Accountability and Consumer Protection

Problem:

Injuries and losses occur when services or products are defective; ambiguity about who is liable slows compensation and undermines trust.

Solution(s):

Explicit provision on the liability of service providers and of manufacturers (and, if relevant, importers or even distributors) for harm caused by defective products.

Reference(s):

India – Consumer Protection Act, 2019 (No. 35 of 2019), Chapter VI, Sections 82–87: provides that a product liability action may be brought against a product manufacturer, a product service provider, or a product seller, as the case may be.

India — Bureau of Indian Standards Act, 2016 (No. 11 of 2016): Section 31.

Colombia – Ley 1480 de 2011 (Estatuto del Consumidor), Articles 19–22: establishes the general warranty obligation — every producer and supplier is obliged to guarantee the quality, suitability, safety, good condition, and proper functioning of the goods and services they place on the market; imposes joint and several liability on the *productor* (manufacturer or producer) and the *proveedor* (distributor or retailer) for harm caused by defective products or services — the consumer may direct the claim against either party; prescribes

defences, including that the product was not defective at the time of supply and that the defect arose solely from compliance with a mandatory public standard or that it was technically impossible to detect the defect.

Note(s):

- Consider also requiring mandatory liability insurance with direct rights against the insurance, namely to cover cases of insolvency.
- Refer to non-compliance as an alternative reason for strict liability, unless the definition of "defect" includes "non-compliance".

Liability for Correctness of Information

Regulatory Function:

Consumer and User Protection, Safety

Problem:

Actors do not always stick to the truth in their communication. This can trick consumers and other clients into purchasing a product or service. This can also trigger sub-optimal safety choices.

Solution(s):

Establish a liability for the correctness, completeness and fairness of information provided.

Reference(s):

India – Consumer Protection Act, 2019 (No. 35 of 2019), Sections 84 (c), (d) and (e) and 85 (c) and (d).

Brazil – Código de Defesa do Consumidor (Lei nº 8.078, de 11 de setembro de 1990), Articles 20, 36–38: establishes a direct liability of the service provider for defects in service delivery where those defects include the provision of incomplete or misleading information; and the advertiser's liability is strict in the

sense that the burden of proving the correctness and completeness of the information rests entirely on the advertiser, not on the consumer; imposes on the *anunciante* (advertiser) the burden of proving the truthfulness and correctness of all advertising claims.

Note(s):

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Liability Insurance for Actors

Regulatory Function:

Accountability, Protection of Rights and of Goods

Problem:

Actors are not necessarily able to compensate for damages they cause.

Solution(s):

Require mandatory liability insurance with direct rights against the insurance.

Reference(s):

United Kingdom – Nuclear Installations Act 1965, Section 19, and Nuclear Installations (Insurance Certificate) Regulations 2017 (SI 2017/922).

Cuba – Ley Nº 150 - Ley del Sistema de los Recursos Naturales y el Medio Ambiente, Article 192.

Note(s):

Can be used to exert control on actors via insurers.

Liability and Compensation for Immaterial Damage

Regulatory Function:

Compensation and Deterrence

Problem:

Actors do not always respect immaterial rights or interests.

Solution(s):

Establish a liability and compensation rule for immaterial damages.

Reference(s):

Sierra Leone – Anti-Human Trafficking and Migrant Smuggling Act 2022, Section 31; and Prohibition of Child Marriage Act 2024, Section 17.

Chile — Ley No. 19.628/1999 (Ley sobre Protección de la Vida Privada), Article 23.

Note(s):

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Multiple Liable Persons

Regulatory Function:

Legal Clarity, Effective Protection of Victims

Problem:

The law of states varies as to the question who is liable when different persons have contributed to damage.

Solution(s):

Establish joint and common/several liability and recourse rules.

Reference(s):

Malaysia – Consumer Protection Act 1999 (Act 599), Part X, Section 68: Section 68(1) imposes strict liability for defective products jointly on (a) the producer, (b) any person who affixes their own name, trademark, or other distinguishing mark to the product (own-brander), and (c) any person who imported the product into Malaysia in the course of business — creating three categories of primary defendants who are simultaneously and equally liable for the same defect; Section 68(6) provides that where two or more persons are liable under Part X for the same damage, they are liable jointly and severally, allowing the claimant to pursue any one of them for the full amount.

Colombia – Ley 1480 de 2011 (Estatuto del Consumidor), Articles 10 and 20: Article 10 establishes the rule of responsabilidad solidaria (joint and several liability) between productores and proveedores — manufacturer/importer and distributor/retailer — for compliance with the legal warranty obligation; the Article expressly states that "ante los consumidores, la responsabilidad por la garantía legal recae solidariamente en los productores y proveedores" and that Parágrafo 1 extends the joint and several liability rule to all parties that participated in the distribution chain subsequent to the party who originally issued the supplementary warranty; Article 20 then extends the same “responsabilidad solidaria” rule explicitly to liability for damage caused by defective products — "el productor y el expendedor serán solidariamente responsables de los daños causados por los defectos de sus productos" — adding that where the producer is not identified on the product, the person who affixes their name, brand, or distinguishing mark is presumed to be the producer.

Cuba – Ley Nº 150 - Ley del Sistema de los Recursos Naturales y el Medio Ambiente, Article 190: joint liability, unless the individual responsibility (“participation”) can be established (“En caso de pluralidad de responsables, todos responden solidariamente por los daños y perjuicios causados, salvo que pueda establecerse la participación individual correspondiente.”).

Note(s):

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Liability for Subcontractors or Outsourced Operations

Regulatory Function:

Legal Clarity, Effectiveness of Obligations

Problem:

Actors avoid obligations by subcontracting or outsourcing of operations.

Solution(s):

Establish liability for subcontracted or outsourced operations.

Reference(s):

Lesotho — Labour Act, 2024, Section 126.

Uruguay — Ley No. 18.099/2007 and Ley No. 18.251/2008 (Responsabilidad en procesos de descentralización empresarial): Ley 18.099/2007 establishes joint and several liability of the principal company for all labour, social security, accident, and occupational disease obligations of contractors, subcontractors, and labour suppliers — regardless of whether the subcontracted work relates to the principal's core or ancillary activities. Ley 18.251/2008 refines the regime: a principal company that actively exercises its right to be informed (requesting compliance certificates) reduces its exposure to subsidiary liability only; failure to do so maintains full joint and several liability. The principal company can even avoid any liability by paying social security contributions and withholding the respective amount from the contractual payment to the contractor where the contractor has failed to prove the payment of the social security contributions.

Note(s):

The second reference puts into practice a valuable principle: mutual conformity control of economic actors.

Liability Extension to Legal Persons

Regulatory Function:

Protection of the Victims' and of the State's Financial Interests

Problem:

Legal persons do not always take over responsibility for their agents.

Solution(s):

Extend liability to the legal persons for which the agents have been operating.

Reference(s):

India — Environmental Protection Act 1986, Section 16.

Brazil — Lei No. 9.605/1998 (Lei de Crimes Ambientais), Articles 2-4.

Note(s):

We assume that the doctrine is operative across all Commonwealth jurisdictions as judge-made law rather than statute. Moreover, the civil codes of Latin American states are likely to contain similar generic provisions.

Liability Limitation to Promote Innovation

Regulatory Function:

Fostering Innovation and Economic Growth

Problem:

Actors might sue innovating companies and institutions and thereby stifle innovation and economic growth. Even the abstract liability risk may stifle innovation.

Solution(s):

Limit the liability for non-commercial sandbox operations, trials etc. subject to the fulfilment of certain minimum requirements and good faith operations.

Reference(s):

El Salvador – Decreto Legislativo Nº 234 - Ley de fomento a inteligencia artificial y tecnologías, Article 19 b) and c): fine-tuned balancing of interests.

Note(s):

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Liability Limitation for the State, its Agents and Entrusted Persons

Regulatory Function:

Protecting the State's Agents and Entrusted Persons

Problem:

Actors might sue the state's agents and its entrusted persons unfairly to deter state action. This may reduce the readiness of persons to engage as agent or entrusted person.

Solution(s):

Limit the liability of the state's agents and entrusted persons.

Reference(s):

Canadian Environmental Protection Act 1999 (CEPA 1999), SC 1999, c. 33, Sections 253 to 255.

Sierra Leone –Prohibition of Child Marriage Act 2024, Section 25.

Namibia – Road Act, 2025, Section 45.

Brazil — Lei 13.655/2018 (Lei de Introdução às Normas do Direito Brasileiro), Article 28: liability only in case of dolus or gross negligence.

Note(s):

The Namibian reference also covers the state liability exclusion for certain types of events and the recovery of liability costs from any person who caused the liability.

Liability Rights of the State

Regulatory Function:

Protecting Financial Interests of the State

Problem:

In certain contexts, there is a noteworthy likelihood that actors cause harm to the state, be it directly, be it indirectly.

Solution(s):

Provide the State tailor-made compensation rights.

Reference(s):

Namibia – Road Act, 2025, Sections 57 and 45(5).

Brazil — Lei No. 9.966/2000 (Water Pollution), Article 23.

Nicaragua – Decreto Presidencial Nº 09-2022 - Reglamento para el Control de las Sustancias que Agotan la Capa de Ozono, Article 49: recovery of costs for

the processing and destruction of illegally handled ozone layer depleting substances.

Note(s):

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For other aspects of civil liability, see Australia (NSW) — Civil Liability Act 2002. It covers a large range of aspects that merit being covered in the context of civil liability.

I. Risk Management and Technology Ethics

See also the last entry of Section G.

Risk-Based Supervision/Control Requirements

Regulatory Function:

Efficient Oversight and Prioritisation

Problem:

Resources of authorities are too scarce to cover all products, services or processes.

Solution(s):

Impose a duty to apply "risk-based" principles not only for approvals and certification, but also for surveillance, inspections, and supervision.

Reference(s):

India – Food Safety and Standards Act, 2006 (No. 34 of 2006), Sections 16(2)(i), 16(3)(c), 18(1)(b) and 18(2)(c).

Colombia – Decreto 1595 de 2015, Article 3, inserting Article 2.2.1.7.6.6. into Decreto 1074 de 2015.

Note(s):

Establishment of a concrete risk is very cumbersome whilst formal non-compliance may indicate inaccurate work methods and thus risks. Hence it is often preferable to start with formal checks of high risk products, services or processes.

Risk Management System Requirements

Regulatory Function:

Efficient Oversight and Risk Reduction

Problem:

Without a systemic approach to risks, authorities and other actors cannot identify and reduce risks in the best possible way.

Solution(s):

Impose a duty to apply a risk management system or framework, whether tailor-made or based on an international risk management standard.

Reference(s):

For authorities:

Australia (Commonwealth) – Public Governance, Performance and Accountability Act 2013 (Cth), Section 16, establishes a duty incumbent on authorities to establish and maintain systems relating to risk and control.

Colombia – Ley 872 de 2003 (Sistema de Gestión de la Calidad), in particular Article 4(e) and (f).

For other actors:

South Africa – Financial Intelligence Centre Act 38 of 2001, Section 42, as amended by the Financial Intelligence Centre Amendment Act 1 of 2017, imposing a *Risk Management and Compliance Programme* (RMCP): Section 42 requires every *accountable institution* — a list covering banks, insurers, lawyers, accountants, estate agents, and dealers in high-value goods — to develop, document, maintain, and implement a Risk Management and Compliance Programme that enables the institution to identify, assess, monitor, mitigate, and manage the risk that its products or services may be used for money laundering or terrorist financing; the RMCP must cover: (i) identification of the legal and regulatory requirements applicable to the institution; (ii) the risks to which the

institution is exposed; (iii) the measures applied to manage each identified risk; (iv) internal rules, policies and procedures; and (v) monitoring and testing of compliance; failure to establish and maintain an RMCP is a criminal offence; additionally.

Brazil – Resolução CMN nº 4.557, de 23 de fevereiro de 2017 (consolidated version), Articles 2–15.

Costa Rica – Reglamento para la prevención, preparación y respuesta ante accidentes químicos (N° 44741-S-MAG) (2024), Article 11.

Note(s):

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Joint or Centralised Technology Assessment

Regulatory Function:

Joint Assessment and Avoidance of Fragmentation

Problem:

States or provinces fragmentation in assessing new products, services or technologies delays market entry and burdens applicants.

Solution(s):

Establish multi-country joint assessment mechanisms, coordinated by nominated bodies.

Reference(s):

Australia / Canada / New Zealand / United Kingdom – Commonwealth HTA Collaboration under the QALY-paradigm work-sharing arrangement between the Pharmaceutical Benefits Advisory Committee (PBAC) (Australia), Canadian Drug Agency (CDA-AMC) (Canada), Pharmac (New Zealand), and NICE (United Kingdom): these four Commonwealth HTA bodies have developed a structured

work-sharing and joint assessment collaboration under which: (i) submissions from pharmaceutical and health technology developers may be assessed using a common evidence framework aligned with the QALY (quality-adjusted life year) methodology; (ii) HTA bodies share assessment reports and coordinate timelines to reduce the duplication of evidence requirements on applicants.

Latin America (Southern Cone) – COSAVE (Comité de Sanidad Vegetal del Cono Sur) Joint Pest Risk Analysis (PRA): In the Southern Cone, authorities do not rely on simple mutual recognition. Instead, the National Plant Protection Organizations of Argentina, Brazil, Chile, Paraguay, and Uruguay work together within COSAVE to conduct joint technical risk assessments (Joint Pest Risk Analyses) of biological and economic threats, producing unified scientific reports that inform regional phytosanitary standards. The integration of COSAVE's work into the domestic legal order of its member states operates through a two-tiered legal mechanism: an international treaty foundation and national administrative incorporation, e.g. by resolutions or, in the case of Paraguay, direct mandatory application of adopted regional standards.

Note(s):

This approach can also be used within federal states.

Ethics Panels or Committees

Regulatory Function:

Upholding Societal Values in Novel/Emerging Fields

Problem:

Technical or automated rules may lack sufficient protection for ethics or fundamental rights.

Solution(s):

Set up independent ethics panels for AI, biomedical, or data processing proposals.

Reference(s):

South Africa – National Health Act 61 of 2003, Sections 72–77, establishing the National Health Research Ethics Council (NHREC).

Chile – Ley nº 20.120, de 22 de septiembre de 2006 (sobre la investigación científica en el ser humano, su genoma, y prohíbe la clonación humana), Articles 15 and 16.

Note(s):

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Notification and Scrutiny for Emerging Risks

Regulatory Function:

Proactive and Adaptive Regulation

Problem:

Conventional provisions may miss new or rapidly evolving risks (e.g., AI, nanotechnology, gene-editing).

Solution(s):

Develop/adapt "watching" or notification mechanisms for emerging risks and scrutiny mechanisms or panels.

Reference(s):

Kenya – Biosafety Act, No. 2 of 2009 (as amended 2018), Sections 19, 27, 33(5), 38(3), and 39.

Brazil – Lei nº 11.105, de 24 de março de 2005 (Lei de Biossegurança): Mandatory notification and CTNBio authorisation before any activity may commence set out in Article 2, § 3º, Article 6, VI, and Article 7, I and II. CTNBio's power to constitute ad hoc expert subcommittees: Article 13. Obligation to assess risks case by case: Article 14, IV and XX.

Note(s):

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Incentives for Risk Reduction

Regulatory Function:

Risk Reduction

Problem:

Without incentives, actors do not necessarily reduce risks.

Solution(s):

Impose a duty to create or – at least – explicitly permit risk reduction incentives or create them in the regulation.

Reference(s):

India – IRDAI (Health Insurance) Regulations, 2016, Regulation 8(d).

Brazil – Lei nº 10.666, de 8 de maio de 2003, Article 10, regulated by Decreto nº 3.048/1999 (Article 202-A): Creates the Fator Acidentário de Prevenção (FAP), a statutory financial incentive for risk reduction. The FAP is a multiplier (ranging from 0.5 to 2.0) applied to the company's occupational accident insurance premium (RAT). Companies that actively invest in risk mitigation, safety protocols, and demonstrate a reduction in workplace accidents are financially rewarded with a reduced contribution rate (paying as little as half the standard

premium), thereby directly linking regulatory compliance and risk reduction to tangible economic incentives.

Note(s):

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Risk Communication and Public Information

Regulatory Function:

Risk Governance and Trust

Problem:

Failure to inform the public weakens risk prevention and can cause panic or mistrust.

Solution(s):

Impose duties for timely, comprehensible, and proportionate public information when risks are detected.

Reference(s):

Nigeria – Federal Competition and Consumer Protection Act, 2018 (FCCPA), enacted February 2019, Section 135: Mandates manufacturers and distributors to *promptly notify the public* of any unforeseen hazard arising from the use of products already placed on the market and to take decisive measures to remove such products from circulation.

Brazil – Código de Defesa do Consumidor, Lei nº 8.078 de 11 de setembro de 1990 (CDC), Articles 9, 10(§1) to 10(§3).

Note(s):

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Risk Assessment Methodology

Regulatory Function:

Complexity of Risk Assessment, Harmonisation of Practices

Problem:

Risk assessment is extremely complex. Authorities are not necessarily familiar with respective methodologies.

Solution(s):

Mandate or recommend a common risk assessment methodology.

Reference(s):

United Kingdom – Product Safety Risk Assessment Methodology (PRISM): PRISM is the GB market surveillance risk assessment methodology.

Brazil — Decreto nº 10.178, de 18 de dezembro de 2019, Article 4 and INMETRO Nota Técnica Diqre/Dconf-INMETRO (rev. 01) — Metodologia de Classificação de Risco.

Note(s):

See also Chapter 8 of our Handbook 'How to Regulate?'.

J. Public Ensurance of Compliance / Implementation

Confidential Two-Way Digital Communication Channels

Regulatory Function:

Responsive, Transparent Administration

Problem:

Unidirectional communication leads to missed information, misunderstanding, delays.

Solution(s):

Mandate digital, secure two-way communication platforms for regulatory filings, notifications, alerts and appeals.

Reference(s):

Decreto nº 9.492, de 5 de setembro de 2018, Article 16, establishing the "Speak Brazil" Fala.BR platform.

Note(s):

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Confidentiality of Investigations

Regulatory Function:

Effective Enforcement and Sanctioning

Problem:

Where information on investigations spreads, enforcement and sanctioning are hampered.

Solution(s):

Oblige anybody not to share information on ongoing investigations.

Reference(s):

Sierra Leone – Anti-Human Trafficking and Migrant Smuggling Act 2022, Section 34.

Note(s):

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Authentication of Signatures and Documents

Regulatory Function:

Legal Security in E-Administration

Problem:

Disputes about authenticity/acceptance of electronic documents.

Solution(s):

Explicitly require/refer to qualified electronic signatures..

Reference(s):

India – Information Technology Act, 2000 (as amended) – Sections 3, 3A, 4 and 5.

Mexico – Código de Comercio, Libro Segundo, Título Segundo, Capítulo I (Articles 89–95, 97).

Note(s):

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Central Enforcement Information System

Regulatory Function:

Strengthening Enforcement in provinces / states

Problem:

When uncoordinated, provinces / states enforce in an inconsistent and inefficient way.

Solution(s):

Establish a Central Enforcement Information System that collects all relevant data, from individual cases to comprehensive strategies.

Reference(s):

United Kingdom – The UK Product Safety Database (PSD) is operated by the Office for Product Safety and Standards (OPSS) under the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019, and the General Product Safety Regulations 2005 (SI 2005/1803) and product-specific market surveillance legislation: the PSD is the statutory notification system used by over 200 local authority trading standards offices, environmental health officers in Northern Ireland, and nine national regulators to report unsafe and non-compliant products to the Secretary of State — making it the UK's central enforcement information system aggregating market surveillance data from all enforcement authorities into a single OPSS-owned database.

Brazil – Sistema Nacional de Vigilância Sanitária (SNVS), coordinated by ANVISA, under Lei nº 9.782/1999: the SNVS is a national sanitary surveillance system comprising ANVISA (federal), state and municipal health surveillance authorities, and official laboratories.

Note(s):

Such information systems are mostly, but not necessarily implemented by databases.

(Peer) Review of Authorities

Regulatory Function:

Benchmarking and Progressive Improvement of Enforcement

Problem:

Enforcement / Implementation quality assessment may be biased when conducted by an authority's own staff.

Solution(s):

Establish periodic (peer) reviews of authorities by other authorities.

Reference(s):

Australia – Financial Regulator Assessment Authority Act 2021 (Cth, No. 75 of 2021), Sections 12-16: Section 12 establishes the Financial Regulator Assessment Authority (FRAA) as a statutory independent body with the principal function of *assessing and reporting* to the Minister on the *effectiveness and capability* of ASIC and APRA as enforcement and supervisory authorities; Section 13 requires the FRAA to conduct a *biennial assessment* of each of APRA and ASIC at least once every two financial years — making the periodic review of enforcement authority quality a binding statutory obligation rather than a discretionary administrative exercise.

New Zealand – Crown Entities Act 2004, Section 132: Empowers the responsible Minister to review the operations and performance of a Crown entity at any time. The Act mandates that the Minister must provide the entity's board with written notice detailing the scope, terms of reference, and the identity of the

reviewer(s), allowing the Minister to appoint independent external reviewers to assess the authority's performance, thereby ensuring regulatory enforcement is benchmarked by external parties rather than internal staff.

Mexico – Ley General de Mejora Regulatoria, publicada en el DOF el 18 de mayo de 2018 (abrogated), Articles 24 and 25: Establishes the Comisión Nacional de Mejora Regulatoria (CONAMER) as an autonomous body with the statutory mandate to evaluate the regulatory quality, enforcement mechanisms, and administrative performance of all other federal and local authorities (Sujetos Obligados). CONAMER conducts systemic evaluations and issues binding dictámenes, effectively serving as an external review mechanism to benchmark and progressively improve the enforcement quality of other government bodies.

Note(s):

- For a proper peer review mechanism, see Article 12, Regulation (EU) 2019/1020 (Market Surveillance).
- See also the following entry.

Certification of Authorities

Regulatory Function:

Benchmarking and Progressive Improvement of Authorities

Problem:

Quality assessment may be biased when conducted by an authority's own staff.

Solution(s):

Establish an external certification program.

Reference(s):

Mexico – Ley General de Mejora Regulatoria, publicada en el DOF el 18 de mayo de 2018 (abrogated), Articles 85-88 establish a certification mechanism for

authorities, aiming at increasing their quality. However, this is not related to ensuring compliance and enforcement.

Note(s):

See also the previous entry.

Annual Public Enforcement Reporting

Regulatory Function:

Benchmarking and Progressive Improvement

Problem:

Enforcement quality is unmeasurable without transparent reporting.

Solution(s):

Oblige authorities to publish annual statistics and analysis on enforcement actions, risks, and trends, best in accordance with a predetermined format to ensure comparability.

Reference(s):

India – Securities and Exchange Board of India Act, 1992, Section 18(2) and (3).

Mexico – Ley de la Comisión Nacional Bancaria y de Valores (LCNBV), Article 16, Fracción VIII.

Note(s):

-

Public Access to Enforcement Data

Regulatory Function:

Market Trust and Deterrence

Problem:

Enforcement outcomes are opaque; operators may underestimate non-compliance risks.

Solution(s):

Publish data on inspection, enforcement, compliance, and penalties with privacy exclusions.

Reference(s):

Australia (New South Wales) – Protection of the Environment Operations Act 1997 (NSW), Sections 308 and 309.

Colombia – Ley 1480 de 2011 (Estatuto del Consumidor), Article 59(10).

Note(s):

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Multi-annual National Control Plans

Regulatory Function:

Harmonised and Strengthened Enforcement

Problem:

Inconsistent national surveillance leads to gaps in consumer and market protection.

Solution(s):

Mandate multi-annual national control plans, compare and evaluate them.

Reference(s):

United Kingdom – Retained Regulation (EU) 2017/625 as amended by the Official Controls (Animals, Feed and Food, Plant Health etc.) (Amendment) (EU Exit) Regulations 2020 (SI 2020/1481), Articles 109–111: Article 109 of retained Regulation (EU) 2017/625 requires that all official controls in Great Britain *"shall be performed on the basis of a Multi-Annual National Control Plan (MANCP)".*

Brazil – Decreto nº 7.272/2010: Establishes the statutory requirement for the federal government to formulate and execute a multi-year National Food and Nutrition Security Plan (PLANSAN). The plan sets binding, multi-annual targets, and surveillance protocols (Article 7).

Colombia – Resolución 1229 de 2013 del Ministerio de Salud y Protección Social, Article 11(2.1)(b), Article 14(a).

Note(s):

However, the multi-annuality is only implicit for the Latin American references.

Enforcement Actions Database

Regulatory Function:

Coordination of Enforcement

Problem:

Lack of accessible data on which enforcement actions have happened and the results thereof; unnecessary double controls.

Solution(s):

Create a national or international database for enforcement actions.

Reference(s):

Australia – Therapeutic Goods Act 1989 (Cth), Section 61(5C/D); and

Therapeutic Goods (Information Specification—Database of Recalls, Product Alerts and Product Corrections) Instrument 2025 (F2025L00267).

Colombia – Base de Datos de Procesos de Responsabilidad Sanitaria, Instituto Nacional de Vigilancia de Medicamentos y Alimentos (INVIMA), established and maintained pursuant to Decreto 2078 de 2012, Article 24(10).

Note(s):

-

Standardised Procedures for Surveillance and Inspections

Regulatory Function:

Harmonised Enforcement

Problem:

Inconsistent national surveillance leads to gaps in consumer and market protection.

Solution(s):

Define inspections, sampling, and reporting procedures.

Reference(s):

Canada – Safe Food for Canadians Regulations, SOR/2018-108, Part 4 — defining preventive control inspections, commodity inspections, and sample collection as the three standardised inspection task types under the CFIA Standard Inspection Process (SIP), applicable uniformly across all food business lines.

Argentina – Resolución N° 56/2026 (Secretaría de Industria y Comercio, Ministerio de Economía), *Protocolo de Vigilancia de Mercado*, Boletín Oficial

9.3.2026 — establishes uniform guidelines for market surveillance activities including documentary verifications, on-site inspections, risk-based product sampling, laboratory testing, and border controls, with costs of non-compliant sampling borne by the regulated party.

Note(s):
- Regulation (EU) 2017/625 is more granular and therefore might serve as an additional reference.
- See also the references of the following entry.

Border Control of Products

Regulatory Function:
Compliance Verification

Problem:
Once products are inside the country, they are difficult to control.

Solution(s):
Set up a precise border control system, with dedicated own human resources.

Reference(s):
Australia – Imported Food Control Regulations 2019 (Cth), F2019L01006, Part 3 — specifying the detailed procedural framework for the Imported Food Inspection Scheme (IFIS), including classification of food as risk or surveillance food, inspection rates, sampling, laboratory analysis, and food inspection advice outcomes.
Brazil – Resolução da Diretoria Colegiada – RDC No. 81, de 5 de junho de 2008 (ANVISA), the principal regulation governing border control of all health-surveilled products (medicines, medical devices, food, cosmetics, sanitisers) entering Brazil; establishing mandatory sanitary inspection,

documentation verification, and physical inspection procedures at ports of entry, administered by ANVISA's ports, airports, and borders (PVVS) units..

Note(s):

Relying on generic border control by customs authorities does not result in the frequent detection of non-compliant products. The first reference is exemplary in that it covers many aspects of border control, including organisational requirements, frequency, and procedures.

Continuous Improvement Obligation

Regulatory Function:

Better Pursuit of Objectives

Problem:

State actors tend to become complacent.

Solution(s):

Oblige them to continuously improve.

Reference(s):

Australia (Commonwealth) – Public Governance, Performance and Accountability Act 2013 (Cth), Sections 37-40, mandating annual performance reporting, and principle 1 in the Australian finance administration's Regulator Performance Resource Management Guide (RMG-128), Principle 1: Continuous improvement and building trust.

Colombia – Ley 872 de 2003 (Sistema de Gestión de la Calidad), Article 4(i) — "mejora continua" (continuous improvement).

Note(s):

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Sampling of Produced Items or Provided Services

Regulatory Function:

Compliance Verification

Problem:

Even if the technical documentation and the certified or approved type or service are compliant, the items produced or services provided may still be non-compliant.

Solution(s):

Set rules for the systematic and documented sampling of produced items or provided services.

Reference(s):

Canada – Safe Food for Canadians Act, SC 2012, c 24, Section 24(2)(a) and (k), 38, 49.

India – Bureau of Indian Standards Act, 2016 (Act No. 11 of 2016), Sections 9(1)(j), 18(4) and (5)(a), 27(2)(b).

Mexico – Ley General de Salud, Article 401(III), 401Bis, 401Bis-1.

Note(s):

- The references are not ideal in so far as they merely empower sampling, without mandating it with a certain frequency and intensity.
- See therefore also the references of the next entry which are more detailed on frequency and intensity.

Minimum Frequency/Number of Checks

Regulatory Function:

Ensuring Effective Enforcement

Problem:

Under-resourced or infrequent checks enable persistent non-compliance.

Solution(s):

Set binding minimum frequency/number of enforcement checks per product group per period.

Reference(s):

Canada – CFIA Control Measures for Listeria monocytogenes in Ready-to-Eat Foods (2018), Section 6.1.4, Tables 1–3 — establishing binding minimum sampling frequencies by risk level (RRL) category: Category 1 establishments must sample once every two months; Category 2A once every six months; with frequencies escalating proportionally for higher-risk products, constituting a statutory minimum check schedule per product group.

Colombia – Resolución No. 1407 de 2022 (Ministerio de Salud y Protección Social): Establishing microbiological criteria for food and beverages for human consumption and providing that verification of compliance shall be carried out by sanitary authorities through a *proceso sistemático y constante* (systematic and continuous process) of inspection, surveillance, and control actions; setting binding standards whose verification frequency is linked to the risk of each food category. Establishing also a sampling regime adapted to the risk of each food category.

Note(s):

See also the previous entry.

Enforcement Delegation

Regulatory Function:

Ensuring Effective Enforcement

Problem:

Under-resourced authorities cannot enforce alone.

Solution(s):

Set rules on delegation of enforcement powers to geographic entities, agencies or even individuals.

Reference(s):

Pakistan (Sindh) – Protection and Promotion of Breast-Feeding and Young Children Nutrition Act 2023, Section 25(1).

Bangladesh – Energy Regulatory Commission Act, 2003 (Act No. 13 of 2003), Section 60: delegation to individuals.

Belize – Belize Agricultural Health Authority (Prevention, Control and Eradication of New World Screwworm) (Cochliomyia Hominivorax) Regulations 2024 (S.I. No. 143 of 2024), Section 16: encompasses the execution of inspections and their certification, the issuing of permits and fees connected to any of them. It is not clear from the wording whether private "agencies" can be entrusted as well.

Colombia – Decreto 2323 de 2006 (Ministerio de la Protección Social), Article 14, Parágrafo 2° — however only for laboratory tasks.

Note(s):

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Standard Setting Delegation within States/Provinces

Regulatory Function:

Adaptation to Local Context

Problem:

Common standards or requirements may be inappropriate and perceived as intrusive.

Solution(s):

Delegate the power to set standards and to establish requirements to local authorities.

Reference(s):

Australia (Queensland) – Environmental Protection Act 1994, Section 440O.

Paraguay – Ley Nº 6390 - Que regula la emisión de ruidos, Articles 5 and 6.

Note(s):

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Compliance Cooperation with other Actors

Regulatory Function:

Compliance and Information

Problem:

Authorities in charge are often too weak to ensure compliance alone.

Solution(s):

Empower or mandate cooperation with public and private institutions, associations etc.

Reference(s):

Canada – Canadian Food Inspection Agency Act, SC 1997, c 6, Section 14: empowering CFIA to enter into contracts, memoranda of understanding, and other agreements with federal and provincial departments, agencies, *and any other person or organisation* for the delivery of services or activities within CFIA's mandate; constituting a broad statutory enabling power for cooperation with any public or private actor in enforcement and compliance activities.

Mexico – Ley Federal de Protección al Consumidor (DOF 24.12.1992, last amended DOF 12.12.2025), Article 24(XI): PROFECO empowered to enter into agreements with providers, consumers, and their organisations; and Article 24(XII): PROFECO empowered to enter into cooperation agreements with federal, state, municipal and parastatal bodies and with foreign institutions.

Note(s):

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Artificial Intelligence to Detect Diverging Practice or Infringements

Regulatory Function:

Data-Driven Oversight and Harmonisation

Problem:

Without systematic monitoring, divergences in regulatory/certification practice and infringements go undetected.

Solution(s):

Empower and/or require authorities or bodies to use AI/machine learning to detect interpretive or procedural divergences and infringements.

Reference(s):

Currently absent, but see note.

Note(s):

- There are various jurisdictions planning to set out rules limiting the use of artificial intelligence by public authorities, but implicitly assuming that the use of artificial intelligence by authorities is lawful. See for instance: Brazil – Projeto de Lei No. 2.338/2023 (Regulamentação da Inteligência Artificial), approved by the

Senate on 10 December 2024 and apparently still under review by the Câmara dos Deputados.
- An explicit power is needed in many, but not in all jurisdictions.

Testing Infrastructure (Physical, Artificial Intelligence or other Software)

Regulatory Function:
Enhancing Compliance, facilitating Enforcement

Problem:
Products and processes can be extremely cumbersome or difficult to test, both for operators and authorities.

Solution(s):
Empower administrations or bodies to develop a testing infrastructure, mandate or encourage its use.

Reference(s):
Canada – Directive on Automated Decision-Making (Treasury Board of Canada Secretariat, 2019/2024), Section 6.3 — requiring government entities deploying automated decision systems to conduct peer review of those systems and maintain test environments for ongoing quality assurance; constituting an administrative obligation to maintain AI testing infrastructure within public enforcement bodies, though limited to internal government AI systems.
Brazil – Projeto de Lei No. 2.338/2023 (Regulamentação da Inteligência Artificial), approved by the Senate on 10 December 2024, Articles on *sandbox regulatório* — empowering sectoral regulatory authorities to operate AI regulatory sandboxes as supervised testing environments for high-risk AI systems prior to market deployment, with differentiated criteria for SMEs and startups.

Note(s):

- Consider mandating the use of the testing infrastructure.
- Sandboxes can be a pure testing environment or already process real clients. For the latter, see the entry "Regulatory Sandboxes and Experimentation Clauses" in Chapter B, towards the end.

Mandatory Hardware, Software, Software Component(s) or Datasets

Regulatory Function:

Enhancing Compliance, facilitating Enforcement, Interoperability, Comparability

Problem:

Compliance, comparability of products or services, interoperability and easy enforcements are often hampered by the use of a variety of software or, in particular in the case of artificial intelligence, of datasets.

Solution(s):

Mandate the use of specific hardware (e.g. identifier), software, software component(s) or dataset.

Reference(s):

Australia – My Health Records Act 2012 (Cth), Part 3 Division 1A (healthcare provider organisations required to be registered); Section 45 (condition of registration — uploading of records); and Section 78A (mandatory sharing of health information with the My Health Record system by prescribed healthcare provider organisations, subject to defined exceptions) — requiring prescribed healthcare provider organisations to register with and share clinical information through the My Health Record system using the mandated FHIR-based technical

standards, constituting a statutory obligation to use a designated software and dataset architecture for health data exchange.

India – Central Goods and Services Tax Rules 2017, rule 48(4)–(6), read with Notification No. 13/2020–Central Tax and amendments: Prescribed classes of taxpayers must generate invoices using the prescribed GST invoice particulars and obtain an Invoice Reference Number by uploading the invoice data to the designated Invoice Registration Portal. An invoice issued otherwise than in accordance with rule 48(4) is not recognised as an invoice. The regime mandates a common electronic data structure, software interface and validation identifier, while allowing taxpayers to choose their own compatible software.

India – Central Motor Vehicles Rules 1989, Annexure XI: Vehicles in the prescribed classes must be used with an interoperational device.

Mexico – Código Fiscal de la Federación, Articles 29 and 29-A: Required issuers must create digital tax receipts through the Internet using the prescribed CFDI structure and dataset, transmit them for validation, folio assignment and digital sealing, and provide the resulting electronic file or representation to the recipient. The system mandates a common software-compatible document and validation architecture.

Brazil – Portaria do Ministério da Saúde No. 1.434, de 28 de maio de 2020 (back-up link here) — establishing the Rede Nacional de Dados em Saúde (RNDS) and mandating that all private and public health establishments connect to the RNDS using the prescribed FHIR R4-based software architecture and mandatory dataset profiles (including the *Sumário de Alta Hospitalar* and *Registro de Atendimento Clínico*); constituting a statutory obligation to use a designated software component and dataset for health data exchange, operationalised through ANVISA and the Ministry of Health's digital health governance framework.

Note(s):

See also the following entry.

Electronic Compliance Monitoring

Regulatory Function:

Enhancing Compliance, facilitating Enforcement

Problem:

Human remote compliance control is cumbersome to impossible.

Solution(s):

Mandate the use of certain tracking devices, cameras or other electronic surveillance tools.

Reference(s):

New Zealand — Fisheries (Electronic Monitoring on Vessels) Regulations 2017 (SR 2017/558), Regulations 6-12.

Peru — Decreto Supremo No. 003-2018-PRODUCE, Article 5.2(d).

Note(s):

See also the previous entry and Liberia — Fisheries and Aquaculture Management and Development Law of 2019, Section 11.27.

Notification of Draft State/Province Measures/Deviations

Regulatory Function:

Legal Certainty, National Alignment

Problem:

Unannounced state or province deviations fragment the national market or system or contain other unwishful content.

Solution(s):

Require states/provinces to notify draft measures to the central government prior to adoption.

Reference(s):

Australia – Intergovernmental Agreement for the Australian Consumer Law (2009)], Clause 3.2.

Canada – Canadian Free Trade Agreement (CFTA) (2017, as amended), Chapter Five (Technical Barriers to Trade), Article 402 — requiring all Canadian provinces, territories, and the federal government to notify all other Parties of any draft technical regulation, standard, or conformity assessment procedure that may affect internal trade *before* adoption, allowing a minimum 60-day comment period.

Mexico – Ley General de Mejora Regulatoria, publicada en el DOF el 18 de mayo de 2018 (abrogated), Articles 71–79.

MERCOSUR (Regional) – Decisión CMC No. 02/93 (Consejo del Mercado Común, 1993), Notificación de Reglamentos Técnicos — establishing the obligation for all MERCOSUR member states to notify draft national technical regulations to the *Grupo Mercado Común* before adoption.

Note(s):

Only the reference from Mexico contains a classic statutory provision - the other references relate to agreements.

Central Government as Arbiter in case of States/Provinces Dissent

Regulatory Function:

Alignment of States/Provinces

Problem:

States/provinces may have diverging views on concrete matters relevant for several of them.

Solution(s):

Give a national institution—possibly acting on referral by the central government—the power to resolve defined disputes between subnational authorities, with binding effect and, where appropriate, central responsibility for implementation.

Reference(s):

India – Constitution, Article 262, and Inter-State River Water Disputes Act 1956, Sections 3–6 and 6A: The Central Government must constitute a national tribunal when an inter-State water dispute cannot be resolved through negotiation. The tribunal's published decision has the force of a Supreme Court order or decree, and the Central Government may establish the implementation scheme.

South Africa, Intergovernmental Relations Framework Act 2005, Sections 40–45.

Argentina – Constitution, Articles 116, 117 and 127: Complaints between provinces must be submitted to the Supreme Court, which has original jurisdiction in cases involving a province.

Mexico – Constitution, Article 105, read with the Ley Reglamentaria de las Fracciones I y II del Artículo 105: The Supreme Court resolves constitutional controversies between the Federation and States and between States or municipalities.

Note(s):

Dispute settlement between states or provinces can also be provided for at a more technical level, see Article 29, Regulation (EU) 2023/988 (General Product Safety).

Training and Capacity-Building for Authorities

Regulatory Function:

Regulatory Quality and Efficiency

Problem:

Authorities' competence may lag behind policy or market developments.

Solution(s):

Impose continuing training and capacity-building obligations, including for coordinated pan-jurisdiction implementation.

Reference(s):

United Kingdom – Legislative and Regulatory Reform Act 2006, Section 22, read with the Regulators' Code (2014): Section 22 of the Act imposes a statutory duty on all regulatory authorities to have regard to the Regulators' Code. The Code explicitly mandates that "Regulators should ensure that their officers have the necessary knowledge and skills to support those they regulate".

Colombia – Ley 909 de 2004 (Ley de Empleo Público), Article 36: Mandates continuous training and formation of public employees.

Brazil – Lei No. 9.782, de 26 de janeiro de 1999, Article 7(XXIII) — conferring on ANVISA the institutional mandate to *"fomentar o desenvolvimento de recursos humanos para o sistema e a cooperação técnico-científica nacional e internacional"* (foster the development of human resources for the [SNVS] system and national and international technical-scientific cooperation).

Note(s):

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Qualification of Interviewers or Decision-makers

Regulatory Function:

Regulatory Quality, Efficiency and Protection of Applicants

Problem:

Certain procedures or investigations have better results where the interviewer or decision-maker has undergone particular training or is otherwise particularly qualified.

Solution(s):

Require particular qualification of interviewers or decision-makers in authorities.

Reference(s):

Rwanda – Refugees Law No. 42, 2024, Article 11(3)(b).

Colombia — Decreto No. 2840/2013, Article 16, second paragraph.

Note(s):

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Early Regulatory Dialogue / "Pre-Notification" of Measures

Regulatory Function:

Anticipatory Implementation

Problem:

Operators can be surprised by enforcement measures and might be ready to comply with obligations once informed of the authority's concerns.

Solution(s):

Duty on authorities to pre-notify compliance concerns prior to taking enforcement measures.

Reference(s):

South Africa – Promotion of Administrative Justice Act 3 of 2000, Section 3(2)(b)–(3): Before materially and adversely affecting rights or legitimate expectations through administrative action, the administrator must ordinarily give adequate notice of the nature and purpose of the proposed action and a reasonable opportunity to make representations, subject to reasonable and justifiable departures.

Brazil — Lei No. 9.784/1999 (Lei do Processo Administrativo Federal), Articles 2, 3, 26, 38 and 44: Federal administrative proceedings must respect adversarial process and broad defence. Interested parties must be notified of relevant procedural acts and their factual and legal basis and must have opportunities to submit allegations, evidence and final submissions before the decision.

Note(s):

Evidently not appropriate in cases where a pre-notification would endanger the enforcement.

Serious Incidents / Corrective Actions to Be Notified

Regulatory Function:

Central Learning and Prevention

Problem:

Repeated mistakes or hazards go undetected unless reported and evaluated centrally.

Solution(s):

Obligation of economic operators and certification bodies to notify the authorities of serious incidents and recalls.

Reference(s):

Australia – Therapeutic Goods Act 1989 (Cth), as amended by the Therapeutic Goods Amendment (2022 Measures No. 1) Act 2023, Part 4-8A, Section 41JM.
Colombia – Resolución No. 4816 de 2008 (Ministerio de la Protección Social), Articles 5-9.

Note(s):

The Colombian reference establishes notification obligations down to the level of users (see the end of Article 9).

Certification Bodies or Auditors to Report on Infringements

Regulatory Function:

Better Information of Authorities

Problem:

Authorities are not necessarily aware of infringements committed by operators.

Solution(s):

Mandate certification bodies to report on infringements they happen to observe.

Reference(s):

Australia – Corporations Act 2001 (Cth), Section 311: An auditor must notify ASIC in writing where, in the course of performing an audit, the auditor has reasonable grounds to suspect that a contravention of the Corporations Act has occurred, may have occurred or may occur, and the matter is relevant to the company or the auditor's functions.
Chile – Ley nº 18.045, Ley de Mercado de Valores, Título XXVIII, Article 246: External audit firms registered with the CMF must report material matters

identified in the course of their audit, including acts or omissions that may constitute infringements of securities legislation or regulations and circumstances affecting the reliability of the audited entity's financial information.

Argentina – Decreto Nº 779/1995, Annex 1, Article 34 Sections 27 and 28: Authorised vehicle-inspection centres record and transmit inspection failures and material safety defects through the regulated inspection system, allowing the competent authority to identify vehicles that do not satisfy mandatory roadworthiness requirements and to stay informed on recurring issues.

Note(s):

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Observers following Activities

Regulatory Function:

Better Information of Authorities, Compliance

Problem:

Authorities are not necessarily aware of infringements committed by actors.

Solution(s):

Install observers within the business or administrative structures of the actors.

Reference(s):

New Zealand – Fisheries Act 1996 (NZ), ss. 223–227a.

Ecuador — Ley Orgánica para el Desarrollo de la Acuicultura y Pesca (2020), Article 3 No. 41 (definition of "Observador de pesca") read with Articles 161(e) and 214(f).

Note(s):

See also the next entry.

Controllers steering Activities

Regulatory Function:

Better Information of Authorities, Compliance

Problem:

Actors do not necessarily abide by the law unless they are forced to do so. Moreover, it might be difficult for an authority to assess remotely which measures should be taken.

Solution(s):

Place controllers with decision-making powers within the actors' business or administrative structures.

Reference(s):

Fiji –Credit Union Act 2025 (Act 30 of 2025), Sections 112 and 118-123.

Mexico — Código Fiscal de la Federación, Articles 164–166: Interventor con Cargo a la Caja / Interventor Administrador.

Note(s):

See also the previous entry.

Reporting Forms, Templates, and IT Tools

Regulatory Function:

Uniformity and Efficiency

Problem:

Variation in reporting or documentation increases burden and confusion.

Solution(s):

Mandatory use of forms, templates or digital tools for reporting and declaration.

Reference(s):

Canada — Safe Food for Canadians Regulations, SOR/2018-108, Section 13(1).

Perú – Decreto Supremo No. 050-2016-PCM (Reglamento del procedimiento para la eliminación o reducción de riesgos no previstos de productos o servicios), Article 10 — requiring all providers to notify INDECOPI of unsafe products or services *using the mandatory formats (formatos) approved by the Presidencia del Consejo Directivo del INDECOPI.*

Note(s):

Aids interoperability, multilingualism, and data quality.

Enforcement Funding and Cost Recovery

Regulatory Function:

Resourcing Enforcement

Problem:

Underfunded authorities cannot carry out effective enforcement or surveillance. Understaffing is to be observed in many jurisdictions.

Solution(s):

Rules on how costs may be recovered from non-compliant actors, market fees, or earmarked public funding.

Reference(s):

India – Bureau of Indian Standards Act, 2016 (Act No. 11 of 2016), Section

20(1): Establishing the BIS Fund as a dedicated fund into which all fees, charges, grants, and receipts are credited and from which all BIS expenditure is met.

Belize – Belize Agricultural Health Authority (Prevention, Control and Eradication of New World Screwworm) (Cochliomyia Hominivorax) Regulations 2024 (S.I. No. 143 of 2024), Section 17: see in particular the hourly rate for certain functions.

Guyana – Sea and River Defence Act (No. 9 of 2024), Articles 29(2) and 31.

Colombia – Decreto 1290 de 1994 (as incorporated into Decreto Único Reglamentario 780 de 2016), Article 13(4).

Panamá – Decreto Ejecutivo No. 6 (2024) (Meat Control), Article 50: responsibility for laboratory costs where an inspection indicates an issue.

Note(s):

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Prevention of Avoidance / Circumvention

Regulatory Function:

Legal Certainty, Fairness and Enforcement

Problem:

Operators tend to avoid or circumvent obligations by contractual arrangements, e.g. letting employees become independent workers, splitting entities or assets.

Solution(s):

Dedicated provisions hindering avoidance / circumvention arrangements.

Reference(s):

Papua New Guinea – Income Tax Act 2025, Part VIII.

Bahamas – Commercial Entities (Substance Requirements) Act, 2023, Section 25: avoidance arrangements being void.

Chile, Código Tributario, Articles 4° bis, 4° ter and 4° quáter (Cláusula General Antielusión).

Note(s):

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Prevention of Test Cheating

Regulatory Function:

Legal Certainty, Fairness and Enforcement

Problem:

Operators tend to interpret provisions on testing in their own way, which may not necessarily be the intended way. Operators sometimes try to cheat.

Solution(s):

Ban certain cheating behaviours or measures related to tests.

Reference(s):

Canada – On-Road Vehicle and Engine Emission Regulations, SOR/2003-2, Section 11.

Brazil – Resolução CONAMA No. 230, de 22 de agosto de 1997, Articles 1 and 2.

Note(s):

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Definition of Technical Protocols and Test Methods

Regulatory Function:

Adaptive and Future-Proof Norms

Problem:

Technical methods/protocols need to evolve with science and practice.

Solution(s):

Empower the Government (or agencies) to specify protocols and standards via statutory acts, regularly updated.

Reference(s):

Australia – Competition and Consumer Act 2010 (Cth), Schedule 2 (Australian Consumer Law), Section 104 — empowering the Commonwealth Minister to make, by legislative instrument, mandatory safety standards specifying the requirements (including test methods and technical protocols) that consumer goods must meet.

Chile – Ley Nº 20.417, Ley Orgánica de la Superintendencia del Medio Ambiente, Article 3(ñ): The Superintendence may issue generally binding technical directives defining the protocols, procedures and methods of analysis that inspection bodies, accredited entities and regulated operators must apply when testing and measuring compliance with environmental quality and emission standards.

Note(s):

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Pass-fail-Criteria for Tests

Regulatory Function:

Compliance and Level Playing Field

Problem:

Where different institutions test, they will be more or less lenient. This creates an

issue of compliance and fairness. In some sectors and jurisdictions, assessment by conformity assessment bodies has degenerated to a kind of consulting service: tests are repeated until the criteria are matched.

Solution(s):

Lay-down clear pass-fail-criteria for tests: what is to be tested, how often, and what are the consequences of one or several failures.

Reference(s):

Brazil — Portaria INMETRO nº 118/2022, Section 6.2.4.2.1.

Note(s):

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Testing Laboratories' Equipment and Procedures

Regulatory Function:

Reliability and Comparability of Test Results

Problem:

Inadequately equipped or biased labs can undermine regulatory confidence.

Solution(s):

Set minimum technical requirements and quality assurance/traceability for test laboratories.

Reference(s):

India – Bureau of Indian Standards Act, 2016 (Act No. 11 of 2016), Section 13(4) (Conformity Assessment scheme — establishing the scheme under which only BIS-recognised laboratories meeting prescribed technical requirements may conduct testing for BIS certification purposes); the specific minimum technical requirements for recognised laboratories are prescribed in subordinate

instruments made under Section 39 (Power to make regulations) — constituting the statutory basis for testing laboratory equipment and procedure requirements in India, with the detailed standards set at regulatory rather than primary legislation level.

Brazil – Lei No. 9.933, de 20 de dezembro de 1999, Article 3 — empowering INMETRO to accredit conformity assessment bodies including testing laboratories; operationalised through Portaria INMETRO No. 200, de 29 de abril de 2021 Section 6.2.4.3 — prescribing that all laboratories accredited by INMETRO's Cgcre (General Coordination for Accreditation) must comply with ABNT NBR ISO/IEC 17025 (for testing and calibration) or ABNT NBR ISO 15189 (for clinical laboratories).

Note(s):

Consider referencing ISO 17065.

National Reference Laboratories

Regulatory Function:

Benchmarking and Consistency of Testing

Problem:

Fragmented or inconsistent testing undermines market confidence and fairness. The more laboratories are active in a certain sector, the more methodological divergence can be observed. Moreover, the knowledge and expertise is fragmented where there are many laboratories.

Solution(s):

Designate a limited number of National Reference Laboratories to provide highest-level comparative testing and arbitration.

Reference(s):

Canada – Health of Animals Act, SC 1990, c 21, Section 29 — empowering the Minister to designate laboratories as national reference laboratories for specific animal diseases and to prescribe their functions, including provision of authoritative confirmatory testing, method validation, and technical arbitration.

India – Food Safety and Standards (Recognition and Notification of Laboratories) Regulations, 2018.

Colombia – Ley 9 de 1979 (Código Sanitario Nacional), Article 484-487; and Decreto 2323 de 2006 — establishing the Red Nacional de Laboratorios (RNL) under INS coordination, designating INS as the apex national reference laboratory responsible for method validation, proficiency testing, technical arbitration, and capacity building across the laboratory network

Note(s):

Section 30 of the Canadian reference provides the right to designate foreign laboratories – a useful addition.

Contact Points/Digital Gateways

Regulatory Function:

Market Access Assistance and (Compliance) Support

Problem:

SMEs and cross-border operators struggle to obtain reliable information on national provisions, namely with regard to compliance.

Solution(s):

Government to provide fully accessible product contact points and digital "one-stop-shops".

Reference(s):

Australia – Business Names Registration Act 2011 (Cth), A New Tax System (Australian Business Number) Act 1999 (Cth), Section 24 (establishing the Australian Business Register as the authoritative national business registration database) and Section 26 (providing public access to ABR information) — forming part of the statutory underpinning of business.gov.au, the Commonwealth's whole-of-government digital one-stop-shop for business regulatory information, grants, registrations, and compliance guidance. business.gov.au itself operates under administrative arrangements of the Department of Industry, Science and Resources rather than enabling acts.
Brazil – Lei Complementar No. 123, de 14 de dezembro de 2006 (Estatuto Nacional da Microempresa e da Empresa de Pequeno Porte), Articles 4 and 8 — mandating a single entry point for all business registration, licensing, and regulatory compliance data (*entrada única de dados cadastrais*); operationalised through the REDESIM (Rede Nacional para a Simplificação do Registro e da Legalização de Empresas e Negócios) — the statutory national digital one-stop-shop integrating federal, state and municipal regulatory information, compliance requirements and clearance procedures for micro and small enterprises.

Note(s):

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Social Partners in Regulatory Committees

Regulatory Function:

Inclusive and Balanced Governance

Problem:

Labour, employer and civil society interests need structured voices alongside technical authority.

Solution(s):

Mandate participation rights for social partners in formal and advisory committees.

Reference(s):

Australia – Fair Work Commission, operating under a series of acts.

Colombia – Ley 278 de 1996.

Note(s):

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Cooperation and Information-Sharing between Authorities

Regulatory Function:

Supervisory Consistency, Efficiency and mutual Control

Problem:

Authorities do not necessarily cooperate well and do not necessarily share information.

Solution(s):

Mandate cooperation and in particular information sharing between authorities.

Reference(s):

United Kingdom – Financial Services and Markets Act 2000, Section 354A and 354B.

Cuba – Decreto-Ley Nº 102/2025 sobre el uso de la energía nuclear y las radiaciones ionizantes, Articles 19, 20.2, 43, 45.1 and 45.2.
Nicaragua – Decreto Presidencial Nº 09-2022 - Reglamento para el Control de las Sustancias que Agotan la Capa de Ozono, Article 50.
Argentina – Decree 1759/1972 (Reglamento de la Ley 19.549), Article 14: clarifying that the obligation to cooperate has to be respected regardless of the hierarchical position.

Note(s):

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Information-Sharing between External Auditors or Certification Bodies and Authorities (Obligations and Empowerments)

Regulatory Function:

Supervisory Consistency and Quality Control

Problem:

Authorities need to learn from auditors or certification bodies "on the ground", whilst the latters' activities can easily become inconsistent if done in isolation.

Solution(s):

Impose and empower detailed information-sharing mechanisms between external auditors or certification bodies and authorities.

Reference(s):

Australia – Food Act 2003 (NSW), Section 95, in particular paragraph (5).

Brazil – RDC No. 687, de 13 de maio de 2022, Article 9(§1) — requiring recognised external Auditing Organisations to forward action plans for identified non-conformities directly to ANVISA.

Note(s):

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Mandating Good Administrative Practices

Regulatory Function:

Fairness, Efficiency and Compliance

Problem:

Administrations do not always behave in a fair and efficient way.

Solution(s):

Mandate the respect of good administrative practice (codes).

Reference(s):

South Africa – Promotion of Administrative Justice Act, No. 3 of 2000 (PAJA) — giving effect to Section 33 of the Constitution (right to lawful, reasonable, and procedurally fair administrative action) by prescribing mandatory good administrative practice standards for all organs of state; Section 6 — establishing judicial review grounds including unreasonableness, bias, error of law, and failure to follow due process; Section 10 — empowering the Minister to issue a Code of Good Administrative Conduct providing administrators with practical guidelines on fair and efficient administration.

Chile – Ley No. 19.880, de 29 de mayo de 2003 (Ley de Bases de los Procedimientos Administrativos), Capítulo I.

Note(s):

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Capping of Compliance Costs

Regulatory Function:

Market Fairness and Access

Problem:

High prices for compliance procedures, standards or technical documents act as barriers to compliance.

Solution(s):

Set legal maximum prices for essential procedures or standards/documents to ensure all actors can comply.

Reference(s):

Bureau of Indian Standards (Conformity Assessment) Regulations, 2018, Annexure I — establishing reduced fees for small and medium enterprises.

Colombia – Ley 2069, de 31 de diciembre de 2020 (Ley de Emprendimiento), Article 2 — mandating differentiated INVIMA (health product regulatory authority) fees according to enterprise size classification; prescribing that micro-enterprises are fully exempt from INVIMA fees for the granting, modification and renewal of all product registrations; and requiring INVIMA to define the percentage reduction in fees applicable to small and medium enterprises relative to large enterprise rates.

Note(s):

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Sanction Waiver or Reduction for Information on Infringement

Regulatory Function:

Long-term Compliance

Problem:

In many areas, infringements can only be detected where insiders disclose them. However, persons might not disclose infringements where they fear to be sanctioned.

Solution(s):

Provide sanction waivers or reduction in return for information on infringements committed by the same and other persons.

Reference(s):

Ghana — Penalty and Interest Waiver Act, 2021.

Chile — Decreto Ley No. 211 (DL 211), Arts. 39 bis and 63 (Delación Compensada).

Note(s):

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Incentives/Prizes for Voluntary Over-Compliance, Innovation, or Social Good

Regulatory Function:

Promoting Exceedance of Minimum Standards in View of Legislative Goals

Problem:

Minimum compliance does not reward extra effort or innovator-early adopters. The minimum compliance does not necessarily reach the optimum.

Solution(s):

Recognition schemes, simplified procedures, or reduced audits for documented superior performance.

Reference(s):

New Zealand – Waste Minimisation Act 2008, Section 15 — empowering the Minister to accredit voluntary product stewardship schemes meeting the requirements of Section 14 (measurable waste minimisation objectives, participant responsibilities, and performance reporting), with accreditation constituting the statutory recognition of superior voluntary performance; Section 9(3)(d) — requiring the Minister, before declaring a product a priority product subject to mandatory regulation, to consider the effectiveness of any existing voluntary product stewardship scheme; thereby providing a statutory incentive for voluntary over-compliance in that operators who establish effective voluntary schemes demonstrably reduce the risk of mandatory regulatory intervention.

Namibia — Vehicle Mass Act, 2024, Section 10.

Mauritius — Protection and Promotion of the Rights of Persons with Disabilities Act 2024, Sections 41 to 44: from tax deduction to allowances.

Mexico — Ley General del Equilibrio Ecológico y la Protección al Ambiente (LGEEPA), Articles 3, 6, 25, 28, 31 and 38 BIS: Article 38 BIS empowering PROFEPA to promote voluntary environmental audits (*auditorías ambientales*); operationalised through the Reglamento de la LGEEPA en Materia de Autorregulación y Auditorías Ambientales (RLGEEPAMAAA), Articles 3 (defining *autorregulación* as a voluntary process adopting standards more stringent than legally required), 6 (establishing the *Programa Nacional de Auditoría Ambiental* with a statutory system of recognition and incentives), 25 (providing procedural advantages for certification renewal), 28 (prescribing the *Certificado de Industria*

Limpia as a recognition of performance superior to legal requirements) and 31 (establishing the *Reconocimiento de Excelencia Ambiental* for enterprises at the maximum level of environmental performance).

Mexico — Ley Federal sobre Metrología y Normalización (LFMN), Article 110 (quality award).

Note(s):

See also the Section on incentives (Section 4.1) in our Handbook "How to regulate?".

K. Enforcement Powers

Proactive Surveillance and Own-Initiative Audits

Regulatory Function:

Risk Detection and Preventive Action

Problem:

Authorities previously acted almost solely on complaints or "signals".

Solution(s):

Legal basis for authorities to conduct surveillance or audits without exogenous triggers.

Reference(s):

Jamaica — Consumer Protection (Amendment) Act, 2012, Section 3 amending Section 6(3)(a) of the principle act: The Consumer Affairs Commission "may investigate on its own initiative, any breach by a provider of any provision of this Act".

Chile — Ley Marco de Ciberseguridad e Infraestructura, Ley No. 21.663, 2024, artículo 11, letter ñ), second paragraph: The Agencia Nacional de Ciberseguridad (ANCI) may conduct inspections and order audits — either itself or via authorised third parties — based on objective risk evaluation criteria. There is no complaint, incident, or external trigger required: the power is an inherent supervisory competence exercisable at ANCI's own initiative.

Note(s):

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"Stress Tests" and Real-Time Audits

Regulatory Function:

Risk Detection and Preventive Action

Problem:

Paper compliance may miss vulnerabilities; only real-world tests expose failures.

Solution(s):

Empower/require authorities to commission or perform stress tests and real-time ("live") audits.

Reference(s):

Australia — Security of Critical Infrastructure Act 2018 (Cth), as amended by the Security Legislation Amendment (Critical Infrastructure Protection) Act 2022: Sections 30CU–30CZ (Part 2C, Division 4 — Vulnerability Assessments): The Secretary may require entities to undertake a vulnerability assessment, and designated officers may themselves conduct that assessment (s. 30CW). This is an authority-initiated, live inspection of the operational environment.

Brazil — Resolução CMN No. 4.557, de 23 de fevereiro de 2017 (Risk Management and Capital Management Framework), Artigo 19: "O Banco Central do Brasil poderá determinar: I — ajustes ao programa de testes de estresse, incluindo o uso de cenários que diferem [dos adotados pela instituição]." The BCB may order a supervised institution to run specific stress test scenarios — including scenarios of BCB's own choosing — against the institution's live operational risk exposure across all business areas and the prudential conglomerate as a whole (Arts. 12–14). The stress test is explicitly defined as "a forward-looking assessment of potential impacts arising from adverse events [...] related to the institution itself or to the market" performed on the operating institution, not a documentary review. The BCB's power under Art. 19 is own-initiative, not complaint-triggered.

Note(s):

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Authority to Test as Client (e.g. Mystery Shopping)

Regulatory Function:

Real-World Compliance Checks

Problem:

Manufacturers or sellers might present compliant samples to authorities while offering different (non-compliant) products on the market. Services and other processes might be executed with less care when no inspection is expected.

Solution(s):

Grant explicit power to authorities to carry out tests as clients—including covert or "mystery shopping"—to verify real-world compliance.

Reference(s):

Bermuda — Consumer Protection Act 1999 (Act 1999:45), Section 28: "Any inspector may, for the purposes of enforcement of this Act or the regulations, make test purchases of goods or otherwise ascertain whether the safety provisions or any other provisions of this Act or the regulations or of an order under this Act are being complied with."

Brazil – Resolução CNSP nº 382/2020, Article 9 and sole paragraph: SUSEP may designate an official to act as a "cliente oculto" and research, simulate or test, in person or remotely, the contracting, distribution, intermediation, promotion, advertising and information practices used for insurance, capitalisation and open supplementary-pension products. The supervised entity or intermediary need not be notified of the supervisory activity. This expressly authorises covert client-side testing to determine whether operators' real-world conduct complies with applicable regulation.

Note(s):

In Peru, mystery shopping has been authorised, on the basis of the given legislation, by virtue of a tribunal ruling (INDECOPI Tribunal, in Resolución No. 0215-2020/SPC-INDECOPI, 22 January 2020).

Proportional/Graduated Enforcement Toolkit / Comprehensive Catalogue of Powers

Regulatory Function:

Proportional Enforcement and Deterrence

Problem:

Rigid enforcement can be unfair or unworkable. Effective enforcement depends on having powers to act appropriately in all situations of non-compliance.

Solution(s):

Legally set out a range of enforcement actions—from warnings to fines, recalls and withdrawals—matched to risk/gravity. Establish a comprehensive catalogue of powers / empowerments.

Reference(s):

Australia — Regulatory Powers (Standard Provisions) Act 2014 (No. 93, 2014): quite extensive.

India – Consumer Protection Act, 2019 (No. 35 of 2019), Sections 18 and 20–22: rather concise.

Nigeria — Federal Competition and Consumer Protection Act, 2018 (Act No. 1 of 2019): Parts VI and XVII: medium detailed.

Colombia – Ley 1480 de 2011 (Estatuto del Consumidor), Article 59.

Chile – Ley No. 18.892/1989 (Ley General de Pesca y Acuicultura), Art. 122.

Brazil — Código de Defesa do Consumidor (Lei nº 8.078, de 11 de setembro de 1990), Article 56: Art. 56 enumerates twelve graduated administrative sanctions applicable to consumer law violations, including: (I) fine; (II) product seizure; (III) product destruction; (IV) revocation of product registration; (V) prohibition of manufacture; (VI) suspension of supply; (XI) administrative intervention; (XII) counter-advertising. The catalogue is explicitly open to cumulative application ("podendo ser aplicadas cumulativamente, inclusive por medida cautelar").

Note(s):

The Australian reference is close to what we would deem as a comprehensive enforcement toolkit or catalogue of powers. See our "List of Powers and Obligations" with several hundred empowerments useful for enforcement.

Layered Administrative, Civil, Criminal Enforcement

Regulatory Function:

Proportionate and Effective Enforcement

Problem:

One channel of enforcement may be too weak or inflexible.

Solution(s):

Enable various pathways (administrative, civil, criminal) for different levels of breach, defined by law.

Reference(s):

New Zealand — Resource Management Act 1991, Sections 314–343D: *inter alia* providing for (a) administrative — abatement notices (ss. 322–327), infringement notices (s. 336); (b) civil — enforcement orders by the Environment Court (ss. 314–324), applications open to any person with standing; (c) criminal — offence provisions (ss. 338–340), prosecuted in the District Court.

Brazil — Environmental Crimes Act, Lei No. 9.605, de 12 de fevereiro de 1998, Article 3: All three pathways — administrative (Title V, Arts. 70–76: sanctions catalogue from warnings to suspension of activities), civil (Art. 14 §1 of Lei 6.938/1981, incorporated by reference: strict liability for remediation), and criminal (Title VI, Arts. 29–69: imprisonment + fines) — are declared by name in a single article and operationalised in the same statute.

Note(s):

See also our "List of Powers and Obligations" with several hundred empowerments useful for enforcement and the parallel "List of Sanctions and Collateral Measures".

Targeted Information Interventions by Authorities

Regulatory Function:

Tailored Risk Communication

Problem:

Generic warnings are ignored or misunderstood.

Solution(s):

Allow for special, sectoral, or real-time targeted warnings issued via regulatory platforms or media.

Reference(s):

India – Consumer Protection Act, 2019 (No. 35 of 2019), Section 18(2)(j): The Central Consumer Protection Authority (CCPA) may "issue safety notices to alert consumers against dangerous or hazardous or unsafe goods or services."

Barbados — Consumer Protection Act 2002 (Cap. 326D), Sections 55 and 56: "Warning notices".

Note(s):

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Blacklisting and Shaming

Regulatory Function:

Effective Sanctions, Prevention of future Non-compliance

Problem:

Ordinary sanctions might not suffice to deter effectively.

Solution(s):

Explicit exclusion mechanisms or "blacklisting" or "shaming" in public databases.

Reference(s):

Kenya — Public Procurement and Asset Disposal Act, 2015, Section 41 (debarment) + Public Procurement and Asset Disposal Regulations, 2020, Regulation 22: The Director-General may initiate debarment proceedings on own motion following investigations or inspections (Reg. 22(1)(b)), or on referral from a law enforcement agency. Minimum debarment period: three years. Section 41(5) and Regulation 22(8) extend the debarment to any legal entity in which the debarred person holds a controlling interest — preventing blacklist circumvention through corporate restructuring. The debarment is entered in the public Authority register.

Brazil — Lei Anticorrupção, Lei No. 12.846, de 1º de agosto de 2013, Articles 22 and 23. Article (CNEP — Cadastro Nacional de Empresas Punidas): all federal, state and municipal agencies must submit and maintain in the CNEP full details of every administrative sanction applied under the Lei Anticorrupção, including corporate name, CNPJ, penalty imposed, penalty period and responsible official. The register is publicly accessible via the Portal da Transparência. Article 23

(CEIS — Cadastro Nacional de Empresas Inidôneas e Suspensas): all agencies must register entities suspended or declared ineligible under procurement law. The Integrated CEIS/CNEP System (Banco de Sanções) thus creates a single public blacklist covering both procurement debarment and anti-corruption sanctions. Both registers combine the shaming and blacklisting functions in one database architecture.

Note(s):

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Blocking Online Access to Non-Compliant Products or Services

Regulatory Function:

Effectiveness in the Digital Economy

Problem:

Authorities lack the ability to block online access to non-compliant products or services.

Solution(s):

Give powers for temporary or permanent digital blocking, subject to proportional safeguards.

Reference(s):

United Kingdom — Digital Markets, Competition and Consumers Act 2024, Sections 160–162, especially Section 161: A court may, on application by a public designated enforcer, order the removal or modification of online content, the disabling or restriction of access to an online interface, the display of consumer warnings, or the deletion and transfer of a domain name. The court

must be satisfied that a relevant consumer-law infringement has occurred, is occurring or is likely to occur; that other available enforcement measures would not be wholly effective; and that the order is necessary to avoid serious harm to consumers' collective interests. Section 162 permits interim orders.
Uruguay — Ley No. 19.924 (Ley de Presupuesto Nacional 2020–2024), artículo 712: "La URSEC podrá requerir a los proveedores de acceso a internet (ISP) el bloqueo de acceso desde el territorio nacional a las direcciones IP y/o URL, según correspondan, que sean utilizados para desarrollar tales actividades ilícitas en forma excepcional, con carácter provisorio, revocable y por un plazo no mayor a treinta días corridos, tendientes a impedir la transmisión y sujeto a revisión judicial."

Note(s):
- See also Article 9, Regulation (EU) 2022/2065 (Digital Services), OJ L 277, 27.10.2022, p. 1–102.

Ban Based on Comparison

Regulatory Function:
Optimising Regulatory Goals

Problem:
Some policy goals merit being pursued in the best possible way. Setting a benchmark will mostly lag behind the optimal solution.

Solution(s):
Create a legal base for banning less than optimal products, substances, services, processes or actors.

Reference(s):
United Kingdom (Great Britain) — Regulation (EU) No 528/2012 concerning

biocidal products, as retained and amended in domestic law, Articles 10 and 23, especially Article 23(3): The competent authority must comparatively assess a biocidal product containing an active substance identified as a candidate for substitution. It must prohibit or restrict the product where a sufficiently effective authorised product or non-chemical method for the same use presents a significantly lower overall risk without significant economic or practical disadvantages. The regime therefore enables less desirable products to be removed or restricted by comparison with available superior alternatives, rather than solely by reference to a fixed risk ceiling.

Peru – Decreto Legislativo Nº 1059 (Ley General de Sanidad Agraria), Article 15: establishes National Agricultural Health Authority shall prioritize measures to restrict or prohibit use of WHO Category 1A (extremely hazardous) and 1B (highly hazardous) chemical pesticides for agricultural use "provided that technical and economic alternatives exist and, above all, of lower risk to health and environment" (siempre que cuenten con alternativas técnicas y económicas y, sobre todo, de menor riesgo para la salud y el ambiente), applied through Resolución Jefatural 307-2011-AG-SENASA suspending registrations for 90-day evaluation period to assess availability of safer alternatives, thereby establishing comparative assessment of existing safer alternatives as procedural requirement for maintaining or restricting authorization of high-hazard pesticides.

Note(s):

- This approach is particularly relevant for environmental and health aspects.
- The comparative assessment can also be integrated into licensing / authorisation procedures, see the separate entry “Comparative Assessment in View of Goals” in Chapter D.
- Moreover, both can be matched by an obligation to optimise, incumbent on actors, e.g. to apply the best available option or technique or the obligation to reduce risks as much as possible.

Powers for "Recall" of Digital Content or Correction of Published Errors or Misleading Advertisement

Regulatory Function:

Digital Era Consumer/Market Protection

Problem:

Unlawful, misleading, or dangerous digital content can spread rapidly with lasting damage. Consumers or businesses may have been misled or harmed by non-compliant marketing or claims.

Solution(s):

Statute-based power for authorities to order removal or correction of digital content or services. Express power for authorities to require corrective advertising or notices to reach affected audiences.

Reference(s):

Singapore — Protection from Online Falsehoods and Manipulation Act 2019 (POFMA, Act 18 of 2019), Sections 11, 21, (22) and 23: detailed layered response scheme.

Brazil — Lei No. 8.078/1990 (Código de Defesa do Consumidor — CDC), Article 60: Article 60 establishes contrapropaganda (counter-advertising) as a mandatory administrative sanction applicable whenever a supplier engages in misleading or abusive advertising.

Colombia — Ley 1480 de 2011 (Estatuto del Consumidor), Article 54: "La Superintendencia de Industria y Comercio, de oficio o a petición de parte, podrá imponer una medida cautelar hasta por treinta (30) días calendario, prorrogables por treinta (30) días más, de bloqueo temporal de acceso al medio de comercio electrónico, cuando existan indicios graves que por ese medio se están violando los derechos de los consumidores, mientras se adelanta la investigación

administrativa correspondiente." Targets the e-commerce medium through which misleading or unlawful content is being disseminated during the investigation.

Note(s):

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Economic Powers Catalogue - External Administrator

Regulatory Function:

Enforcement Ensurance in Complex or Difficult Business Settings and (Threat of) Insolvency

Problem:

Enforcement is difficult or impossible where the targeted operator is in a complex or difficult business setting or even under threat of insolvency.

Solution(s):

Select some of the powers from the references, and in particular the right to impose external administration (Chile) or “to assume control” (Singapore).

Reference(s):

Singapore — Financial Services and Markets Act 2022 (Act 22 of 2022), in force 10 May 2024, Part 7 provides inter alia the : (i) power to assume control of a covered financial institution; (ii) power to effect transfer of business/assets/liabilities; (iii) power to implement bail-in of liabilities and reduce share capital (cancellation of unpaid shares); (iv) power to stay early termination rights (preventing close-out netting from fragmenting the institution during resolution); (v) power to require changes to business practices, legal, operational or financial structures or organisation.

Chile — Decreto con Fuerza de Ley No. 3, de 19 de diciembre de 1997 Decreto con Fuerza de Ley No. 3, de 19 de diciembre de 1997 (Ley General de Bancos), as amended by Ley No. 21.130 (D.O. 12.01.2019), Artículo 117: Provisional administration (administración provisional) — triggered when "hechos graves que hagan temer por la estabilidad económica del banco" occur.

Note(s):

- These powers are here recommended as means to ensure the fulfilment of obligations other than those established in recovery and resolution legislation.
- Less invasive than an external administrator: external inspector integrated into the operations.

Fees, Charges, Cost-Sharing for Regulatory Services

Regulatory Function:

Fair and Effective Resourcing

Problem:

Regulation is hampered if costs fall solely on the public purse or are distributed unfairly.

Solution(s):

Set transparent rules for levying fees for approvals, surveillance, or market controls.

Reference(s):

New Zealand — Food Act 2014, Sections 198–214 (Cost Recovery): Section 199 provides: The methods by which costs may be recovered under this subpart are as follows: (a) fixed fees or charges: (b) fees or charges based on a scale or formula or at a rate determined on an hourly or other unit basis: (c) the recovery by way of fee or charge of actual and reasonable costs expended in or

associated with the performance of a service or function: (d) estimated fees or charges, or fees or charges based on estimated costs, paid before the provision of the service or function, followed by reconciliation and an appropriate further payment or refund after provision of the service or function: (e) refundable or non-refundable deposits paid before provision of the service or performance of the function: (f) fees or charges imposed on users of services or on third parties: (g) levies: (h) any combination of the above.

Kenya — Standardization Marks (Permits and Fees) Regulations (L.N. 154/1977), Regulation 8: every applicant for a standardisation mark permit pays an application fee (reg. 8(1)); every permit holder pays an annual permit fee (reg. 8(2)); and a marking fee proportionate to the quantum of annual production (reg. 8(3)). The Bureau retains power to "at any time vary or change the marking fee payable in respect of any commodity" — enabling dynamic cost recovery.

India – Bureau of Indian Standards Act, 2016 (Act No. 11 of 2016), Section 20(1), — establishing the BIS Fund as a dedicated fund into which all fees, charges, grants, and receipts are credited and from which all BIS expenditure is met.

Ecuador — See the references on top of this document and its differentiated approach.

Brazil – Lei n.º 9.782/1999*, de 26 de janeiro de 1999*, Article 23: Article 23(IX) of the ANVISA enabling act confers power to "cobrar taxa de fiscalização das atividades e dos produtos sujeitos ao regime de vigilância sanitária" — to levy a supervision tax on all activities and products subject to the sanitary surveillance regime. The implementing instrument is the Taxa de Fiscalização de Vigilância Sanitária (TFVS), which generates ANVISA's primary operational funding. The TFVS is differentiated by risk class and product category, linking fee levels to regulatory burden and risk level.

Note(s):

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Measures targeting Company Groups

Regulatory Function:

Efficiency of Enforcement, Risk Reduction

Problem:

Deficiencies and risks are often spreading over several companies belonging to the same group (covering at least all mother, daughter or sister companies).

Solution(s):

Introduce empowerments to act against an entire company group on the basis of a presumed non-compliance or risk.

Reference(s):

South Africa — Financial Sector Regulation Act, 2017 (Act 9 of 2017), Chapter 12 — Financial Conglomerates.

Kenya — Public Procurement and Asset Disposal Act, 2015, Section 41 (debarment) + Public Procurement and Asset Disposal Regulations, 2020, Regulations 22(8) and 41(5) extend the debarment to any legal entity in which the debarred person holds a controlling interest — preventing blacklist circumvention through corporate restructuring or shielding.

Colombia — Ley 1870 de 2017 (Ley de Conglomerados Financieros de Colombia), Articles 2o-6o. Broad powers related to the entire group even where only parts of it are problematic.

Note(s):

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Precise Delegation for Enforcement Powers

Regulatory Function:

Strengthening Enforcement and institutional balancing

Problem:

Vague or excessive delegation may bypass checks and balances.

Solution(s):

Explicitly define what may / may not be delegated, with limits and procedures for subdelegation.

Reference(s):

New Zealand — Crown Entities Act 2004 (2004 No. 115), Sections 73–76: Section 73 — Ability to delegate: The board of a statutory entity may delegate any of its functions or powers, either generally or specifically, to named persons or classes of persons. Section 74 — Powers of delegate: The delegate may exercise delegated powers to the same extent as the delegating body, but may not further sub-delegate unless expressly authorised. Section 75 — Effect of delegation on entity or board: Delegation does not prevent the entity or board from exercising the same function or power — the delegating authority retains concurrent power. Section 76 — Revocations of delegations: The delegating board retains power to revoke any delegation at any time, in whole or in part. The Act further establishes an explicit non-delegation rule for ministerial powers: "The responsible Minister may not delegate any power under this Act except as provided in subsection (4)" — ministerial enforcement powers are therefore non-delegable as a default, subject only to the narrow statutory exceptions in s. 73(4).

Colombia — Ley 489 de 1998 (Estatuto Básico de Organización y Funcionamiento de la Administración Pública), Artículos 9–14: Art. 9: Delegation permitted only to persons with "funciones afines o complementarias" (related or complementary functions) — scope limitation by subject-matter affinity. Art. 10:

Delegation must always be in writing; the delegating authority must "informarse en todo momento" (remain permanently informed) of the exercise of delegated functions and issue general orientations — the supervision obligation is statutory. Art. 11 — negative list: Three categories that cannot be delegated: (1) enactment of general regulatory acts (except where expressly authorised by law); (2) functions received under a prior delegation — explicit prohibition on subdelegation; (3) functions which by their nature or by constitutional or legal mandate are not susceptible to delegation. Art. 12: Delegation transfers responsibility to the delegate; the delegating authority is relieved of liability but retains power at any time to reassume competence and review acts of the delegate. Art. 13: Presidential functions may be delegated only to the specific officers listed (Ministers, Directors of Administrative Departments, representatives of decentralised entities, Governors, Mayors) — a closed list for the highest-level delegation. Art. 14: Delegation to public entities of a different level (national → territorial) requires a convention setting out mutual rights and obligations and must be for a defined term (Corte Constitucional condition, Sentence C-727/2000). There is a prohibition on subdelegation in Art. 11(2) — "las funciones, atribuciones y potestades recibidas en virtud de delegación".

Note(s):

Sector-specific delegation rules may be useful in absence of generic delegation rules, like the ones referred to above, or to complement or derogate the generic delegation rules.

Urgency Enforcement Powers and Hot Pursuit

Regulatory Function:

Effective Enforcement

Problem:

Ordinary enforcement powers do not always suffice in urgent cases. Unlawful actors may leave the area of geographic responsibility of the authority.

Solution(s):

Provide extraordinary powers with less procedural control. Permit action outside the area of geographic responsibility.

Reference(s):

Canada — Coastal Fisheries Protection Act, RSC 1985, c. C-33.15, Sections 7.5 and 8.

Argentina — Ministerio de Seguridad, Resolución 396/2018, Article 1 and Annex I, Section 4.5: Pursuit may continue into the high seas, and the protocol authorises necessary, gradual and proportionate measures—including regulated use of force—to stop and board the vessel.

Note(s):

See also Liberia — Fisheries and Aquaculture Management and Development Law of 2019, Sections 11.8 ("hot pursuit") and 11.9 ("without a warrant").

Joint Multidisciplinary Inspections

Regulatory Function:

Burden Reduction and Efficiency

Problem:

Multiple Inspections create more burden and detect less non-conformities.

Solution(s):

Permit (and thereby encourage) or mandate joint multidisciplinary inspections.

Reference(s):

United Kingdom – Criminal Justice and Court Services Act 2000, Sch. 1A paras. 5 and 7(3): the inspectorate may act jointly with another public authority when carrying out inspections, permitting combined inspection procedures that cover multiple requirements in a single process.

Colombia — Decreto-Ley 019 de 2012, Article 108: Where INVIMA and ICA exercise inspection, surveillance and control functions over the same natural or legal person, they must establish mechanisms for conducting joint inspections or visits, taking relevant evidence and exchanging the information required for their respective mandates. The provision mandates coordinated, multidisciplinary inspections by the food, medicines and public-health regulator and the agricultural-health regulator, reducing duplicate visits while preserving each authority's competence.

Note(s):

For Latin America, we found no statutory provisions, but the Dominican Republic Draft "Protocolo de Inspección Conjunta para la Facilitación del Comercio Exterior", administered by DGA (Dirección General de Aduanas) as Entidad Coordinadora provides: A designated "Coordinating Entity" coordinates all requests via a shared technology platform, assigning individual inspectors from each participating institution for a single joint visit. Each participating institution operates within its own mandate and competencies but participates in the same inspection event — the functional definition of multidisciplinary joint inspection. Where an assigned inspector cannot attend, the institution must substitute an alternative inspector before the scheduled date — ensuring the joint inspection proceeds without delay.

Criteria for Selection of Enforcement or Sanctions

Regulatory Function:

Fairness and Effectiveness of Enforcement and Sanctions

Problem:

Authorities do not necessarily select fair and effective enforcement measures or sanctions.

Solution(s):

List criteria for the selection of measures.

Reference(s):

South Africa — Consumer Protection Act 68 of 2008, Section 112.

Peru — Ley No. 29571, Código de Protección y Defensa del Consumidor, Article 112°.

Note(s):

- See also the entry "Penalty Regime with Proportionality and Discretion" below.
- See also Article 32(7), Directive (EU) 2022/2555 (Cyber Security), OJ L 333, 27.12.2022, p. 80–152.

Sanctions for Failure to Cooperate with Authorities

Regulatory Function:

Enforcement and Deterrence

Problem:

Operators concerned, but also their partners, clients and employees may simply refuse to cooperate with market surveillance or investigation.

Solution(s):

Express penalties for non-cooperation, especially where information or access is legally required.

Reference(s):

Nigeria — Federal Competition and Consumer Protection Act 2018 (FCCPA), Sections 80, 111, 112 and 113. These sections apply to any undertaking required to cooperate — including partners, clients and employees of the operator under investigation.

Brazil — Lei No. 12.529, de 30 de novembro de 2011 (Competition), Article 40.

Note(s):

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Sanctions for Tolerating Infringements

Regulatory Function:

Enforcement and Deterrence

Problem:

It is often difficult to prove that persons supported infringements.

Solution(s):

Establish a sanction for not taking reasonable steps against infringements that the person became or should have become aware of.

Reference(s):

Solomon Islands — National Building Standards Act 2025, Section 34(2).

Colombia — Ley 1778 de 2016 (Ley Anticorrupción — responsabilidad de personas jurídicas), Article 2(3): "tolerancia".

Note(s):

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Sanctions and Withdrawal of Licences based on Demerit Systems

Regulatory Function:

Enforcement and Deterrence

Problem:

A sanction or the withdrawal of a licence or authorisation based on one single infringement may be too harsh.

Solution(s):

Establish a demerit system based on infringement points.

Reference(s):

Namibia — Vehicle Mass Act, 2024, Section 11.

Peru — Ley N° 29365, Ley que establece el Sistema de Control de Licencias de Conducir por Puntos.

Note(s):

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Tougher Sanctions for Continuation of Infringement

Regulatory Function:

Enforcement and Deterrence

Problem:

Where actors continue infringing the law though they have already been called to order, they demonstrate a particular non-respect of the legal order.

Solution(s):

Establish tougher sanctions for continued infringements, ideally covering also the responsible staff.

Reference(s):

Trinidad and Tobago — The Virtual Assets and Service Providers Act 2025, Section 4(13).
Colombia — Ley 1341 de 2009 (Ley TIC), Article 22(19).

Note(s):

Continuation of infringement is to be distinguished from repetition of infringement. Tougher sanctions for repetition are commonplace.

Administrative and Collateral Sanction Package

Regulatory Function:

Enhancing enforcement, harmonising too diverging penal practices

Problem:

Many sanctions do not really target legal persons.

Solution(s):

Establish a complete system of administrative and collateral sanctions that includes, inter alia, the following: public statements on infringements; administrative fines of at least twice the profit made or loss avoided; maximum administrative fines of at least X % of the annual turn-over, including the turn-over of mother or daughter companies; disgorgement of the profits gained or losses avoided due to the infringement; withdrawal or suspension of the

authorisations; temporary ban preventing any member of the management body, or any other natural person who is held responsible for the infringement, from exercising management functions.

Reference(s):

Canada (Ontario) — Securities Act, R.S.O. 1990, Section 127(1).

Chile — Ley No. 21.000 (Crea la Comisión para el Mercado Financiero, CMF), Título IV, suplemented by Article 5 No. 20.

Note(s):

- See also our much more complete "List of Sanctions and Collateral Measures".
- See also Article 111, Regulation (EU) 2023/1114 (Crypto Assets), OJ L 150, 9.6.2023, p. 40–178.
- Check whether provisions are needed to avoid that administrative and penal sanctions are applied in parallel for the same deed; see e.g. Bahamas – Commercial Entities (Substance Requirements) Act, 2023, Section 22:

Penalty Regime with Proportionality and Discretion

Regulatory Function:

Effective Deterrence

Problem:

Unreasonably harsh or fixed penalties can discourage compliance or distort competition.

Solution(s):

Set criteria for the proportionality of fines/sanctions, possibly with escalation scales.

Reference(s):

India — The Digital Personal Data Protection Act, 2023 (Act No. 22 of 2023), Section 33 and Schedule.

Argentina — Ley No. 27.442 de Defensa de la Competencia (B.O. 26 May 2018), Chapter VII.

Note(s):

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Precise Catalog of Infringements

Regulatory Function:

Legal Certainty and Fairness

Problem:

In practice, it is often disputed whether a certain behaviour constitutes an infringement or not.

Solution(s):

Precise catalog defining infringements.

Reference(s):

Kenya – Consumer Protection Act 2012 (Act No. 46 of 2012), Section 12 (False, misleading or deceptive representations): The provision introduces the catalogue with the formula "the following are included as false, misleading or deceptive representations" and then lists specific conduct items. The Act's Section 5 (Unfair practices — general catalogue) provides a further closed list of conduct categories constituting unfair practices at the supply stage. Together, Sections 5 and 12 form a two-tier infringement catalogue covering both conduct and misrepresentation.

Brazil — Código de Defesa do Consumidor (Lei nº 8.078, de 11 de setembro de 1990), Article 39 (*Das Práticas Abusivas*): 17-item statutory catalogue of specific abusive practices.

Note(s):

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Deferred Prosecution and Similar Agreements

Regulatory Function:

Efficient Sanctioning and Increased Compliance

Problem:

Ordinary prosecution or administrative sanctioning may be lengthy, costly and poorly adapted to cases in which the operator is willing and able to remediate the harm, co-operate with the authority and implement a credible compliance programme. A purely punitive outcome may also fail to address the causes of the infringement.

Solution(s):

Suspend prosecution where the (typically) legal person or the natural person engages in a program leading both to increased compliance and an implicit sanctioning. Permit the competent prosecutor or authority, subject to judicial or independent approval, to suspend or defer prosecution where the person or organisation: 1. admits or accepts responsibility for specified conduct, where required; 2. pays a financial penalty or compensates affected persons; 3. disgorges unlawful gains; 4. co-operates with the investigation; 5. implements or improves a compliance programme; 6. accepts monitoring, reporting or auditing obligations; and 7. complies with any other remedial conditions.

Reference(s):

Canada – Criminal Code, Part XXII.1, Sections 715.3–715.43, especially Sections 715.31–715.38: Remediation agreements with organisations may impose penalties, compensation, disgorgement, co-operation and compliance measures. Court approval is required; approval stays the prosecution, successful completion produces the statutory termination consequences, and breach permits the prosecution to resume.

United Kingdom (England) – Crime and Courts Act 2013, Schedule 17, especially Paragraphs 1, 2, 5 and 7–10: A designated prosecutor may enter into a Deferred Prosecution Agreement with an organisation for specified economic offences. Terms may include penalties, compensation, disgorgement, co-operation and compliance-programme obligations. The Crown Court must approve the agreement, which suspends the prosecution; successful completion leads to discontinuance and breach may revive the proceedings.

Chile – Código Procesal Penal, Párrafo 6°,Articles 237–240: Conditional suspension of proceedings may be approved by the court subject to reparative, rehabilitative and behavioural conditions. Breach permits revocation, while successful completion produces the statutory termination effect.

Mexico – Código Nacional de Procedimientos Penales, Articles 191–200: Conditional suspension may be approved on the basis of a reparation plan and compliance conditions, with revocation for breach and statutory consequences upon completion.

Note(s):

This technique might be useful for sector-specific legislation as well, not just for generic penal provisions.

Automatic Expiry of Sanctioning Procedure

Regulatory Function:

Creating Legal Certainty

Problem:

Started, but not formally finalised sanctioning procedures create legal uncertainty.

Solution(s):

Automatic ending of sanctioning procedures after a certain deadline or duration of non-communication.

Reference(s):

Peru – Texto Único Ordenado de la Ley N° 27444, Ley del Procedimiento Administrativo General, Article 237-A: differentiated balancing of interests between the person concerned and the administration.

Note(s):

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See also our "List of Powers and Obligations" with several hundred empowerments useful for enforcement and the parallel "List of Sanctions and Collateral Measures".

L. Third-Party Enforcement Assistance

Right to Comment in Procedures and Public Registers

Regulatory Function:

Transparency and Broad Information Base

Problem:

Public procedures and public registers may have a sub-optimal information base.

Solution(s):

Right to comment, reply, annotate, or supply evidence to procedures and entries in official registers.

Reference(s):

India — Patents Act, 1970, Act No. 39 of 1970, Section 25(1) and 25(2).

Colombia — Ley 99 de 1993, por la cual se crea el Ministerio del Medio Ambiente, Articles 69–76.

Note(s):

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Public Complaint and Whistleblower Mechanisms

Regulatory Function:

Integrity of Enforcement and Compliance

Problem:

Regulators may miss breaches without inside or third-party reporting systems.

Solution(s):

Impose robust complaint procedures and protect/reporting structures (including whistleblower protection, see next entry).

Reference(s):

New Zealand — Privacy Act 2020, Public Act 2020 No 31, Section 70 onward.

UK — Employment Rights Act 1996 (c. 18), Sections 43A–43L.

Brazil — Decreto nº 9.492, de 5 de setembro de 2018, Article 16, establishing the "Speak Brazil" Fala.BR platform.

Uruguay — Decreto No. 345/022, 25 October 2022.

Note(s):

See also our "Cross-sectoral Standard Provisions", Sections 68 to 70, and our articles on whistleblower protection.

Protection of Informants / Whistleblowers / Witnesses

Regulatory Function:

Integrity and Detection

Problem:

Potential informants and witnesses fear retribution, limiting the detection of wrongdoing.

Solution(s):

Comprehensive sectoral and cross-sectoral whistleblower and witness protection statutes.

Reference(s):

UK — Employment Rights Act 1996 (c. 18), Sections 43A–43L.

Sierra Leone – Anti-Human Trafficking and Migrant Smuggling Act 2022, Section 32.

Sri Lanka – Proceeds of Crime Act 5/2025, Section 32.

Peru — Decreto Legislativo N° 1327 de 2017 (whistle-blower protection in corruption and administrative infringement cases).

Venezuela — Ley de 7 de octubre de 2021 (sexual abuse of minors), Section 18.

Note(s):

See also our "Cross-sectoral Standard Provisions", Sections 68 to 70, and our articles on whistleblower protection.

Central Complaint Portal with Re-routing

Regulatory Function:

Streamlined Market Intelligence and Redress

Problem:

Fragmented complaints handling creates blind spots for enforcement. Citizens cannot know which administration is in charge of a certain complaint.

Solution(s):

Establish a central portal for complaints, with automated routing to responsible authorities—except when the complaint concerns that authority.

Reference(s):

India — Consumer Protection Act 2019 (No. 35 of 2019), Section 16 onward (Central Consumer Protection Authority: mandate and powers to receive and act on complaints from any source) and Sections 35–38 (tiered routing of complaints to District, State, or National Consumer Disputes Redressal Commission based on claim value, with automatic jurisdictional assignment).

Brazil — Decreto nº 9.492, de 5 de setembro de 2018, Article 16, establishing the "Speak Brazil" Fala.BR platform.

Note(s):

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Right—and Obligation (in Serious Risk)—to Inform Authorities on Infringements by Others

Regulatory Function:

Peer-Controlled Market Supervision

Problem:

(Economic) Actors may have knowledge of competitor wrongdoing, but no route or obligation to notify.

Solution(s):

Right for (economic) actors to inform authorities on presumed infringements by others, and mandatory duty to do so when serious risks are identified.

Reference(s):

Sierra Leone – Prohibition of Child Marriage Act 2024, Section 26.

Eswatini – Suppression of Terrorism Act, 2008, Sections 26 and 27.

Australia – Corporations Act 2001 (Cth), Section 912DAB.

Brazil — CVM Resolution No. 35 of 26 May 2021, Article 33(IV), based on Lei N° 6.385/1976 (Lei do Mercado de Valores Mobiliários), Article 18.

Note(s):

- The references establish obligations incumbent on economic actors to inform authorities on infringements. We also found provisions permitting anybody to inform authorities on presumed infringements. However, we did not find provisions permitting solely economic actors to inform authorities on presumed infringements.
- More references for reporting obligations can be found in anti money laundering legislation worldwide.

Obligation to Inform on Suspected Criminal Acts

Regulatory Function:

Preventing and Countering Criminality

Problem:

Authorities rarely become aware of criminal acts.

Solution(s):

Oblige (economic) actors or even everybody to report on suspected criminal acts.

Reference(s):

UK — c. 50, Online Safety Act 2023, Section 66 — every UK provider of a regulated user-to-user service must operate systems and processes that ensure

all detected and unreported Child Sexual Exploitation and Abuse (CSEA) content present on the service is reported to the National Crime Agency (NCA); Section 69 establishes a criminal offence for non-compliance or provision of materially false information; the obligation is restricted to regulated service providers, not the public.

Sri Lanka – Proceeds of Crime Act 5/2025, Section 31: anybody in a professional context or in execution of a contract has to report to the police.

Colombia — Ley 679 de 4 de agosto de 2001 (Sexual exploitation, pornography and sexual tourism with minors), as amended by Ley 1336 de 21 de julio de 2009, Article 8 — internet service providers and operators of global information networks are obliged to report to the competent authorities any criminal act against minors of which they become aware, including the dissemination of child sexual abuse material.

El Salvador — Decreto Legislativo Nº 209 - Ley anticorrupción, Article 15: obligation for everybody to report even on suspected corruption.

Note(s):

Can be extended to severe non-conformities. However, when extended to all non-conformities, the authorities might obtain too many notices.

Trusted Flaggers to Inform on Suspected Non-conformities / Filtering Non-compliance Notices

Regulatory Function:

Preventing and Countering Non-conformities

Problem:

Authorities rarely become aware of non-conformities, but risk becoming flooded with low-quality notices if anybody was to report.

Solution(s):

Establish a Trusted Flaggers system in which the Trusted Flaggers filter the notices coming from non-experts.

Reference(s):

UK — Ofcom's Illegal Content Codes of Practice (December 2024), based on Online Safety Act 2023, Part 3 Chapter 6.

Note(s):

We presume that these codes have the value of secondary legislation (see the involvement of the Parliament).

Independent Observers

Regulatory Function:

Preventing and Countering Non-conformities

Problem:

In particular in complex social or economic settings, authorities have difficulties in detecting non-conformities.

Solution(s):

Nominate independent observers with access rights and dedicated reporting channels.

Reference(s):

Malawi — Prison Act 2025, Sections 143-145: "independent visitors".

Brazil — Lei No. 7.210/1984 (Lei de Execução Penal), Articles 80 and 81 (Conselho da Comunidade).

Note(s):

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Third-Party Rights (Standing) in Regulatory Appeals and Independent Procedures

Regulatory Function:

Access to Justice and Better Enforcement

Problem:

Only directly regulated companies often have formal standing in regulatory challenges and at court, whilst authorities do not have the administrative capacities to address all non-compliances.

Solution(s):

Legally enable broader third-party participation (competitors, NGOs, affected parties) in appeals and reviews. Authorise third-parties to sue non-compliant actors at court for injunction, repair and compensation.

Reference(s):

Australia — No. 91, 1999, Environment Protection and Biodiversity Conservation Act 1999 (Cth), Section 487 — extended standing for judicial review: any individual who has engaged in activities related to environmental protection, conservation, or research in Australia for a continuous period of at least two years before the impugned decision qualifies as a "person aggrieved" under the Administrative Decisions (Judicial Review) Act 1977 (Cth); incorporated organisations whose stated purposes include environmental protection qualify on the same basis; the provision removes the restrictive common law "special interest" requirement.

Bangladesh Biodiversity and Community Knowledge Protection Act, (1998), Article 7(3): legal standing extended to communities, as defined in Article 4.
Brazil — Lei N° 4.717 de 29 de junho de 1965 (Ação Popular), Article 1 — any Brazilian citizen (qualquer cidadão) has standing to bring a popular action (ação popular) before the courts to annul acts of public administration harmful to public patrimony, administrative morality, the environment, or public heritage; this is the broadest-spectrum third-party administrative standing provision in Brazilian law, covering any regulatory act harmful to the public interest.
Colombia — Ley 472 de 5 de agosto de 1998 (Acciones Populares y de Grupo), Article 12 — any person (cualquier persona) has standing to bring a popular action (acción popular) before administrative courts to defend collective rights and interests, including the right to a clean environment, public health, consumer protection, administrative morality, and public security; organisations pursuing those interests are explicitly included.

Note(s):

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Invalidity Clauses for Contravening Private Acts

Regulatory Function:

Opens access to private law courts, indirectly supporting enforcement

Problem:

Rules/decisions adopted in breach of the applicable Regulation/Directive could otherwise cause confusion.

Solution(s):

Legal provision annulling actions taken in breach (e.g., without procedure or out-of-scope).

Reference(s):

Sierra Leone – Prohibition of Child Marriage Act 2024, Section 15 (see also Section 16: to be declared void on the basis of a petition).

South Africa — Consumer Protection Act 68 of 2008, Section 51 (3) — a provision of a transaction or agreement that contravenes Section 51(1) or (2) is void to the extent of the contravention, automatically and without requiring a court or tribunal order; the remainder of the transaction continues in force unless it is not capable of being given effect without the void provision.

Peru — Ley No. 29571, Código de Protección y Defensa del Consumidor, Articles 50 and 52 — clauses in consumer contracts that reduce, waive, or restrict the rights recognised by the Code are null and without effect; INDECOPI may declare the nullity of such clauses in administrative proceedings, and courts may do so in civil proceedings.

Note(s):

Interestingly, Article 51 of the Peruvian reference establishes a "relative voidness" of provisions - a voidness subject to the appreciation of the concrete case.

See also the first entry of the next Section M.

M. Dispute Resolution and Appeals

Third Party Standing and Representation Rules

Regulatory Function:

Access to Justice, Access to Procedures

Problem:

Individuals may be unable to enforce rights on their own.

Solution(s):

Define which organisations/groups can represent the public interest or claimants collectively in court or administrative procedures.

Reference(s):

Australia — No. 156, 1976, Federal Court of Australia Act 1976 (Cth), Sections 33A–33ZJ (Part IVA — Representative Proceedings), in particular Sections 33C and 33D — any person who has a sufficient interest may commence representative proceedings on behalf of seven or more persons with claims arising from the same or similar circumstances and raising a substantial common question of law or fact; unlike other jurisdictions, Australia does not require state recognition of representative organisations: any person with a claim may act as representative plaintiff subject to the threshold criteria; section 33T empowers the Court to substitute a different representative plaintiff if the existing one cannot adequately represent the group.

Ghana — Domestic Violence Act, 2007, Act 732, Section 6(3): social workers, probation officers and health care providers to report to police where reporting is in the interest of the victim.

Chile — Ley N° 19.496 de 1997 (Consumer Richts), Article 51 — collective consumer actions may only be brought by: (i) SERNAC (Servicio Nacional del Consumidor) on behalf of all consumers affected; (ii) registered consumer associations whose institutional purposes include consumer protection, provided they have a minimum of 50 members and have been registered with the SERNAC registry for at least six months prior to filing; or (iii) any group of 50 or more directly affected consumers acting through a common representative.
Argentina — Ley 24.240 (Consumer Protection), Article 52.

Note(s):
Article 54 of the Argentinian reference provides for a mechanism that renders the outcome of a collective action or proceeding generally applicable.

Transparency regarding Procedures and Appeals

Regulatory Function:
Access to Justice

Problem:
Individuals and NGOs cannot contribute to procedures and appeals when they are not aware of them.

Solution(s):
Institutions and bodies to publish all requests for internal reviews or appeals, and final decisions online.

Reference(s):
Canada — S.C. 2019, c. 28, s. 1, Impact Assessment Act, Section 104 — the Impact Assessment Agency of Canada must establish and maintain the Canadian Impact Assessment Registry as a publicly accessible online database; section 104(2) requires the Registry to include all information filed in connection

with each impact assessment, including all documents relating to any review proceedings, public comments, panel reports and final decisions; the Registry is accessible continuously at no cost to the public and enables any person to follow, comment on, and track pending reviews and final decisions in real time.
Chile — Ley N° 20.285 de 20 de agosto de 2008 (Access to Public Information), Article 7(g) — public bodies must proactively maintain on their websites, updated at least monthly, the administrative acts and resolutions (actos y resoluciones) adopted in the exercise of their functions; this covers final decisions on regulatory proceedings and appeals but does not extend to publication of pending review requests.

Note(s):
See also Regulation (EU) No. 1367/2006 (Aarhus Convention), Article 11a, which provides transparency regarding ongoing appeals.

Right to be Heard prior to Adverse Decisions

Regulatory Function:
Procedural Rights and Good Administration

Problem:
Operators should be able to present their case and defend themselves before sanctions or adverse decisions.

Solution(s):
Oblige authorities to hear affected parties and provide reasons for decisions.

Reference(s):
South Africa — Act No. 3 of 2000, Promotion of Administrative Justice Act 2000 (PAJA), Section 3(1) — administrative action that materially and adversely affects the rights or legitimate expectations of any person must be procedurally fair;

section 3(2)(b) specifies the minimum content of procedural fairness: adequate notice of the nature and purpose of the proposed action, a reasonable opportunity to make representations, a clear statement of the administrative action, adequate notice of any right of review or appeal, and adequate notice of the right to request written reasons.

Argentina — Ley N° 19.549 de 1972 (Ley de Procedimientos Administrativos), Article 1(f)(1) — the right to due process (debido proceso adjetivo) includes: the right to be heard (ser oído), to present the case and provide evidence before a decision is issued.

Note(s):

Both reference acts and, for Argentina, the complementary Decree 1759/1972 (Reglamento de la Ley 19.549), are commendable when searching for references regarding administrative procedures.

Central Oversight or Appeals Bodies

Regulatory Function:

Consistency and Judicial Review

Problem:

Decisions by certification bodies or authorities may be inconsistent or challenged as arbitrary.

Solution(s):

Set up national appeals/oversight bodies.

Reference(s):

India — Act No. 15 of 1992, Securities and Exchange Board of India Act 1992, Section 15K — the Securities Appellate Tribunal (SAT) is established as a statutory, autonomous, quasi-judicial body; Section 15T — any person aggrieved

by an order of SEBI, an adjudicating officer, or a recognised stock exchange may prefer an appeal before the SAT.

Brazil — Lei N° 13.506 de 13 de novembro de 2017, Articles 17(§4) and 29, and Decreto N° 9.889 de 27 de junho de 2019, Articles 1–2 — the Conselho de Recursos do Sistema Financeiro Nacional (CRSFN) is the permanent collegiate body serving as final administrative instance for appeals against sanctions imposed by the Banco Central do Brasil (BCB) and the Comissão de Valores Mobiliários (CVM), as well as, in money laundering proceedings, sanctions imposed by COAF, SUSEP, and other competent authorities.

Note(s):

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Ex ante Judicial Approval

Regulatory Function:

Legal Protection, Reliability and Stability of Decisions

Problem:

Administrative decisions are often reversed by later judicial decisions. This creates important damage and reduces trust in the state's action.

Solution(s):

Permit or mandate ex ante judicial approval.

Reference(s):

Canada — RSC 1985, c. C-34, Competition Act, Section 15(1) — the Commissioner of Competition may not conduct a search of premises unless a judge of a superior or county court, satisfied on the basis of an ex parte sworn information that there are reasonable grounds to believe that an offence has been committed or grounds exist for a civil order, has first issued a search

warrant; the judge must independently assess the grounds before authorization is granted; the warrant may specify conditions and its scope; Section 16 extends the same prior judicial authorization requirement to searches of computer systems.

Chile — Decreto Ley N° 211 de 1973 (Free Competition), Article 39(n) — the FNE's intrusive investigative powers (facultades intrusivas) require a double prior authorization: first, the authority must obtain prior approval from the Tribunal de Defensa de la Libre Competencia (TDLC); then, with that approval, it requests authorization from a Minister of the Court of Appeals; only with both authorisations may the measure be executed — a uniquely demanding double ex ante judicial/quasi-judicial approval structure.

Note(s):

Where issued by administrations, decisions on curatorship or liquidation of companies may also require prior consent of courts.

Administration or Body to replace First Instance Tribunal or Court

Regulatory Function:

Efficiency and Affordability of Legal Protection, Efficiency of Enforcement

Problem:

Tribunal / Court procedures are often slow and judges not necessarily knowledgeable in certain technical areas.

Solution(s):

Establish a court-like procedure with a specialised administration.

Reference(s):

India — Act No. 12 of 2003, Competition Act 2002, Section 27 — the Competition Commission of India (CCI) is empowered, following an investigation by the Director General and a hearing of the parties, to issue cease-and-desist orders, directions for modification of conduct, and financial penalties of up to 10% of average turnover for each year of infringement; no court or tribunal is involved at first instance.

Colombia – Ley 1480 de 2011 (Consumer Protection), Articles 57 and 58.

Note(s):

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Special and ad hoc Tribunals or Courts

Regulatory Function:

Efficiency, Specialisation and Independence of the Judiciary

Problem:

Certain matters require particular knowledge or independence of judges.

Solution(s):

Establish special tribunals or courts with specially qualified judges and/or ad hoc tribunals or courts composed of judges from various other tribunals or courts.

Reference(s):

Nigeria — Electoral Act 2026, Sections 135 and 136.

Colombia — Acto Legislativo No. 01/2017, Articles 5–7 (Special Peace Jurisdiction).

Note(s):

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Bar to parallel Judiciary Proceedings

Regulatory Function:

Efficiency and Alignment

Problem:

Claimants may pursue in parallel public and private judiciary proceedings. This may lead to a waste of scarce judiciary resources and conflicting rulings.

Solution(s):

Establish the obligation to declare that no parallel judiciary proceedings will be initiated or pursued.

Reference(s):

Mauritius — Environment Act, 2024, Section 122.

Argentina — Decreto 1823/2015, Annex, regulation of Article 4 of Ley 27.139, Article 4: To obtain compensation under the special administrative scheme, an applicant must submit a sworn declaration renouncing future judicial actions concerning the relevant claim. Applicants who have already commenced proceedings against the State based on the same facts must provide judicial proof that they have withdrawn both the action and the underlying right.

Note(s):

Such waivers are more common as precondition for national or international alternative dispute resolution proceedings. See e.g. DR-CAFTA, Art. 10.18.2(a).

Scope and Benchmarks of Review by Tribunals or Courts

Regulatory Function:

Legal Certainty and Balance of Powers

Problem:

There can be legal uncertainty as to the degree of liberty of judges. To what extent may they place their decision at the place of the decisions of administrations? Cross-sectoral rules on this may require fine-tuning or modification for a specific sector.

Solution(s):

Define the aspects or reasons for which judges may revise the decisions of the administration (scope) and the (e.g. likelihood) benchmarks.

Reference(s):

Uganda — Anti-Terrorism Regulations, 2025, Section 16(2).

South Africa – Promotion of Administrative Justice Act 3 of 2000, Sections 6 and 8.

Chile — Ley Nº 20.600 (Environmental Tribunals), Articles 17 and 30: Article 17 defines the categories of environmental administrative decisions subject to review by the Environmental Courts. If a challenge succeeds, Article 30 requires the court to declare the decision contrary to the applicable law and authorises total or partial annulment or an order to modify the challenged administrative action. The court may not, however, substitute its own specific generally applicable rule for one it annuls or determine the discretionary content of an annulled administrative act. The provision therefore defines both the scope of judicial review and the boundary between judicial correction and administrative decision-making.

Note(s):

See also Argentina — Ley N° 19.549 de 1972 (Ley de Procedimientos Administrativos), Articles 14-17 and 22-24, setting up a distinction between flaws

that make the administrative act nil and those that can lead to its annihilation, in line with the classic continental European administrative law doctrine.

Reverse Burden of Proof

Regulatory Function:

Effective Redress

Problem:

Injured parties struggle to prove complex or hidden harms.

Solution(s):

Statutory presumption of liability/reversing burden where required for justice (e.g., product liability).

Reference(s):

Sierra Leone – Prohibition of Child Marriage Act 2024, Sections 3(2), 5(2), 6(2), 7(2), 11(3).

Australia – Competition and Consumer Act 2010, Schedule 2, Sections 138–141: A manufacturer of goods is liable to compensate any person who suffers loss or damage as a result of a safety defect in the goods; section 142 — the manufacturer is not liable if they can prove one of five statutory defences, including that the defect did not exist when the goods left their control, or that the state of scientific and technical knowledge at the relevant time was insufficient to enable the defect to be discovered; the burden of establishing each defence, and in particular of the good being deficient when leaving the manufacturer, rests entirely on the manufacturer, not on the claimant.

Argentina – Ley 24.240 (Consumer Protection), Article 40: Where damage is caused by a defective product, the producer, maker, importer, distributor, supplier, and seller are jointly and severally liable for the harm.

Note(s):

Alternatively, the burden of proof can be imposed on the side that has better means of proof. See Cuba – Ley Nº 150 - Ley del Sistema de los Recursos Naturales y el Medio Ambiente, Article 189.1.

Victim/Complainant Assistance Provisions

Regulatory Function:

Access to Redress

Problem:

Users, consumers, or affected parties struggle to pursue claims or protections in complex sectors.

Solution(s):

Require authorities or market actors to provide independent helpdesks, legal support, or compensation schemes. Establish procedural protections.

Reference(s):

South Africa — Consumer Protection Act 68 of 2008, Section 77: Support not directly to consumers, but to groups supporting the consumers.

Sierra Leone – Prohibition of Child Marriage Act 2024, Section 21: Injunction orders.

Sierra Leone – Anti-Human Trafficking and Migrant Smuggling Act 2022, Section 11 (support fund), 17 (irrelevance of victim's "consent") and 18 (victim's criminal immunity).

Ghana — Domestic Violence Act, 2007, Act 732: Various sets of provisions.

Brazil — Lei nº 13.431/2017, Articles 5 and 9–12: Children and adolescents who are victims or witnesses of violence are entitled to legal and psychosocial assistance, appropriate information, privacy and protection from intimidation and

revictimisation. They must be protected from contact with the alleged perpetrator, and their evidence is obtained through specialised interviewing and testimony procedures in an appropriate setting, generally avoiding repeated testimony and using trained professionals and audiovisual recording. The court must prevent the accused or others from threatening, coercing or embarrassing the victim during the procedure.

Mexico — Ley General de Víctimas, Articles 12–43 and 165–167: Exemplary comprehensive and detailed protection system. Authorities must provide victims immediately and free of charge with complete and clear information and professional advice concerning the judicial, administrative and other procedures available to protect their rights. The Act establishes a specialised federal victim legal-advice service and entitles victims to request a legal adviser for assistance and representation. Victims also have rights to submit evidence, intervene in criminal proceedings and lodge available remedies.

Chile — Ley N° 19.496 de 1997 (Consumer Protection), Article 8(b): "Informar, orientar y educar a los consumidores para el adecuado ejercicio de sus derechos y brindarles asesoría cuando la requieran".

Note(s):

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Representation of Victims/Claimants by NGOs

Regulatory Function:

Protection of Rights

Problem:

Individuals have difficulties in defending their rights, whilst lawyers are expensive.

Solution(s):

Allow legal representation by non-profit organisations.

Reference(s):

South Africa — Consumer Protection Act 68 of 2008, Section 78.

Colombia – Ley 1480 de 2011 (Consumer Protection), Article 3 Section 1.9.

Note(s):

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Alternative Dispute Resolution (ADR) Pathways

Regulatory Function:

Efficient Resolution of Market and Consumer Disputes

Problem:

Judicial litigation is lengthy and costly for SMEs and end users.

Solution(s):

States to mandate, facilitate, or operate ADR/mediation as an option or obligation prior to judicial litigation.

Reference(s):

South Africa — Consumer Protection Act 68 of 2008, Section 70.

Lesotho — Labour Act, 2024, Chapter IV: Directorate of Dispute Prevention and Resolution, with independent legal personality, clear powers and assignments, but also limitations (prerogatives of the judiciary).

Tanzania – Investment Act 2022, Sections 32 and 33: differentiated national and international pathways.

Tanzania – Arbitration Act, 2020: Complete detailed provisions.

Bangladesh Energy Regulatory Commission Act, 2003 (Act No. 13 of 2003), Section 40.

Peru — Ley N° 26.872 de 13 de novembro de 1997 (Ley de Conciliación), as amended by Decreto Legislativo N° 1070/2008, Article 6 — extrajudicial conciliation before an accredited conciliation centre is a mandatory pre-litigation requirement (requisito de admisibilidad) for civil and commercial claims, including consumer disputes; no civil action may be admitted by a court without a conciliation certificate evidencing either agreement or the failure of conciliation.

Note(s):

The Tanzanian Arbitration Act, 2020 demonstrates that there are a multitude of aspects to be regulated.

N. Data, Information and Artificial Intelligence

Access to Own File within Administration

Regulatory Function:

Transparency and Fairness

Problem:

During investigations and the preparation of authority measures, persons concerned are mostly left in the dark. Hence they cannot properly defend themselves. Moreover, they cannot provide crucial information that would probably even stop the investigation or the preparation of authority measures. This leads to a waste of resources on the side of the authority.

Solution(s):

Mandatory release of investigative files on request, with protection of the identity of informants.

Reference(s):

Canada — RSC 1985, c. A-1, Access to Information Act 1985, Section 4(1) — every Canadian citizen, permanent resident, and individual or corporation present in Canada has a right of access to any record under the control of a government institution; combined with RSC 1985, c. P-21, Privacy Act, Section 12(1) — every individual has a right to, and shall on request be given, access to personal information about themselves under the control of a government institution; Section 22 — access may be refused where disclosure could reasonably be expected to be injurious to the enforcement of a law or to the conduct of a lawful investigation.

Peru — Ley N° 27444 (Ley del Procedimiento Administrativo General), Article 160.1 — administered persons, their representatives, or their lawyers have an explicit right of access to the administrative file at any moment during its processing, as well as to all documents, precedents, studies, and reports forming part of the file; Article 160.2 — the request for access may be made verbally and must be granted immediately, without the need for a formal written decision, at the office where the file is located.

Colombia — Ley 1437 de 18 de enero de 2011 (Código de Procedimiento Administrativo y de lo Contencioso Administrativo — CPACA), Articles 5 and 8.

Note(s):

Not appropriate for all sectors or matters. Beware of the repercussions on the informants.

Open Data and Access to Public Sector Information

Regulatory Function:

Transparency and Reusability

Problem:

Restrictive or paywalled access to public data stifles innovation and accountability.

Solution(s):

Mandatory proactive release of public sector data and digital accessibility under open licences.

Reference(s):

Australia — No. 3, 1982, Freedom of Information Act 1982 (Cth), Part III: Detailed, fine-tuned provisions.

Colombia — Ley 1437 de 18 de enero de 2011 (Código de Procedimiento Administrativo y de lo Contencioso Administrativo — CPACA), Article 24 — all persons have the right to consult documents and administrative files at the offices of public authorities, except those that are reserved; Article 25 — authorities must respond to consultation requests within 10 business days; the CPACA does not permit withholding of a person's own file on grounds of confidentiality unless the information was supplied by a third party under statutory confidentiality protection, in which case only the third-party portion may be withheld.

Note(s):

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Retention and Deletion of Data

Regulatory Function:

Privacy and Data Protection

Problem:

Unrestricted retention increases risks to privacy and unnecessary regulatory burden.

Solution(s):

Specify strict rules for the periods for which data may/must be retained and when it must be deleted.

Reference(s):

South Africa - POPIA (Protection of Personal Information Act 4 of 2013), Section 14: Retention and restriction of records.

Colombia - Ley 1581/2012 (Estatuto de Protección de Datos), Articles 8(e) and 18(c).

Note(s):

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Right to Correct Data

Regulatory Function:

Accuracy, Correction, and Fairness

Problem:

Inaccurate data can cause legal issues.

Solution(s):

Statutory right of concerned persons to correct or contest official data.

Reference(s):

Canada — RSC 1985, c. P-21, Privacy Act, Section 12(2).

Colombia - Ley 1581/2012 (Estatuto de Protección de Datos), Articles 8(a), 17(f) and (g) and 18(c).

Note(s):

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Data Portability and Interoperability

Regulatory Function:

Switching, Competition, and User Rights in Digital Markets

Problem:

Closed systems lock users into providers and hamper competition.

Solution(s):

Legal right to receive and transfer data between systems, and mandates for technical interoperability.

Reference(s):

UK — UK General Data Protection Regulation, Article 20(1) (as retained in UK law and given effect by c. 29, Data Protection Act 2018, Section 2 and Schedule 1).

Brazil – Lei Geral de Proteção de Dados (LGPD), Lei nº 13.709 (14 August 2018), Article 18(V).

Note(s):

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Open API / Third-Party Access in Digital Services

Regulatory Function:

Technical Interoperability and Competition

Problem:

Closed digital environments hinder innovation and competition.

Solution(s):

Statutory obligation for open API (application programming interfaces) and secure third-party access for defined markets.

Reference(s):

Australia — Competition and Consumer Act 2010 (Cth), Part IVD (Consumer Data Right), in particular sections 56FB-FE.

Brazil — Resolução Conjunta do Banco Central do Brasil e Conselho Monetário Nacional nº 1, of May 4 2020 (Regulamento do Open Banking), as amended by Resolução BCB nº 400/2023 (extending to Open Finance), Articles 5 and 7.

Note(s):

The Australian reference goes further insofar it provides the power to mandate a certain data standard in Section 56FA. A person aggrieved by the failure to apply the mandatory data standard can solicit a court (Section 56FE).

Transparency Requirements for Algorithmic Systems

Regulatory Function:

Accountability in Automated Decision-Making

Problem:

Algorithms create risks of bias, error, or unfairness whilst the use of algorithms is often even not known.

Solution(s):

Mandate clear disclosure of (1) use of automated systems and (2) automated systems' logic, criteria, and operation, especially where affecting rights or access to services.

Reference(s):

Australia — Privacy Act 1988 (Cth), Schedule 1, Subclauses 1.7, 1.8 and 1.9, intended to be inserted by the Privacy and Other Legislation Amendment Act 2024 (Cth), No. 113 of 2024 with effect from 10 December 2026; see its No. 88.
Brazil – Lei Geral de Proteção de Dados (LGPD), Lei nº 13.709 (14 August 2018), Article 20 §1.

Note(s):

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Right to Human Review of Automated Decisions

Regulatory Function:

Redress for Individuals

Problem:

Automated rejection or profiling can harm individuals without transparency or recourse.

Solution(s):

Require clear explanation and avenue for human review of significant automated decisions.

Reference(s):

United Kingdom — Data Protection Act 2018 (c. 12), Sections 50A–50C: Right to human review of significant automated decisions.

Brazil – Lei Geral de Proteção de Dados (LGPD), Lei nº 13.709 (14 August 2018), Article 20.

Note(s):

The UK reference provides further essential rights with regard to automated decisions or processing.

Prohibition of "Dark Patterns" in Digital Interfaces

Regulatory Function:

Upholding Fairness in Digital Markets

Problem:

Manipulative digital design tricks ("dark patterns") undermine user autonomy and trust.

Solution(s):

Define and prohibit manipulative digital-interface practices. Where appropriate, require platforms to audit or monitor their interfaces and remedy prohibited designs.

Reference(s):

India — Consumer Protection Act 2019, Section 18, as legal base for the Guidelines for Prevention and Regulation of Dark Patterns, 2023, Clauses 2–5 and Annexure I, and the CCPA Advisory on Self-Audit by E-Commerce Platforms of 5 June 2025: The Guidelines define dark patterns as deceptive UI or UX designs that impair consumer autonomy, decision-making or choice and expressly prohibit any person, including a platform, from engaging in them. Annexure I identifies and explains prohibited techniques, including false urgency, basket sneaking, confirm shaming, forced action, subscription traps and interface interference. The 2025 Advisory called on e-commerce platforms to audit their interfaces for dark patterns within three months and encouraged publication of self-declarations.

Peru — Ley No. 29571 (Consumer Protection), Article 56(1)(h), inserted by Decreto Legislativo Nº 1729: Suppliers may not use commercial practices or strategies, particularly through platforms, applications or other digital-commerce channels, that employ the design, configuration or operation of online user interfaces to limit, distort or manipulate consumer autonomy or freedom of choice, inducing or compelling unwanted consumer decisions that cause harm. The provision establishes an express statutory prohibition of manipulative interface design, although it does not use the label "dark patterns."

Note(s):

See also Articles 25-27, Regulation (EU) 2022/2065 (Digital Services).

Protection of "Know-How" and Trade Secrets

Regulatory Function:

Commercial Confidentiality

Problem:

Assessment procedures may force companies to reveal confidential innovation or trade secrets.

Solution(s):

Mandatory protections and secure handling arrangements for confidential business information during regulatory assessment and publication.

Reference(s):

United Kingdom — Trade Secrets (Enforcement, etc.) Regulations 2018 (SI 2018/597), Regulations 2–3 and 7–14, and in particular Regulation 10: definition of trade secret and undisclosed know-how; confidentiality measures during proceedings.

Brazil — Lei nº 9.279 (Industrial Property), Article 195(XI)–(XIV): unlawful disclosure or use of confidential know-how and trade secrets as unfair competition.

Note(s):

We recommend establishing dedicated confidentiality rules for administrative proceedings and certification proceedings involving conformity assessment bodies or auditors, unless it is unquestionable that generic rules, like to ones referred here, suffice to protect the confidentiality interests.

For other aspects regarding data, please check the quite progressive and comprehensive laws of Australia, the UK, Canada and Brazil referred to above.

O. Emergencies

Power for Emergency/Provisional Measures

Regulatory Function:

Risk Management and Crisis Response

Problem:

Standard procedures are too slow for urgent threats, and powers not necessarily sufficient.

Solution(s):

Allow the government, a ministry or other authorities to set emergency, time-limited measures, also with regard to legal requirements.

Reference(s):

United Kingdom — Energy Act 1976 (c. 76), Sections 3–5: power of the Secretary of State, upon declaration of an actual or imminent emergency threatening fuel or electricity supplies, to make Orders and Directions temporarily overriding normal sector requirements; operationalised through the Electricity Supply Emergency Code (made under the Electricity Act 1989).

United Kingdom — Civil Contingencies Act 2004 (c. 36), Part 2, Sections 20–30: power by Order in Council or senior Minister to make emergency regulations having force of law, capable of amending or disapplying primary legislation, triggered by threats to human welfare, the environment, or national security (including war); regulations time-limited to 30 days, renewable, subject to immediate parliamentary scrutiny.

Papua New Guinea — Prices Regulation (Amendment) Act 2025, Section 2.

Brazil — Lei nº 13.979, de 6 de fevereiro de 2020, Article 3: Exceptional and time-limited sectoral measures — including suspension or acceleration of regulatory requirements — triggered by declaration of a Public Health Emergency of National Importance (ESPIN).

Brazil — Constituição da República Federativa do Brasil de 1988, Article 62: power of the President of the Republic to adopt medidas provisórias with immediate force of law in cases of relevance and urgency, subject to congressional conversion within 60 days (extendable once).

Guatemala — Decreto Número 25-2024 (Vaccination Law), Article 25.

Note(s):

We have chosen for two jurisdictions (UK and Brazil) a pair of cross-sectoral powers and complementary sector-specific powers to illustrate that the two sets of powers are sometimes needed. Generic emergency provisions hardly can cover all sector needs. We recommend generic powers, whilst some jurisdictions have chosen to provide only specific powers; see e.g. for overriding public tender provisions: Eswatini – Coronavirus (Covid 19) Regulations 2020, Section 31.

Rapid Regulatory Adaptation via Emergency / Temporary Government Acts

Regulatory Function:

Short-term, Targeted Crisis Response

Problem:

Full legislative revision is too slow to address fast-moving emergencies or innovation shocks.

Solution(s):

Empower the government or a ministry to adopt temporary or emergency acts subject to review/expiry.

Reference(s):

See the references of the previous entry.

Note(s):

-

Periodic Disaster Risk Assessment, Exercise or Audit

Regulatory Function:

Preparedness and Resilience

Problem:

Crisis laws are untested until a real event, risking failure.

Solution(s):

Require risk assessments, simulation exercises or external audits of emergency regulatory and coordination procedures.

Reference(s):

New Zealand — Civil Defence Emergency Management Act 2002 (No. 33 of 2002), Sections 17(1), 48 and 49, in particular 49(2)(b): CDEM Groups required to identify, assess and manage hazards and risks on an ongoing basis, and to prepare and maintain a Group Plan incorporating risk assessment outcomes, subject to mandatory five-year review.

Colombia — Ley nº 1523, de 24 de abril de 2012 (Disaster Risk Management Policy), Articles 37–38 Paragrapho: Obligation on all public entities at national,

departmental and municipal level to maintain updated disaster risk assessments as a precondition for institutional planning and authorisation processes.

Note(s):

-

Risk Management for Emergencies

Regulatory Function:

Preparedness and Resilience

Problem:

Resilience depends on plans on how to deal with emergencies, which presupposes risk management for emergencies.

Solution(s):

Mandate risk management.

Reference(s):

Fiji — National Disaster Risk Management Act 2024, Part 7.

Bolivia — Ley No. 602 de 2014 (Risk Management), Título II.

Note(s):

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Contingency Plans

Regulatory Function:

Preparedness and Resilience

Problem:

Resilience depends on plans on how to deal with emergencies.

Solution(s):

Mandate detailed contingency plans.

Reference(s):

Mauritius — Environment Act, 2024, Part V: Detailed provisions mandating different contingency plans for different types of emergencies.

Brazil — Lei No. 12.608/2012 (Civil Protection), Articles. 12-A, 12-B and 12-E: Mandatory contingency plans for private and public entities, precondition for licensing.

Cuba – Decreto-Ley Nº 102/2025 (Nuclear Energy), Capítulo XII.

Note(s):

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Safeguard Regimes for "Critical" Infrastructure, Institutions, Enterprises or other Actors

Regulatory Function:

Resilience and Special Risk Mitigation

Problem:

Generic rules may not address risks/vulnerabilities for critical infrastructure.

Solution(s):

Dedicated safeguard regimes, with enhanced obligations, oversight, and reporting.

Reference(s):

Australia — Security of Critical Infrastructure Act 2018 (Cth), as amended, Parts 2 to 2D: Mandatory registration of critical infrastructure assets across 11 designated sectors; obligation on responsible entities to establish and maintain a Critical Infrastructure Risk Management Program (CIRMP) with annual reporting; enhanced obligations and government step-in powers for Systems of National Significance (SoNS);

Chile — Ley nº 21.663, de 8 de abril de 2024 (Cyber Security and Critical Information Infrastructure), Articles 4–6 and 27–34: Two-tier critical infrastructure safeguard regime distinguishing Essential Service Providers (PSE) and Vital Importance Operators (OIV) across critical sectors; OIVs subject to certified Information Security Management Systems, periodic continuity testing, mandatory incident reporting, and oversight by the National Cybersecurity Agency (ANCI).

Note(s):

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P. Financial Implementation and General Planning

Imposing Regional or District Cooperation

Regulatory Function:

Increasing Efficiency

Problem:

Regional entities planning on their own without consulting their neighbors miss efficiency opportunities.

Solution(s):

Mandate cooperation of regional entities or districts.

Reference(s):

Australia — Water Act 2007 (Cth), Parts 1A and 2 and Schedule 1 (Murray-Darling Basin Agreement): statutory imposition of cross-boundary regional cooperation between the Commonwealth and five states for integrated basin-wide water resources planning through the Murray-Darling Basin Authority (MDBA); state Water Resource Plans must conform to the Basin Plan, overriding unilateral planning.

Colombia — Ley nº 1454, de 28 de junio de 2011 (Ley Orgánica de Ordenamiento Territorial — LOOT), Articles 3, 9 - 18: Mandatory principle of territorial associativity; obligation on the National Government to promote and incentivise regional associative schemes; departments and municipalities required to integrate development plans in a joint comprehensive planning model (*modelo de planificación integral conjunto*) when forming associative territorial schemes.

Note(s):

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Multiannual Programming/Planning Obligations (e.g., in Funding or Implementation)

Regulatory Function:

Stability and Predictability

Problem:

Stop-start annual planning undermines longer-term regulatory, funding, or supply stability.

Solution(s):

Mandate multiannual implementation and funding plans, with review/update requirements.

Reference(s):

New Zealand — Climate Change Response Act 2002 (No. 40 of 2002), as amended by the Climate Change Response (Zero Carbon) Amendment Act 2019 (No. 61 of 2019), Section 5X–5ZI: Mandatory rolling 5-year emissions budgets (three in place simultaneously); Minister required to prepare and publish a multiannual emissions reduction plan at least 12 months before commencement of each budget period, tabled before the House of Representatives; independent monitoring by the Climate Change Commission.

Bahamas – Air Navigation Services Act 2021, Schedule, Section 7 (business plan): Mandating financial targets and performance indicators.

Colombia — Ley nº 152, de 15 de julio de 1994 (Ley Orgánica del Plan de Desarrollo), in particular Articles 1, 4, 5, 7, 10 and 14: Mandatory 4-year multiannual national development plan (*Plan Nacional de Desarrollo*) comprising

sectoral objectives and a public investment budget with multiannual financing specifications; obligation on all public entities to maintain 4-year indicative plans with annual action plans; annual execution reporting to the legislature.

Note(s):

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Mandatory Financing by Government

Regulatory Function:

Ensuring Efficiency of the Law, namely with regard to Implementation

Problem:

Financial resources are scarce. The implementation of regulation suffers from insufficient financial means on the side of the Government.

Solution(s):

Mandate the financing of certain activities.

Reference(s):

Australia — Securities and Investments Commission Act 2001 (Cth), Section 8 establishes ASIC as a body corporate, with section 9A implicitly requiring that ASIC receive the financial resources needed to carry out its functions.

Honduras — Ley de Educación Integral de Prevención al Embarazo Adolescente, Decreto No. 8-2023, Section 8.

Note(s):

Reinforces the position of the respective ministries, departments or other government entities in the annual budget negotiations. Might be legally problematic to the extent that it aims at binding the future budget legislator. See also the references of the parallel EU Legislators' Toolbox.

Business or Strategy Plan for Authorities

Regulatory Function:

Ensuring medium-term financial Stability and successful Implementation

Problem:

Authorities often plan just from one year to the next.

Solution(s):

Mandate multi-annual business or strategy plans.

Reference(s):

Bahamas – Air Navigation Services Act 2021, Schedule, Section 7 (business plan): Mandating financial targets and performance indicators.

Brazil, Lei 13.848 de 25 de junho de 2019 (Lei das Agências Reguladoras), Article 17: The plan must enumerate the objectives and expected results relating to management and the agency's regulatory, supervisory and normative competences; an indication of external factors beyond the agency's control that may affect results.

Note(s):

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Power to Borrow and to Invest

Regulatory Function:

Providing some Independence to Authorities or Bodies to Ensure Implementation despite Budgetary Uncertainty

Problem:

Authorities are often hampered in the execution of their tasks where they have little financial flexibility.

Solution(s):

Provide authorities the power to borrow and to invest, subject to some control by a ministry.

Reference(s):

Bangladesh Energy Regulatory Commission Act, 2003 (Act No. 13 of 2003), Section 18.

Bahamas – Air Navigation Services Act 2021, Section 14.

Australia — Securities and Investments Commission Act 2001 (Cth), Sections 8 and 8A.

Colombia – LEY 1002 DE 2005 (ICETEX), Article 4.

Note(s):

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Independent Implementation Fund

Regulatory Function:

Ensuring Implementation despite Budgetary Uncertainty

Problem:

Financial resources are scarce. The implementation of regulation and policies suffers from insufficient financial means on the side of the Government, often exacerbated by uncertainty.

Solution(s):

Create an independent implementation fund, with independent sources of financing and controlled expenditure.

Reference(s):

Pakistan (Sindh) — Regulation of Electric Power Services Act, 2023, Sections 9 and 10.

Solomon Islands — Special Economic Zones Act 2025, Sections 79-81.

Colombia — Ley 1341 de 2009 (Ley TIC), Articles 34–37 (Fondo Único de Tecnologías de la Información y las Comunicaciones).

Dominican Republic Ley No. 41-23 (Espaillat como provincia ecoturistica), Sections 17–19.

Panamá — Ley Nº 430 (2024) (Dirección Nacional de Control de Alimentos y Vigilancia Veterinaria), Articles 22 and 23: The fund referred to in Article 23 may be administered by a recognised international or regional organisation or by a financial institution accredited in Panamá.

Note(s):

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Cross-subsidising Mechanism

Regulatory Function:

Ensuring Implementation despite Budgetary Uncertainty

Problem:

Financial resources are scarce. The implementation of regulation and policies suffers from insufficient financial means on the side of the Government, often exacerbated by uncertainty.

Solution(s):

Create a cross-subsidising mechanism by law or authorise the creation thereof by an authority, be it by a unilateral act, be by a public agreement with the entity concerned.

Reference(s):

Pakistan — State-Owned Enterprises (Governance and Operations) Act, 2023, Schedule II, Section 5.

Colombia — Ley 142 de 1994 (Public Home Services), Articles 89–99: Sistema de Subsidios y Contribuciones — Fondo de Solidaridad y Redistribución.

Note(s):

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Joint Procurement or Buying Schemes

Regulatory Function:

Leveraging Scale, Reducing Prices and Ensuring Availability

Problem:

Crisis or specialised markets benefit from aggregated purchasing power.

Solution(s):

Enable joint procurement or buying schemes used by regions or districts or other public entities.

Reference(s):

South Africa — Public Procurement Act 28 of 2024, Section 1 (definition of *transversal term contract*), Section 25 (use of another organ of state), Section 63(1)(x).

Colombia — Ley nº 1150, de 16 de julio de 2007, Article 2, numeral 2, literal (a), second paragraph: for goods and services of uniform technical characteristics and common use, public entities must, where the regulation so requires, use catalogue purchase instruments derived from *acuerdos marco de precios* (framework price agreements); Article 2, numeral 2, literal (j): extends framework price agreements and demand aggregation instruments to non-uniform goods of common use, with mandatory use for all entities subject to the *Estatuto General de Contratación*.

Note(s):

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Procurement Rules Integrating Compliance Requirements

Regulatory Function:

Compliance

Problem:

Non-compliant products or services could be purchased with public money if procurement rules don't check regulatory compliance.

Solution(s):

Procurement authorities must verify and ensure that only compliant products and services (and economic operators) are considered.

Reference(s):

Australia — Commonwealth Procurement Rules 2025, Paragraphs 6.6, 7.27 and 7.28.

Colombia — Ley nº 80, de 28 de octubre de 1993 (Estatuto General de Contratación de la Administración Pública), Article 4, numeral 5°.

Note(s):

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Procurement Rules Furthering Policy Goals

Regulatory Function:

Making Procurement a Policy Means

Problem:

Legal requirements might fall behind what is wishful in terms of risk reduction, performance or other characteristics expressing policy goals.

Solution(s):

Permit or mandate that sector specific procurement rules require a higher level than the legal minimum.

Reference(s):

UK — Procurement Act 2023 (c. 54), Section 13: "National procurement policy".

UK (Scotland) — Procurement Reform (Scotland) Act 2014 (asp 12), Section 9 (Sustainable Procurement Duty): Before carrying out any regulated procurement, all contracting authorities — including local councils — must consider how procurement can improve the economic, social and environmental wellbeing of the authority's area, facilitate SME and third sector involvement, and promote innovation; contracting authorities must then act with a view to securing those improvements.

Chile — Ley nº 19.886, de 30 de julio de 2003 (Ley de Bases sobre Contratos Administrativos de Suministro y Prestación de Servicios), Article 2 bis and Article 6, Paragraph 1: Mandatory transversal incorporation of sustainability criteria in all

public procurement (Article 2 bis); for habitual service contracts procured through periodic tenders, tender bases must establish evaluation criteria awarding higher scores to bidders offering employment conditions and remuneration above the statutory minimum wage, indefinite-term contracts, and better working conditions, going beyond the legal employment minimum (Article 6, Paragraph 1); for waste collection services specifically, the employment and remuneration criterion must be weighted at a minimum of 30% of the total evaluation score (Article 6, Paragraph 4).

Note(s):

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Control Agreements with Court of Auditors

Regulatory Function:

Compliance and Financial Control

Problem:

State entities and public bodies sometimes struggle to implement (financial) provisions correctly.

Solution(s):

Provide the opportunity for state entities and public bodies to conclude agreements with the Court of Auditors permitting the latter to control the correct application of (financial) provisions.

Reference(s):

Australia — Auditor-General Act 1997 (Cth), Section 20: The Auditor-General may enter into an arrangement with any person or body to audit its financial statements, conduct a performance audit, or provide other services commonly performed by auditors. The provision enables public bodies, beyond audits

otherwise mandated by law, to arrange additional financial, performance or audit-related scrutiny by the supreme audit institution.

Honduras — Ley de Reactivación Económica y Desarrollo Humano, Decreto No. 17-2026, Artículo 8.

Note(s):

This comes evidently on top of the statutory control rights of the Court of Auditors.

See also the entries "Enforcement Funding and Cost Recovery" in Chapter J and "Fees, Charges, Cost-Sharing for Regulatory Services" in Chapter K. Fees and cost-recovery can lead to a full (re-)financing of authorities.

Q. Final Provisions / Miscellaneous

Gradual Phase-in of Regulatory Obligations

Regulatory Function:

Supporting SMEs and Sectors Undergoing Transition

Problem:

Sudden full entry into force may overwhelm some market actors.

Solution(s):

Stepwise or staged application dates for different categories of actor/product/type.

Reference(s):

New Zealand — Therapeutic Products Act 2023 (No. 39 of 2023), Schedule 1 (transitional, savings and related provisions): Establishes differentiated transition periods by product category and prior regulatory status — medicines with existing consents gain standard authorisations until expiry of those consents; unlisted medical devices and previously unregulated products receive automatic temporary market authorisations for 6 months; unregulated natural health products (NHPs) receive automatic temporary market authorisations for 2 years; medical devices previously listed on the WAND Database receive automatic temporary market authorisations expiring after 5 years (or 3 years for Class 3 and AIMD devices); existing licences continue in force under the new Act, with unlicensed operators given a transitional period to apply.

Colombia — Ley nº 1314, de 13 de julio de 2009 (Financial Information), Articles 14-16.

Note(s):

The New Zealand Therapeutic Products Act 2023 has been repealed, but is nonetheless an excellent reference for fine-tuned transitional provisions.

Transitional Product / Service Approval or "Grandfathering" of Existing Approvals

Regulatory Function:

Transition Management

Problem:

Existing/legacy products, processes, or certifications may require a transition path to the new regime.

Solution(s):

Explicit "grandfathering" clauses for licences, certificates, or products lawfully authorised under prior rules.

Reference(s):

New Zealand — Therapeutic Products Act 2023 (No. 39 of 2023), Schedule 1 (transitional, savings and related provisions): Some existing licences stay in force under the new Act.

Tanzania – Investment Act 2022, Section 37: Certificates and agreements stay in force; the fulfilment of superseded obligations suffices.

Chile — Decreto Supremo Nº 3 de 2010 del Ministerio de Salud, Second Transitional Article: Pharmaceutical sanitary registrations granted under the former regulation remain valid until the expiry of the period specified in the respective authorising resolution. The entry into force of the replacement regulatory regime therefore does not require already authorised products to obtain an immediate new registration.

Note(s):

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Continuity of Proceedings, Liabilities and Rights after Legislative Change

Regulatory Function:

Transition Management

Problem:

Without dedicated provisions, it may be questionable whether proceedings can be continued and whether liabilities or rights continue to exist after the coming into application of new legislation.

Solution(s):

Explicit clauses on the continuity of proceedings, liabilities and rights.

Reference(s):

Zambia – Agricultural Credits and Warehouse Receipts Act, 2026, Second Schedule, Sections 4 and 5.

Zambia – Food Reserve Act, 2026, Schedule: also with dedicated provisions on the transfer of assets from an outgoing agency to a new one.

Chile – Ley sobre Efecto Retroactivo de las Leyes (1861), see in particular Articles 22–24.

Note(s):

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Government to decide on Application Date / Fulfilment of Conditions Necessary for Application

Regulatory Function:

Application dates adapted to reality

Problem:

The application of certain provisions might be subject to certain conditions that are not yet fulfilled at the time of adoption of the act adopted by the legislators.

Solution(s):

Let the Government decide on whether and when the necessary conditions are fulfilled. A Government act triggers the application of the legislation.

Reference(s):

Canada - Cannabis Act (SC 2018, c. 16), Section 226: "... the provisions of this Act … come into force on a day or days to be fixed by order of the Governor in Council.".

Colombia — Ley nº 1314, de 13 de julio de 2009 (Financial Information), Article 14: implementing dates adapted by the Ministries of Finance and of Commerce.

Note(s):

It is also possible to link the application date(s) to the fulfilment of external conditions. However, in terms of legal certainty, it is often preferable to let the Government state that the external conditions have been fulfilled.

Regional Postponement Option or Timing Adaptation

Regulatory Function:

Balance between Ambitious Goals and Feasibility / Flexibility

Problem:

The same deadlines might not be suitable in all regions, states or provinces.

Solution(s):

Give regions, states or provinces a postponement option under control of the central Government, to avoid abuse. Or establish similar mechanisms for the regionally differentiated entry into application of the act, certain parts or certain provisions.

Reference(s):

Australia – Water Act 2007 (Cth), Section 2 and Schedule 1 (ratification dates of the various agreements), giving the states control by determining the date of ratification.

India - Mahatma Gandhi National Rural Employment Guarantee Act 2005 (MGNREGA), Section 1(3): States were given timelines to implement the scheme in different phases. The Central Government determined the schedule for expanding coverage to different districts.

Colombia - Ley 1564/2012 (Código General del Proceso), Article 627(6): The Consejo Superior de la Judicatura determined different entry-into-force dates for different judicial districts, with full national rollout completed by January 2016.

Brazil - Lei 12.651/2012 (Código Florestal), superseded (strikethrough) versions of Article 59 and Article 59 § 2, providing for the possibility of prolonging the implementation once by one year.

Note(s):

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Remedies against Overregulation or Regulatory Overlap

Regulatory Function:

Regulatory Simplification

Problem:

Layered or competing requirements create legal uncertainty and cost.

Solution(s):

Petition or appeal rights for operators or citizens where cumulative or conflicting requirements exist.

Reference(s):

New Zealand – Resource Management Act 1991 (RMA), Section 85B: An applicant can request the Environment Court to decide to devalidate one of the conflicting rules (the lower one).

Peru - Decreto Legislativo No. 1256/2016 (Ley de Prevención y Eliminación de Barreras Burocráticas), Article 7 provides the right to request an investigation of any bureaucratic obstacle.

Note(s):

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Remedies against Conflicting Authority Instructions

Regulatory Function:

Fairness and Burden Reduction

Problem:

Different responsible authorities may issue conflicting instructions, creating a disproportionate burden.

Solution(s):

Provide the right to call for aligned decisions or one authority being the lead.

Reference(s):

UK – Regulatory Enforcement and Sanctions Act 2008 (RESA 2008), Part 2 (Primary Authority): Section 24: A business (or a trade association on behalf of members) can apply to a local authority to become its "primary authority". Other enforcing authorities cannot take enforcement action inconsistent with the primary authority's advice without first notifying the primary authority.

Mexico – Ley General de Mejora Regulatoria, publicada en el DOF el 18 de mayo de 2018 (abrogated), Articles 61-63 ("protesta ciudadana").

Note(s):

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Public Call for Evidence for Individual Cases

Regulatory Function:

Evidence Gathering and General Interest

Problem:

It is sometimes not easy to gain evidence for treating individual cases appropriately. Moreover, aspects of general interest might need to be taken into account.

Solution(s):

Provide for the power to launch public calls for evidence.

Reference(s):

Malawi — Competition and Fair Trading Regulations, 2026, Section 11(j): evidence gathering.

Brazil — Lei No. 9.784/1999 (Lei do Processo Administrativo Federal), Articles 31 and 32: public interests.

Note(s):

The second reference also provides for public hearings.

Expert or Stakeholder Consultation

Regulatory Function:

Expertise for Technically or Legally complicated Regulation

Problem:

Rules adopted without expert knowledge may falter in practice.

Solution(s):

Consultation with defined stakeholder groups or experts before adoption of secondary legislation or guidance.

Reference(s):

Australia — Legislation Act 2003, Section 17(2).

Kenya – Statutory Instruments Act, 2013 (No. 23 of 2013), Section 5.

Brazil — Lei 13.848/2019 (Lei Geral das Agências Reguladoras), Article 9.

Note(s):

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Whole Society Consultation

Regulatory Function:

Increasing the Knowledge Base, enhancing Engagement

Problem:

Important change processes require the involvement of the whose society, not just of administrations and certain stakeholders.

Solution(s):

Consultation mechanism covering the entire society.

Reference(s):

Namibia — Regulations on Rule-Making Procedures, GN 334/2010 (under Communications Act 2009), Regulations 6–7**.**

Mexico – Ley General de Mejora Regulatoria, publicada en el DOF el 18 de mayo de 2018 (abrogated), Article 73.

Note(s):

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Citizen Regulatory Initiative

Regulatory Function:

Citizen Right to Request Initiation of Rule-Making

Problem:

Regulatory gaps or deficiencies affecting the public may go unaddressed if only the regulator or government can initiate rule-making proceedings. Citizens and affected parties who identify a need for regulation have no formal channel to trigger the process.

Solution:

A statutory right enabling any person — without institutional standing, signature thresholds, or formal qualifications — to petition the competent authority in writing to initiate rule-making proceedings, with a requirement that the authority consider and respond to the petition.

Reference(s):

Namibia — Regulations on Rule-Making Procedures, GN 334/2010 (under Communications Act 2009), Regulation 5**.**

Canada (Ontario) — Environmental Bill of Rights, 1993, Part IV, Sections 61–73: Two Ontario residents may apply in writing to the appropriate minister for review of an existing policy, Act, regulation, or instrument that should be amended, repealed, or revoked to protect the environment, or for review of the need for a new policy, Act, or regulation. The minister must consider whether the public interest warrants the review and generally must notify the applicants within 60 days whether it will be conducted, providing brief reasons. Where a review is undertaken, the applicants must also be notified of its outcome and resulting action.

Note(s):

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Citizen Administrative Protest

Regulatory Function:

Identification of Maladministration

Problem:

Administrative deficiencies affecting the public may go unaddressed if citizens and affected parties who identify a need for change of administrative practice have no formal channel to trigger the process.

Solution:
A statutory right enabling any person — without institutional standing, signature thresholds, or formal qualifications — to petition the competent authority or a central supervising authority in writing to initiate rule-making proceedings, with a requirement that the authorities consider and respond to the petition.

Reference(s):
Mexico – Ley General de Mejora Regulatoria, publicada en el DOF el 18 de mayo de 2018 (abrogated), Articles 61-63.

Note(s):
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Stakeholder Forum

Regulatory Function:
Increasing the Knowledge Base, enhancing Engagement

Problem:
Important change processes and good implementation require the involvement of stakeholders.

Solution(s):
Create a forum for stakeholders.

Reference(s):
South Africa — National Economic Development and Labour Council Act, No. 35 of 1994.

Mexico – Ley General de Mejora Regulatoria, publicada en el DOF el 18 de mayo de 2018 (abrogated), Articles 31-37.

Note(s):

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Federation or Amalgamation of Representing Organisations

Regulatory Function:

Facilitating Consultative Processes or Representation of Stakeholders

Problem:

In case of multi-party negotiations e.g. in labour law,, there is an interest in limiting the number of organisations representing stakeholders. However, requesting a formal merger under company law is a big step, hardly acceptable for trade unions and similar organisations.

Solution(s):

Permit federations or amalgamations for purposes of representation and negotiation, leaving the question of formal merger under company law aside.

Reference(s):

Lesotho — Labour Act, 2024, Sections 79-82.

Brazil — Decreto-Lei No. 5.452/1943 (Consolidação das Leis do Trabalho — CLT), Articles 533-538.

Note(s):

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Ombudsman or Auditorium

Regulatory Function:

Increasing the Knowledge Base, enhancing Engagement, improving Administration

Problem:

Information on sub-optimal functioning does not reach decision-makers.

Solution(s):

Create an "auditorium" or mandate the nomination of an ombudsman to receive and process complaints and information about dysfunction.

Reference(s):

Australia — Ombudsman Act 1976 (Cth), Sections 5, 6, 15, and 19.

Brazil — Lei 13.848/2019 (Lei Geral das Agências Reguladoras), Articles 22 and 23.

Note(s):

The Australian reference creates one generic ombudsman and a few specialised ones. The Brazilian mandates the creation of an auditorium in the various agencies so that there is a network of specialised independent investigators.

Impact and Progress Assessment or Reporting

Regulatory Function:

Evidence-Based and Sustainable Law Making and Implementation

Problem:

Lack of robust analysis can yield counterproductive or unsustainable regulation or other measures.

Solution(s):

Require integrated ex post progress reports and ex post impact assessments (including social, environmental, digital, and fundamental rights dimensions).

Reference(s):

UK – Small Business, Enterprise and Employment Act 2015 (c. 26), Sections 28 and 30.

Mexico – Ley General de Mejora Regulatoria, publicada en el DOF el 18 de mayo de 2018 (abrogated), Articles 70(II) and 73-77.

Note(s):

- High administrative burden, absorbing scarce human resources. Preferable with precise metrics / performance indicators.
- Much more problematic: ex ante impact assessments.

Binding Sectoral Roadmaps/Action Plans

Regulatory Function:

Structured Forward-Looking Policymaking

Problem:

Sectoral reform intentions may not bind unless legally formalised.

Solution(s):

Mandate public, revisable, and enforceable sectoral roadmaps with clear reporting.

Reference(s):

United Kingdom — Climate Change Act 2008, Sections 13–14.

Brazil — Lei 13.848/2019 (Lei Geral das Agências Reguladoras), Articles 17-21.

Note(s):

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Voluntary Agreements on Top of or as Alternative to Regulation

Regulatory Function:

Furthering Policy Goals

Problem:

Pursuing all policy goals by legislation is not always possible or appropriate.

Solution(s):

Establish a two-tiered system, with one tier laid down in legislation and a second pursued by voluntary agreements integrated into the legal system, with fall-back regulatory solution.

Reference(s):

New Zealand — Waste Minimisation Act 2008, Sections 8–22: encouraging — and in certain circumstances requiring — producers, importers, retailers, and consumers to share responsibility for end-of-life products. It explicitly foreshadows both voluntary and mandatory schemes within the same statutory framework and provides for a backstop mechanism in Section 22.

Brazil — Lei 12.305/2010 (National Solid Waste Policy), Articles 3(I), 33 §7 and 35 IV.

Note(s):

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Adaptation to Highest Courts' Rulings

Regulatory Function:

Alignment with Higher Law

Problem:

Declared invalid or misapplied rules may linger and be enforced contrary to Court rulings.

Solution(s):

Require the administration or government, after a final higher-court ruling, to:
(a) adapt future administrative decisions in comparable cases;
(b) formally review the affected rule and report within a fixed period whether and how it will be amended or withdrawn; and, in stronger regimes,
(c) amend or repeal the rule automatically or within a statutory deadline.

Reference(s):

New Zealand — New Zealand Bill of Rights Act 1990, Sections 7A–7B, as inserted by the New Zealand Bill of Rights (Declarations of Inconsistency) Amendment Act 2022: When a senior court's declaration that legislation is inconsistent with the Bill of Rights becomes final, the Attorney-General must notify Parliament and the responsible Minister must, generally within six months, present a report advising Parliament of the Government's response. The mechanism prevents an authoritative finding of inconsistency from remaining without a formal governmental and parliamentary response.

Brazil — Lei nº 9.784/1999, Articles 64-A and 65-B: Where the Federal Supreme Court upholds a complaint because an administrative act violated a binding precedent, the authority that issued the act and the body responsible for administrative appeals must adapt future administrative decisions in similar cases to the Court's ruling.

Mexico — Ley de Amparo, Arts. 231–235 (Declaratoria General de Inconstitucionalidad): After the Supreme Court (SCJN) establishes jurisprudence

finding a general norm unconstitutional through two consecutive amparo rulings, it must notify the issuing authority. The issuing authority has 90 calendar days to implement the pertinent amendments. If the authority fails to act within 90 days, the SCJN may issue a Declaratoria General de Inconstitucionalidad with *erga omnes* effect, invalidating the norm with general force.

Note(s):

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Integration of Traditional or Religious Law

Regulatory Function:

Acceptance of Law, Clarity, Avoiding Contradictions

Problem:

New legislation might not be accepted where it is understood to compete with or go against traditional or religious law. Moreover, there can be contradictions between the two.

Solution(s):

Recognise relevant traditional or religious norms as complementary sources or statutory decision-making considerations; establish expert bodies to translate those norms into regulatory standards; and define coordination, conflict and cooperation rules where customary or religious institutions coexist with state authorities.

Reference(s):

Tanzania — Banking and Financial Institutions (Non-Interest Banking Business) Regulations, 2025: look for "Shari'ah".

Malaysia — Islamic Financial Services Act 2013, Sections 28–30 and 35–38: Islamic financial institutions must ensure that their objectives and all aspects of

their operations comply with Shariah. The Act bridges religious and statutory regulation by treating compliance with rulings of the national Shariah Advisory Council as Shariah compliance, authorising the central bank to specify Shariah standards and requiring each licensed institution to maintain a Shariah committee. Religious-law expertise thus complements prudential and market regulation within a single statutory framework.

New Zealand — Resource Management Act 1991, Sections 2 ("kaitiakitanga"), 6(e), 7(a), 8, 39(2)(b), 42(1)(a) and 61(2)(a)(iii): Environmental decision-makers must recognise and provide for Māori cultural and traditional relationships with ancestral lands, water, sites, sacred places and other treasures, have particular regard to guardianship principles, and take Treaty principles into account. Hearing procedures may recognise tikanga Māori—defined as Māori customary values and practices—where appropriate.

Bolivia — Ley Nº 073 de Deslinde Jurisdiccional, Capítulos III and IV: The Act integrates Indigenous Native Peasant law into the wider justice system by recognising its jurisdiction alongside ordinary and agro-environmental jurisdiction and prescribing coordination and cooperation among them. Coordination may include information-sharing, dialogue on human-rights compliance and exchanges concerning dispute-resolution methods, while authorities of the respective jurisdictions must provide legally permissible cooperation. The legislation thereby addresses overlaps and potential contradictions without subsuming Indigenous law into ordinary law.

Peru — Ley Nº 29824, Ley de Justicia de Paz, Article IV, and Article 4(3): Justices of the peace decide according to their honest knowledge and understanding and must respect local culture and customs.

Note(s):

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Referring Generically to other Law as Completion

Regulatory Function:

Closing Loopholes

Problem:

New legislation cannot always cover all aspects of what merits being regulated, whilst precise limited references might not be workable.

Solution(s):

Refer to a named enactment or general body of law as supplementarily applicable to matters not specifically regulated, or insofar as compatible, while expressly preserving the priority of the special legislation. State whether the reference incorporates the external law as in force from time to time or at a fixed date.

Reference(s):

Kenya — Retirement Benefits (Tribunal) Rules, 2000, Rule 12: In procedural matters not governed by the Retirement Benefits Act or the Tribunal Rules, the Tribunal may apply the Civil Procedure Rules where applicable. The special retirement-benefits regime therefore retains priority, while the general civil-procedure framework may be used to fill procedural gaps.

Costa Rica – Reglamento para la prevención, preparación y respuesta ante accidentes químicos (N° 44741-S-MAG) (2024), Article 3: listing several acts that apply so as to complement the regulation, presumably as dynamic reference as last amended.

Mexico — Ley Federal de Procedimiento Administrativo, Article 2: The Federal Code of Civil Procedure applies supplementarily, insofar as relevant, to matters governed by the Federal Administrative Procedure Act. The clause allows general procedural law to fill gaps without displacing the Act's specific rules.

Brazil — Lei nº 14.133/2021, Article 89: Contracts governed by the Public Procurement and Administrative Contracts Act are regulated by their clauses and

public-law rules, with the principles of general contract theory and private-law provisions applying supplementarily.

Note(s):

- This regulatory technique may cause legal uncertainty. Some jurisdictions therefore limit the referencing or impose conditions. See e.g. Australia – Acts Interpretation Act 1901 (Cth), Part 9 Section 46AA.
- Clarify whether a dynamic or static reference is established.

Optional Electronic Proceedings

Regulatory Function:

Legal Security in E-Administration, Efficiency

Problem:

Electronic communication is not necessarily trustworthy and confidential, whilst speeding up proceedings.

Solution(s):

Set up confidential and reliable transmission systems.

Reference(s):

Uganda — Judicature (Electronic Filing, Service and Virtual Proceedings) Rules, 2025.

Brazil — Lei No. 11.419/2006 (Lei de Informatização do Processo Judicial).

Note(s):

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Mandatory Electronic Proceedings

Regulatory Function:

Efficiency

Problem:

Electronic communication is often faster and more efficient, whilst not always used voluntarily.

Solution(s):

Mandate electronic communication.

Reference(s):

Papua New Guinea — Land (Amendment) Act 2025, Section 2, inserting a new Section 3A.

Chile – Ley No. 19.880, de 29 de mayo de 2003 (Ley de Bases de los Procedimientos Administrativos), Artículo 1.

Note(s):

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Table of Contents

Regulatory Function:

Better Information of Users, Clarity

Problem:

Regulations are often long and difficult to understand, structure-wise.

Solution(s):

For lengthy legislation, include a hierarchical table of provisions before the substantive text. In official electronic publications, make each entry navigable

and provide permanent links to individual provisions; where useful, supplement the structural table with a subject index.

Reference(s):

New Zealand — Legislation Act 2019.

United Kingdom — Online Safety Act 2023.

Argentina — Civil and Commercial Code.

Note(s):

Spreading relatively quickly from one jurisdiction to the next.

Explanatory Hyperlinks and pop-up Definitions

Regulatory Function:

Better Information of Users, Clarity

Problem:

In particular lay-persons find it difficult to understand legislation, as they are not used to jumping between parts and sections to read provisions jointly.

Solution(s):

In official or officially supported electronic publications, hyperlink cross-references to the cited provisions and display the applicable meaning of defined terms through hover text or pop-up panels. Pop-ups should identify and link to the authoritative definition provision. Legislation publishers should clarify that these aids facilitate access but do not themselves form part of the legal text.

Reference(s):

Tanzania — Banking and Financial Institutions (Non-Interest Banking Business) Regulations, 2025: Pop-up definitions.

Zambia – Food Reserve Act, 2026: Explanatory hyperlinks and pop-up definitions.

New Zealand — New Zealand Legislation website, Parliamentary Counsel Office.

Note(s):

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Further Tools

If you haven't found what you were looking for or if you wish further inspiration, please check our Cross-sectoral Standard Provisions, our "List of Powers and Obligations", our "List of Sanctions and Collateral Measures" and our sector model provisions which also contain many generic provisions: Protection of vulnerable persons and persons with special needs; Food and drinks legislation; Alcohol, Cannabis and Tobacco. See also the second edition of the parallel (second edition of the) EU Legislators' Toolbox which contains about 50 entries not paired by the Commonwealth and Latin American Legislators' Toolbox.

When working with Large Language Models or other forms of Artificial Intelligence, we recommend using and referring to our Large Language Models page.

For methodological questions regarding the conception of legislation, including quality control, see our Handbook 'How to Regulate?' and our introductory Training Video 'How to Regulate?'.

Training and Advice

For all other questions or issues, advice or custom-made training, please contact: manager@regulatoryinstitute.org.

Annex I: Nation States referred to

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