SCIENTIFIC EXCELLENCE IN CONSUMER SAFETY
BACKGROUND NOTE
HIGHLIGHTS NOTE 17

- **When managing consumer safety, the primary aim of governments is to ensure that products are safe for their intended use.**
- **When it comes to consumer products, EU citizens currently enjoy a high level of safety, while the existence of an evidence-based regulatory framework creates incentives for innovation.[1]**

This document is designed to examine the context and process by which scientific advice is given to regulators and to identify what characterises the optimal outcome.

The note serves as background reading to the ERIF Workshop on Scientific Excellence in Consumer Safety, to be held on 18 November 2021.

CONSUMER SAFETY – REGULATORY OBJECTIVES

Across the OECD area, the primary aim of governments when managing consumer safety is to ensure that products are safe for their intended use. It is the management of involuntary exposure to potential harms posed by consumer applications of technologies. Consumer safety is the over-riding aim.

High quality regulation of consumer safety has a significant degree of predictability, allowing consumers to enjoy benefits, reducing uncertainty for market participants, and limiting arbitrary implementation by governments. A supportive context for innovation, with consequent benefits for consumers, is an important ancillary benefit.

At EU-level, a final regulatory objective is the good functioning of the Single Market by facilitating the placing on the market of products that meet common standards of safety. This creates additional incentives for investment.

CONSUMER SAFETY – COMPLEX REGULATORY CHALLENGES

(1) In seeking to ensure consumer safety in a complex environment, regulators face a number of challenges. These include:

- **Limitations to regulators' knowledge of technologies, applications and consumer usage behaviours** – these are complex and must be understood, if exposures are to be properly identified, risks characterised, and mitigation measures designed.
- **Sources of knowledge** – producing companies or the academic scientists who work with them hold much of the relevant knowledge needed by regulators to make high quality decisions. In view of this, it is imperative that governments retain access to such expertise, by carefully designing and managing conflict-of-interest policies. Similarly, companies carry out safety research to protect brand equity and reputation. This deep sectorial knowledge must be accessed if consumers are to be protected without reducing benefits or creating unwanted socio-economic costs.
- **Market factors and investment in safety** – it must be recognised that regulatory requirements can be exceeded by the internal standards set by leading companies with their extensive investments in product safety. Such expenditures protect brand equity and reputation, the primary intangible assets of market participants. A challenge for regulators is to engage with these market-based factors and to access industry's knowledge.
- **Regulatory processes and decisions must be perceived to be impartial and evidence-based** – to achieve impartiality and excellence at the same

[1] See, for example, the critique by the German Federal Institute for Risk Assessment (BfR) of the intervention logic used to support European Commission's Chemicals Sustainability Strategy. This was published: Herzler. M. et al 'The EU chemicals strategy for sustainability questions regulatory toxicology as we know it: is it all rooted in sound scientific evidence?' (Archives of Toxiclogy, 95, 2021).

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time requires the systematic application of good governance principles, structures, policies, and guidance to processes of scientific assessments and the experts who provide it. These concepts are still not a part of the Better Regulation agenda of many governments.

- **Regulators and policy makers may have limited understanding of consumers or of market participants and their respective, likely response to regulatory interventions** – this creates challenges for the effective design of measures, unless they are based on deep sectorial knowledge, excellent science, and robust intervention logic.
- **Major likelihood of regulatory failure** – poorly designed measures may fail to ensure consumer safety. They may also trigger significant unintended consequences, including changes in consumer behaviour, reductions in consumer welfare due reduced efficacy or increased costs, and possible risk-risk trade-offs. Also, because of the scale of the usage of consumer products and supporting value chains, major socio-economic costs can be generated and consent for actions by governments undermined.
- **Enjoyment of benefits** – any regulatory process for managing consumer safety must consider the value that citizens place on the functional and emotional benefits of the products they purchase and use. Characterising and understanding such benefits requires access to relevant and reliable data, robust methodologies, and rigour.
- **Complex regulatory objectives** – increasingly, regulators seek to expand the range of social goals to be satisfied through the management of consumer safety, such as sustainability, enhanced protection of biodiversity, greater circularity of products and management of lifestyle choices. Making choices between various health and environmental goals requires regulators to understand the risk profiles of each option. This challenges the use of decision-making philosophies based primarily on intrinsic characteristics (hazard).

CONSUMER EXPOSURES – BEST PRACTICE FRAMEWORK

(1) General – Consistent high quality regulatory decisions needed to manage consumer safety are the outcome of a shared culture and behaviours. These are formed by a governance framework of political commitments expressing regulatory principles and philosophy; institutional architecture setting out the allocation of powers and responsibilities, along with formal processes; core policies setting out expected processes; and principles and guidelines for scientific integrity.

A series of good practices can be identified for each element of the governance framework for managing consumer exposures:

- Regulatory principles and philosophy;
- Institutional architecture;
- Policies; and
- Principles and guidelines for scientific integrity.

(2) Governance: Regulatory Principles and Philosophy – Most important aspects:

- Primary aim is to protect the consumer;
- High quality scientific advice, that meets the highest standards of excellence and relevance, is the foundation on which measures to protect consumers are based;
- Advice is provided through a process of scientific assessments undertaken by the best and most relevant independent experts, using excellent, impartial and transparent processes, and based on the best available scientific evidence;
- Assessments are based on risk, focusing on real world usage and consumption, including reasonable misuse;
- Risk assessment opinions are based solely on scientific evidence and are not influenced by bureaucratic, compliance, political, ideological or other considerations;
- Risk assessment bodies, and the experts that provide scientific assessments, are institutionally independent of risk managers and EU Member States; and
- Assessors collaborate with global bodies, other parts of the European Institutions, and academia to continuously review potential risks and to support the development of new ways of understanding potential risks and of undertaking their assessments.

(3) Governance: Institutional Architecture – Most important elements:

- Clear, institutional separation of risk assessment bodies from risk managers;
- Scientists that undertake risk assessments are organised on the basis of committees that are focused on specific areas and types of consumer exposures;
- Members of scientific committees are selected from the wider community of scientists on the basis of excellence and relevance, using a transparent selection process that combines peer nomination with calls for expression of interest;
- Committee members serve in a personal capacity, commit to act in the public interest, and declare conflicts of interest through a transparent policy that reflects a sophisticated understanding of bias and of the conflicts of interest that cause it;
- A secretariat supports the work of the scientific committees, providing relevant administrative support. It does not draw up risk assessment opinions, and is not involved in technical or scientific processes;

- Committees enjoy significant powers to independently determine access to external experts; set up expert working groups and workshops, identify potential future harms; support new ways of understanding potential harms and of assessing risks; and setting rules of procedure;
- Formal processes of transparent peer review are established for all risk assessment opinions; and
- Parties affected directly by risk assessment opinions have the procedural right to seek a structured reassessment of the findings of an opinion.

(4) Governance: Policies – Specific policies should include:

- Selecting experts;
- Managing conflicts of interest and bias;[2]
- Access to experts and external knowledge;
- Stakeholder and expert consultation, including face-to-face hearings;
- Peer review of risk assessment opinions; and
- Functioning of committees (rules of procedure).

(5) Governance: Scientific Integrity – Principles and guidelines for scientific integrity should be drawn up, taking particular account of the content and structure set out in the principles and guidelines developed by Sir Colin Berry for the European Regulation and Innovation Forum (ERIF). These are set out in *ERIF Communication 20 'Principles and Guideline for Scientific Integrity in Regulatory Studies' (2021)* and encompass the quality of studies, assessments of studies, risk communication, and the selection of experts and management of committees.[3]

Specific additional guidelines may include:

- **Study quality** – relevance of exposure assessment to real world usage and consumption behaviours;
- **Study quality** – sources of evidence of consumer usage and standards established by external bodies;
- **Study quality** – where studies may not fully meet established standards, exercise judgement in a transparent manner to extract the key robust elements;
- **Assessment** – transparency of weight-of-evidence assessments;
- **Assessment** – preference for quantitative risk assessments, wherever possible;
- **Communication** – inclusion of minority opinions;
- **Communication** – express risks quantitatively;
- **Communication** – avoid framing of risks using notions of risk acceptance; and
- **Experts** – recognise that in order for experts to have the level of relevant knowledge it is likely that they will have current or historic links to industry.

THE INDEPENDENT SCIENTIFIC COMMITTEE MODEL

At EU-level, a number of different structural models are used to provide scientific assessments for the management of consumer safety. The most important are: assessments by Member States (so-called 'reference' or 'rapporteur' Member States) overseen or endorsed by a Technical Working Group or Scientific Committee of other experts drawn from Member States – EMA and ECHA use this approach for example; and, independent scientific committees controlled by specific Commission DGs.[4]

One of the most important, and influential, is the combination of scientific assessment of risk by independent scientific committees with risk management decisions by the European Commission.

This model of decision-making has delivered a high level of consumer safety. In turn, a combination of trust and predictable decisions, based on risk and evidence, has helped create market confidence and strengthened incentives to innovate.

A number of factors underpin the effectiveness of this model. These include:

- **Culture** – over time, members of committees have developed a collective approach to decision-making that emphasises the importance of scientific excellence and deep sectorial knowledge, along with a focus on exposures revealed by consumer behaviour. Collectively, there is also a tendency to be curious about developing knowledge and to be led by science rather than procedure.
- **Expertise** – committee members are selected primarily because of their relevant expertise, encompassing technologies, applications, and consumer usage. There is a strong emphasis on selecting committee members with such knowledge, complemented, where necessary, by other experts and information gained from consultation with stakeholders.
- **Excellence** – it is a requirement of the Commission Decisions that provide the authority for the actions of the committees that their

[2] See: *ERIF Monograph 'Risk Management and Scientific Assessments – Understanding Conflicts of Interest and Managing Bias for Scientific Excellence and Impartiality' (2020)*.

[3] The importance of developing horizontal principles and guidelines for scientific integrity at EU-level was identified in a recent opinion provided to the European Commission by the Group of Chief Scientific Advisors. See: European Commission 'Scientific Advice to European Policy in a Complex World (Scientific Opinion No.7 by the Group of Chief Scientific Advisors, 2019). Similar recommendations are included in *ERIF Monograph 'Scientific Evidence and the Management of Risk' (2016)*.

[4] The different models used at EU-level to develop scientific assessments for risk management, along with the wider importance of scientific evidence for decision-making, are discussed in the *ERIF Monograph 'Scientific Evidence and the Management of Risk' (2016)*.

activities be guided by the principle of excellence. This is reflected in the overall process of scientific assessments, the selection of committee members, and the examination of scientific evidence.

- **Independence** – another requirement of the Commission Decisions is that the committees should be independent. Committee members are selected from open application processes and are not nominated by Member States. There is institutional separation of risk assessment and risk management. Assessment processes are designed to ensure impartiality.
- **Risk** – scientific assessments consider risk, based on a deep sectorial knowledge of exposures. Where appropriate, and based on scientific evidence, worst case analyses are also undertaken. This is not, however, a standard part of the scientific assessment. Committee members seek to ensure that the Precautionary Principle plays no part in their scientific assessment of risk, respecting the Commission Communication of 2000.
- **Risk and hazard** – determination of risk relies, in many cases, on hazards identified in other regulatory processes. The ECJ has differentiated the role of hazard identification as focussing on the "intrinsic properties" of a substance as opposed to "the risk arising from consumer exposure to a substance".[5]
- **Scientific Assessments** – there is a strong emphasis on the transparent assessment of the quality of studies, including the relevance of the exposures and sources of evidence of usage. Weight-of-evidence processes are also transparent. Committee members may, if they believe it to be appropriate, quantify risk assessments.
- **Trade-offs** – committee members, when undertaking risk assessments, recognise and communicate to risk managers potential risk-benefit and risk-risk trade-offs, thereby helping to improve the quality of risk management decisions.
- **Forward-looking** – committee members have the institutional independence to identify emerging issues, including potential harms, new risk assessment models, divergences from decisions by risk assessment bodies in other parts of the world or the EU, and scientific advances in understanding the impact of technologies on consumers.
- **Secretariat** – committees have the authority to seek out experts, set up expert working groups and workshops, identify and review emerging harms, and to assess new ways of understanding consumer exposures or carrying out risk assessments. Commission officials supporting the committees adopt a "hands off" approach.
- **Predictable** – many of the risk assessment decisions made by the committees have predictable outcomes because they are based on widely-accepted definitions of scientific quality, respected risk assessment methodologies, a culture of decision-making focused on safety, risk, and exposures, and the views of expert assessors.
- **Respected** – the committees have built a reputation globally for the quality of their risk assessments, helping to build trust and market confidence. It also provides an 'exemplar', as intended in the Commission Decisions setting up the model, for scientific assessments carried out by other EU bodies.

This is a model for the implementation of risk management laws that works well. There is no evidence of significant failure or inadequacy.

European Regulation and Innovation Forum
October 2021

Richard Meads, the Rapporteur at the European Regulation and Innovation Forum (ERIF), wrote this Highlights Note. However, the views and opinions expressed in this paper do not necessarily reflect or state those of ERIF or its member.

[5] Judgment of the General Court (Eighth Chamber), 16 December 2020, Case T 207/18.