EUROPEAN REGULATION AND INNOVATION FORUM – MONOGRAPH

SCIENTIFIC EXCELLENCE IN CONSUMER SAFETY

INSIGHTS FOR THE EU BETTER REGULATION AGENDA

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EXECUTIVE SUMMARY

1. Background

When managing consumer safety the primary aim of governments is to ensure that products are safe for their intended use. This is best achieved when regulation of consumer safety is predictable and based on the likelihood of harm. In turn, this facilitates safe use of technologies, stimulates investment in new sustainable products, limits arbitrary implementation by governments, and allows consumers to enjoy valued functional and emotional benefits. It also contributes to consumer confidence and engenders public trust. These are core objectives of the EU's Better Regulation Agenda.

New initiatives proposed by the European Commission seek to restructure parts of the governance of the provision of scientific assessments for consumer safety. Possible changes include absorbing the responsibilities of existing independent scientific committees into other existing bodies and placing greater emphasis on the intrinsic properties of materials, rather than likelihood of harm, as the major regulatory philosophy for managing consumer safety. Such proposals provide an opportunity to reconsider the challenges facing the future effectiveness of the current independent scientific committees and to examine ways of building on this highly successful approach.

In the light of these issues and to contribute to the evolution of the EU's approach to ensuring consumer safety, the European Regulation and Innovation Forum (ERIF) held a major on-line workshop in November 2021 focusing on *'Scientific Excellence in Consumer Safety'*. More than 100 invited guests, including distinguished scientists, senior officials from the EU institutions and Member States, experts from academia, think tanks, and the business community joined the event and participated in the wide-ranging discussions.

This ERIF Monograph is informed by the presentations, reflections, and discussions that took place at the workshop. It also includes findings from extensive previous work on the role and governance of scientific assessments in the EU undertaken by ERIF. **It is a contribution by ERIF to on-going debates about the future governance at EU-level of scientific assessments for consumer safety.**

2. Ensuring Consumer Safety in the European Union

2.1. Regulation of Consumer Safety

Regulators face a number of challenges when developing measures to ensure consumer safety, but can take advantage of emerging governance and methodological opportunities to further enhance the quality of decisions. Specifically:

- **Distributional impacts and trade-offs** – it is difficult to legislate for the safety of entire populations. Interventions benefit some but not all, leading to the need for regulators to understand trade-offs. Only scientific assessments based on an understanding of exposures and the likelihood of harm can facilitate the process of making choices between sub-groups and potential harms.

- **Marginal improvements** – most societies in the OECD area are well-protected against potential harms posed by the production and use of consumer products. In this mature regulatory context, new interventions frequently seek to achieve very small, often marginal, improvements in safety, whilst potentially triggering behavioural changes

including risk transfers and other forms of risk-risk outcomes that increase overall likelihood of harm.

- **Characteristics of scientific assessments** – proposed interventions to improve consumer safety are, on too many occasions, justified on the basis of low-quality studies, old methodologies, or out-of-date knowledge about issues such as the causes of cancer. To protect consumers interventions should be justified on the basis of scientific assessments that focus on identifying likelihood of harm, based on the best available scientific evidence of exposures, and derived from processes undertaken by eminent and relevant experts with deep sectorial knowledge.

- **Expertise** – amongst regulators there is, in general, a lack of knowledge of technologies, applications, and usage of consumer products. Relevant knowledge is mostly held by producers of consumer products and the networks of academic scientists with which they engage, rather than more widely within academia. Regulators need to design governance policies that recognise this.

- **Management of Conflicts of Interest** – access to relevant and eminent expertise is a critical pre-condition for high quality scientific assessments, particularly when considering consumer safety. Conflict of Interest policies adopted by parts of the European Commission increasingly exclude from assessments scientists with links to industry. Such policies focus primarily on material conflicts, often distant and historic, rather than considering all potential conflicts, including values and political beliefs.

- **Evidence and New Approach Methodologies (NAMs)** – it is in the public interest to ensure that scientific assessments that support consumer safety decisions are based solely on the highest quality and most up-to-date evidence. To achieve this, scientific committees and regulators need to encourage greater use, without prejudice, of scientific evidence generated using New Approach Methodologies (NAMs), as well as adopting formal principles and guidelines for scientific integrity.

- **Clarity of Regulatory Benefit** – clarity of benefit, specifically consumer safety, is essential if the EU is to continue to enjoy a high standard of protection. In contrast, the pursuit of multiple objectives, such as ‘essentiality’, dilutes the purpose of interventions, makes implementation difficult, triggers unpredictable trade-offs, increases administrative discretion, creates regulatory unpredictability, and undermines levels of consumer safety.

2.2. Governance and Scientific Assessments

Governance of scientific assessments plays a major role in ensuring that regulation of consumer safety is of high quality. It encompasses: (1) political and legal commitments; (2) institutional architecture (including powers, responsibilities, and processes); (3) policies; and, (4) guidance. Governance can be strengthened in a number of ways, including:

- **Awareness of the function and nature of good governance** – acknowledging the relevance of the governance of scientific assessments is critical. Governance provides a political, legal, procedural, and structural framework within which decisions are made, including assessment of the likelihood of harm and the management of mitigation measures.

- **Recognition of the benefits of good governance** – properly designed governance informs the culture and behaviours of scientific assessors and regulators, contributing to the predictability, nature, and quality of decisions. It provides the context within which high quality decisions are made. Finally, good governance strengthens trust in the overall decision-making process, enhancing transparency, legitimacy, social acceptance, and consumer confidence.

- **Communication of dedicated regulatory principles** – the statement of regulatory principles for consumer safety is the most important part of the EU governance framework. Requirements include: (1) **primary social aim is to protect the consumer**; (2) **high quality scientific advice** is the justification for State action; (3) **independent experts** provide advice, using excellent, impartial, and transparent processes, and based on the best available scientific evidence, regardless of provenance; (4) assessments are based on the **likelihood of harm**, focusing on real world exposures, and meet the highest standards of excellence, impartiality, and transparency; (5) scientific assessments are undertaken by formally organised **groups of independent experts with deep relevant knowledge** of applications, usage, sectors, and technologies; and, (6) scientific assessment bodies are institutionally independent of regulators and EU Member States;

2.3. Independent Scientific Committees and Consumer Safety

At EU-level, a number of different structural models are used to provide scientific assessments. The most important are: (a) assessments by Member States overseen or endorsed by a Technical Working Group or Scientific Committee of experts drawn from Member States; and, (b) independent scientific committees.

Research undertaken by ERIF has examined the effectiveness of the EU's model of independent scientific committees, as well as highlighting strengths and potential threats:

- **Effective regulation of consumer safety** – at EU-level, the current regulatory framework for managing consumer safety, set out in well-designed legislation, implemented through scientific assessments provided by independent scientific committees and focused on the likelihood of harm, works well.

- **EU good practices for governance of scientific assessments** – the success of the EU's regulatory framework for consumer safety is the result, in part, of the high-quality governance framework that has been established for the independent scientific committees, supported by DG SANTE, that undertake assessments of consumer safety. The EU's independent scientific committees, and governance framework, are an example of a world-leading good practice.

- **High quality scientific assessments** – scientific assessments developed by the independent committees are almost always of the highest quality. This is due to a number of reasons. All actions of the committees are guided by the principle of excellence. Committees are independent. A further aspect of the concept of independence is the degree of flexibility enjoyed by the scientific committees. Processes used to select committee members, manage conflicts of interest and undertake assessments of evidence are transparent ensuring that opinions are perceived to be impartial.

- **Scientific integrity and decision-making culture** – over time, members of committees have also developed a culture of 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. This includes an increasing willingness to accept evidence generated through New Approach Methodologies (NAMs).

- **Threats to independent scientific committee model** – this is a model for the implementation of risk management laws that works well. There is no evidence of significant failure or inadequacy. However, the independent scientific committee model used by the European Commission faces a number of threats: first, threats to the effective operation of the current model because of the progressive loss of expertise and difficulties in gaining access to the best available evidence; and second the threat to the continued existence of the model because of proposals to restructure the provision of scientific assessments at EU-level and basing future regulatory interventions on intrinsic properties rather than the likelihood of harm.

2.4. Independent Scientific Committees – Governance Threats and Opportunities

As part of the EU's Green Deal, proposals have been developed for restructuring the governance of scientific assessments. Ideas include (1) greater emphasis on using intrinsic properties, rather than likelihood of harm, to legitimate regulatory interventions, and (2) the absorption of the responsibilities of the independent scientific committees into other EU bodies organised on the basis of Technical Working Groups.

Both of these ideas, if implemented, may pose serious threats to good governance of scientific assessments for consumer safety and to the protection of citizens. At the same time, however, a review of governance could provide an opportunity to strengthen, rather than weaken, the effectiveness of independent scientific committees.

2.4.1. Governance Threats

- **Weaknesses of Technical Working Groups** – if the proposals are implemented then the responsibilities of the independent scientific committees may be taken over by existing Technical Working Groups (TWGs), possibly within an existing EU agency. There are number of major problems with the effectiveness of the TWG model. These include: inadequate expertise; focus on compliance with procedure rather than science; pursuit of national political goals; lack of relevant and up-to-date scientific knowledge; and inappropriate application of the Precautionary Principle in scientific assessments.

  Moving the responsibilities of the independent committees would put at risk, unless carefully managed, a model for carrying out scientific assessments that is highly successful. A culture focused on expertise, exposures, and mitigation of the likelihood of harm would be threatened, without any obvious compensating benefits for consumer safety. Advances in the adoption of the most up-to-date scientific evidence would also be placed at risk, weakening the protection of consumer safety.

- **Inadequacies of using intrinsic properties for consumer safety** – greater use of intrinsic properties as the principal regulatory philosophy for managing harms is frequently justified because it will, according to supporters, speed up decision-making

and protect the public, leading, in turn, to the replacement of 'unsafe' materials with 'safe' ones. These arguments are controversial and are not robust.

Intrinsic properties alone do not provide an appropriate basis for ensuring consumer protection and the safe enjoyment of benefits. Evidence of the properties of materials, without knowledge of the likelihood of harm when in use, is insufficient to design the specific actions need to ensure consumer safety. In most cases, it is too far removed from everyday life. To design effective interventions that deliver consumer safety, scientific assessments need to be based on an understanding of dose-response relationships, usage, and exposures. Without this, interventions risk triggering unintended trade-offs that increase net harms or a loss of safe enjoyment of benefits.

Use of intrinsic properties to legitimate and shape harm mitigation measures poses a number of additional problems. First, it does not provide the information needed to transparently assess trade-offs or risk-benefit issues. Second, it fails to provide the information needed to legitimate the use of the powers of the State.

2.4.2. Governance Opportunities

- **The merits of a new EU agency** – rather than dispersing the responsibilities of the existing committees, a better approach, and one that would be in the public interest and protect consumer safety, could be to create a new agency focused on non-food consumer safety. This could contain and support the independent scientific committees, as well as providing an institutional architecture that could be used to provide an implementing mechanism for a wide range of 'vertical' product safety legislation, as well as laws regulating the use of detergents and cosmetics. It would be a model of good practice, focusing on products that are essential to the quality of life of Europeans.

- **The importance of regulatory principles for consumer safety** – instead of seeking to base regulatory interventions on intrinsic properties, the review of governance should be used to establish a clear statement of the regulatory principles for consumer safety, building on the successful model established in the late 1990s and confirmed in 2015[1]. This statement should include, amongst other requirements, a commitment to focus on consumer safety as the social objective of interventions and likelihood of harm as the principal regulatory approach.

3. Conclusions

Consumer safety depends upon assessments of the likelihood of harm carried out by relevant, eminent experts and based on an understanding of exposures derived from the best and most up-to-date scientific evidence. Science and expertise, regardless of provenance, protects citizens and ensures safe enjoyment of benefits.

The present EU-level governance of consumer safety is highly effective. It ensures that legislative objectives are delivered, protects consumers, facilitates safe enjoyment of benefits, and helps prevent regulatory failure.

[1] See Commission Decision 97/579/EC *'Setting up Scientific Committees in the field of consumer health and food safety'* (1997), and subsequent Decisions in 2004, 2008, and 2015.

There is no evidence that the existing approach based on independent scientific committees is failing or needs to be restructured. It continues to deliver high quality harm mitigation measures that are trusted, effective, and predictable.

Looking to the future, the existing model of independent scientific committees can be improved in two critical areas: access to expertise and to the availability and utilisation of the most advanced science in scientific assessments. However, the greatest threat to the future effectiveness of consumer safety regulation in the EU comes from the risk posed by inappropriate reforms of governance of scientific assessments.

Instead, the review being undertaken by the European Commission provides an opportunity to strengthen the use and governance of the independent scientific committees, and the high quality opinions they produce, through the **creation of new, dedicated agency**.

At the same time and as part of the review of governance, the European Commission should take the opportunity to issue **a formal statement of the regulatory principles that guide regulation of consumer safety**. It should, for example, emphasise the importance of basing decisions on likelihood of harm rather than intrinsic properties of materials. It should also establish consumer safety as the sole purpose of regulatory interventions.

4. Recommendations

4.1. Overall Structure of Governance

- The **EU Legislator** should establish a **new non-food consumer safety agency**. This will support the existing independent scientific committees and provide, initially, the implementation mechanisms for legislation regulating cosmetics and detergents.

- The **European Commission** should set out, for instance in a new Decision, the **regulatory principles for consumer safety**. This is a fundamental part of the governance framework. It should emphasise, for example, consumer safety as the primary goal of interventions and require decisions to be based on likelihood of harm.

- The **European Commission** should fully apply Better Regulation mechanisms, tools, and processes, when assessing any proposed changes in the governance of scientific assessments for consumer safety.

4.2. Governance and Effectiveness of Existing Scientific Committees

- The **European Commission** should set out, for instance in a new Decision, the key principles for the selection of experts and the operation of scientific committees.

- The **European Commission** should develop and enforce uniform guidelines for the selection of experts and functioning of committees.

- The **independent scientific committees** should jointly draw up substantive guidance designed to encourage the submission of scientific knowledge derived from New Approach Methodologies (NAMs). They should commit to utilising such knowledge whenever NAMs prove to deliver more accurate and reliable evidence.

1. BACKGROUND

1.1. Ensuring Consumer Safety – Restructuring Governance

When managing consumer safety the primary aim of governments is to ensure that products are safe for their intended use. This is best achieved when regulation of consumer safety is predictable and based on the likelihood of harm. In turn, this facilitates safe use of technologies, stimulates investment in new sustainable products, limits arbitrary implementation by governments, and allows consumers to enjoy valued functional and emotional benefits. It also contributes to consumer confidence and engenders public trust. These are core objectives of the EU's Better Regulation Agenda.

Achieving these goals is difficult. Regulators often lack deep knowledge of technologies, applications, and consumer usage: these are areas of applied science where knowledge is held within market participants and the academic networks with whom they engage. Regulators need to gain access to this knowledge whilst, at the same time, ensuring that scientific assessment processes are impartial.

Indeed, avoiding regulatory failure is one of the greatest challenges facing regulators in this risk domain. Decisions based solely on intrinsic properties (hazards) or on incomplete understanding of usage and exposure may trigger risk-risk trade-offs, reductions in consumer welfare, reductions in safety, and less investment in new 'greener' technologies.

To overcome these problems and the risk of failure, regulators throughout the OECD seek to base interventions on high quality scientific assessments of the likelihood of harm, derived from the best available science and an expert understanding of exposures, technologies, and applications. Since the late 1990s, such assessments for consumer health and food safety have been provided to EU regulators by a network of independent scientific committees, some of which are supported by the European Commission's DG SANTE whilst others fall within the European Food Safety Authority (EFSA). All are required to provide advice on the basis of the principles of excellence, independence, and transparency[2].

Scientific assessments provided by the Commission's independent scientific committees form part of the wider process by which EU-level risk management legislation is implemented. It is a model of good practice for the implementation of complex sector-specific risk management laws.

New initiatives proposed by the Commission seek, however, to restructure parts of the governance of the provision of scientific assessments for consumer safety. Possible changes include absorbing the responsibilities of existing independent scientific committees into other existing bodies and placing greater emphasis on the intrinsic properties of materials, rather than likelihood of harm, as the major regulatory philosophy for managing consumer safety[3].

Such proposals provide an opportunity to reconsider the challenges facing the future effectiveness of the current independent scientific committees and to examine ways of building on this highly successful approach.

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[2] See Commission Decision 97/579/EC *'Setting up Scientific Committees in the field of consumer health and food safety'* (1997), and subsequent Decisions in 2004, 2008, and 2015.

[3] Many of these ideas are set out, conceptually, in the European Commission '*Chemicals Strategy for Sustainability: Towards a Toxic-Free Environment*', COM (2020) 667 final.

1.2. Purpose and Structure of ERIF Monograph

As part of a wider, long-term focus on scientific integrity, scientific evidence in decision-making, and better regulation, the European Regulation and Innovation Forum (ERIF) is committed to making a positive contribution to the evolution of the EU's approach to ensuring consumer safety.

This monograph reflects extensive work undertaken by ERIF, including major publications that highlight the importance of science-based decision-making[4]; the importance of the EU's Administrative State[5]; the development of new policies for ensuring access to expertise[6]; and a new framework of policies and guidance for scientific integrity[7]. It is also informed by a literature review and by the insights of panellists and participants at a major on-line workshop held by ERIF in November 2021 focusing on *'Scientific Excellence in Consumer Safety'*.

Held under The Chatham House Rule, the workshop focused on ensuring scientific excellence and impartiality, considering two perspectives: scientists who undertake scientific assessments of likelihood of harm (risk assessments) and who strive to deliver high quality opinions; and, second, the framework of governance that fosters such outcomes. Two distinguished panels addressed these issues, focusing on scientific as well as institutional issues.

More than 100 invited guests, including distinguished scientists, senior officials from the EU institutions and Member States, experts from academia, think tanks, and the business community joined the workshop and participated in the wide-ranging discussions.

Specifically, the workshop set out to:

- Identify the main challenges facing scientific committees when they seek to deliver high quality assessments of the likelihood of harm posed by the intended use of consumer products;
- Consider the reasons why interventions to protect consumer safety are required to be based, in general, on likelihood of harm rather than intrinsic properties of materials;
- Establish the most important regulatory principles and philosophies that frame the context of governance of scientific assessments for consumer safety;
- Assess the characteristics of the institutional architecture, including powers, responsibilities, and formal processes, that support high quality scientific assessments; and,
- Examine the strengths and weaknesses of the existing model of independent scientific committees.

Participants addressed all of these issues. The workshop programme is attached as Appendix A.

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[4] ERF Monograph *'Scientific Evidence and the Management of Risk'* (2016).

[5] ERF Monograph *'Risk Management and the EU's Administrative State: Implementing Law through Science, Regulation and Guidance'* (2019).

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

[7] ERIF Communication 20 *'Principles and Guidelines for Scientific Integrity in Regulatory Studies'* (2021).

This ERIF Monograph is informed by the presentations, reflections, and discussions that took place at the workshop[8], as well as drawing on extensive, earlier research by ERIF on the role and governance of scientific assessments. The resulting insights are grouped together into five themes:

- Regulation of consumer safety (section 2.1.)
- Scientific integrity (2.2.)
- Governance of scientific assessments (2.3.)
- Independent scientific committees (2.4.)
- Restructuring of governance of provision of scientific assessments (2.5.)

2. ENSURING CONSUMER SAFETY IN THE EU

2.1. Regulation of Consumer Safety

A number of important factors affect the regulation of Consumer Safety at EU-level, including:

- Defining and understanding safety (section 2.1.1.)
- Delivering additional net benefits to citizens (2.1.2.)
- Basing interventions on high quality, credible evidence (2.1.3.)
- Gaining access to the best evidence and expertise (2.1.4.)
- Harnessing the resources and knowledge of leading producers (2.1.5.)
- Recognising the problems created by multiple regulatory objectives (2.1.6.)
- Protecting the quality and integrity of regulatory science (2.1.7.)

2.1.1. Defining and Understanding Safety

'Safety' can be defined as the degree to which a temporary disturbance or injury or persistent or permanent disturbance or injury are controlled, avoided, prevented, made less frequent or less probable in a **particular subset or grouping**. It is difficult, therefore, to legislate for the safety of entire populations. Interventions benefit some but not all, leading to the need for regulators to understand trade-offs.

Only scientific assessments based on an understanding of exposures and the likelihood of harm can facilitate the process of making choices between sub-groups and potential harms. Moreover, ethical considerations require these choices, which are essentially political, to be informed by the best available evidence.

2.1.2. Delivering Additional Net Benefits to Citizens

Most societies in the OECD area are well-protected against potential harms posed by the production and use of consumer products. Complex and extensive regulatory frameworks, supported by science-based implementation mechanisms, work well. **In this mature regulatory context, new interventions frequently seek to achieve very small, often marginal, improvements in safety, whilst potentially triggering behavioural changes including risk transfers and other forms of risk-risk outcomes that increase overall likelihood of harm.** Indeed, there is the possibility of regulatory failure.

[8] This ERIF Monograph is not a record of the workshop, nor does it reflect the contribution made by any specific panellist or guest. It is a contribution by ERIF to on-going debates about the future governance at EU-level of scientific assessments for consumer safety.

In the light of this, it is essential to ensure that regulatory actions deliver improvements in the ultimate measures of human health (notably mortality and morbidity) or the environment, and that these benefits justify costs. To achieve this, measures should be based on high quality evidence and expert scientific assessments that ensure a full understanding of the likelihood of harm, and hence the potential benefits from reducing exposures.

Regulators need to establish not only a clear understanding of the potential benefit to be examined but also the likely causes of harm and useful indicators of success. Outcome measures are an essential part of the policy cycle, enabling regulators to review assumptions, to establish whether interventions have been successful, and to justify the use of the powers of the State. They also provide a framework within which laws or implementation decisions can be revised as scientific knowledge advances.

2.1.3. Basing Interventions on High Quality, Credible Evidence

Proposed interventions at EU-level to improve consumer safety are, on too many occasions, justified on the basis of low-quality studies, old methodologies, or out-of-date knowledge about issues such as the causes of cancer. Too many academic studies used by regulators fail to meet accepted standards of scientific integrity, for example. In turn, low quality science amplifies social concerns and the perception of potential harm. This tends to be a more prominent phenomenon in affluent societies.

These are clearly visible weaknesses in the intervention logic used to legitimate risk management measures. They can be dealt with through the adoption by the EU institutions of high-quality principles and guidelines for scientific integrity. Properly applied, such guidelines allow scientific committees to analyse transparently the quality and relevance of evidence, helping regulators reassure citizens.

Moreover, **interventions should be justified on the basis of scientific assessments that focus on identifying likelihood of harm, based on the best available scientific evidence of exposures, and derived from processes undertaken by eminent and relevant experts with deep sectorial knowledge.** Expertise, along with scientific evidence and toxicological methodologies, should be up-to-date.

2.1.4. Gaining Access to the Best Evidence and Expertise

Whilst many regulators possess high levels of expertise, in general they lack cutting-edge knowledge of technologies, applications, and usage of consumer products. These are complex issues and need to be understood fully, if exposures are to be properly identified, the likelihood of harm characterised, and effective mitigation measures designed. Regulators also often have a limited understanding of consumers and their behaviours, market participants, and value chains, and of likely responses to regulatory interventions. All of these factors make it difficult to design high quality interventions and thus create a significant risk of regulatory failure, unless regulators can gain access to the best evidence and expertise.

It is important to recognise that relevant knowledge needed to ensure consumer safety is mostly held by producers of consumer products and the networks of academic scientists with which they engage, rather than more widely within academia. Regulators need to design governance policies that recognise this. This is in the public interest. For example, assessments of studies should focus on the quality and relevance of evidence rather than its provenance; selection of scientific experts for committees should make use of modern understandings of bias, and of the conflicts of interest that cause it, thereby ensuring access to

the most eminent and relevant experts; and, consultation processes should engage extensively with producers, their value chains, and their academic partners.

2.1.5. Harnessing the resources and knowledge of leading producers

When assessing the likelihood of harm and considering mitigation measures, it is important for regulators to recognise the extensive investments made by leading companies in product safety. In most instances, internal standards set by leading companies exceed those required by regulators. Such assessments may also make use of more advanced forms of scientific evidence and means of assessing harms than those specified by legislation or required by regulatory bodies.

Safety is the single most important pre-condition for investment by producers of consumer products and is the basis of brand equity. Indeed, investments in safety protect brand equity and reputation, the primary intangible assets of most leading market participants.

Whilst it will remain important to ensure transparency and to manage potential conflicts of interest, a challenge for regulators is to amplify the influence of these powerful market-based factors, so as to further improve protection, whilst also gaining access to advanced safety knowledge developed and used by market participants. Such knowledge is a vital resource. Regulators need to design governance mechanisms that ensure access to it.

2.1.6. Recognising the Problems Created by Multiple Regulatory Objectives

An emerging challenge for the effective regulation of consumer safety is the increased adoption, by EU decision-makers, of multiple objectives for legislative and regulatory interventions[9]. These include concepts such as ‘essentiality’, ‘sustainability’, or ‘do no harm’. Most are, however, untested, ill-defined, and controversial, and may be incompatible with ensuring consumer safety[10].

Clarity of benefit, specifically consumer safety, is essential if the EU is to continue to enjoy a high standard of protection. In contrast, the pursuit of multiple objectives dilutes the purpose of interventions, makes implementation difficult, triggers additional and unpredictable trade-offs, increases administrative discretion, creates regulatory unpredictability, and undermines levels of consumer safety.

2.1.7. Protecting the Quality and Integrity of Regulatory Science

Good scientific assessments and regulatory science take time. It is in the public interest that regulators recognise, accept, and support this.

High quality regulation of consumer safety delivers protection from harms, ensures safe enjoyment of benefits, and strengthens the framework conditions for investment in choice, new ideas, and sustainability. It facilitates consumer confidence and, because implementation decisions are based on science, expertise and the likelihood of harm, creates regulatory predictability.

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[9] For example, European Commission, *‘Chemicals Strategy for Sustainability. Towards a Toxic-Free Environment’,* COM(2020) 667 final.

[10] ERIF Highlights Note 16 *‘“Essentiality”, Better Regulation, and Management of Risk from Technologies’* (2021).

2.2. Scientific Integrity

Scientific integrity has four distinct and inter-locking dimensions: (1) the quality of scientific studies that underpin opinions; (2) the assessment of studies and the drawing up of scientific opinions; (3) communication of assessments to risk managers; and (4) the expertise of the scientists undertaking assessments, focusing on eminence, excellence, and relevance[11].

Ensuring scientific integrity when undertaking scientific assessments to support consumer safety interventions is challenging. Specific problems include:

- Access to the expertise (section 2.2.1.)
- Access to evidence (2.2.2.)
- Use of good practices in scientific assessments (2.2.3.)

2.2.1. Access to Expertise

Access to relevant and eminent expertise is a critical pre-condition for high quality scientific assessments, particularly when considering consumer safety. Understanding exposures and the complex technologies used in consumer products requires scientists with deep sectorial knowledge to undertake scientific assessments. Much of this knowledge is held within producing companies and the networks of academic scientists with which they engage. It is in the public interest to ensure that scientific assessments are fully informed by this knowledge and expertise.

Conflict of Interest policies adopted by parts of the European Commission increasingly exclude from assessments scientists with links to industry. Such policies focus primarily on material conflicts, often distant and historic, rather than considering all potential conflicts, including loss of impartiality as a result of the influence of values or political beliefs. This approach is partial, narrow, and out-of-date. It contributes to potential regulatory failure. It fails to recognise how knowledge is produced or the influence of non-financial conflicts that may lead to predetermination. It facilitates, moreover, the involvement of less eminent participants who may lack deep sectorial knowledge because they do not work with producing companies, whilst also failing to exclude activist scientists whose views may be predetermined[12]. **Lower quality scientific assessments contribute to the loss of safe enjoyment of benefits whilst, at the same time, eroding consumer safety.**

New Conflict of Interest policies should be adopted for all scientific committees providing assessments that underpin legislation and its implementation. Reflecting the advice of the European Commission's Scientific Advice Mechanism, these policies should be based on the most modern understanding of bias and of the wide range of conflicts of interest, financial and non-financial, that cause it[13]. They should ensure that the primary criterion for the selection of scientific experts is eminence and relevance. All sources of potential conflicts

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[11] Berry Sir Colin 'Frameworks for evaluation and integration of data in regulatory evaluations: The need for excellence in regulatory toxicology', *Toxicology Research and Application*, Volume 4 (2020). The principles and guidelines set out in this peer-reviewed article are also included in ERF Communication 20 *'Principles and Guidelines for Scientific Integrity in Regulatory Studies'* (2021).

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

[13] European Commission *'Scientific Advice to European Policy in a Complex World'*. Scientific Opinion No. 7 by the Group of Scientific Advisers (2019) - the opinion also highlighted the importance of developing horizontal principles and guidelines for scientific integrity at EU-level.

should be disclosed; scientists should be required to make public declarations of their commitment to work in the public interest, recognising their ethical responsibilities; and, wherever possible, potential conflicts should be managed rather than simply excluding eminent experts.

To complement the emphasis on excellence in the selection of scientific advisers, it is essential to ensure that the processes of selection of advisers, assessment of studies, and reporting of opinions are highly transparent. This ensures that opinions are both excellent and impartial thereby reducing the risk of regulatory failure, building trust, and strengthening legitimacy.

2.2.2. Access to Evidence

In too many cases, low quality studies, out-of-date methods, and old, often discredited, studies trigger regulatory proposals and social concern. In general, proposals based on these forms of evidence fail to enhance consumer safety, lead to a loss of the safe enjoyment of benefits, and, in some cases, trigger risk-risk outcomes whereby overall likelihood of harm increases.

In contrast, **it is in the public interest to ensure that scientific assessments that support consumer safety decisions are based solely in the highest quality and most up-to-date evidence.**

To meet this challenge, two changes are needed:

- **The European Commission should adopt written standards for the quality and relevance of studies, supported by transparent processes for assessing them**; and,

- **Scientific committees and regulators need to encourage greater use, without prejudice, of scientific evidence generated using New Approach Methodologies (NAMs).**

In place of the animal testing methods developed over 50 years ago, academics, supported by governments and the corporate sector, have developed new, human-focused ways of understanding mechanisms of toxicity. NAMs focus on the mechanisms that lead to end points, making use, for example, of major scientific advances in bio-medical science. In turn, these more precise and relevant tools are being used to better understand exposures and the likelihood of harm. **NAMs enable protective measures to be better targeted, more accurate, and more effective. Indeed, they are used by some leading companies to assess safety, rather than the findings of traditional animal studies, prior to placing new or improved products on the market.**

Despite these advances, **regulatory requirements at EU-level often constrain of effectively inhibit the use of evidence generated by NAMs. Regulators also often lack the expertise to interpret it without drawing over-precautionary conclusions.** Instead, regulators continue to require animal-based evidence: a conservative policy that prevents scientific assessments being based on the best available science. In contrast, regulators in other parts of the OECD area, most notably the USA, have begun to engage more extensively with the scientific evidence generated by NAMs[14].

[14] See for example, US National Academy of Science *'Toxicity Testing for the 21st Century: A Vision and a Strategy. A report by the National Research Council'*, (2007).

Scientific assessments that inform consumer safety interventions should be based on the best and most up-to-date scientific evidence. Where appropriate, and with expert interpretation, this should increasingly involve making use of evidence generated by NAMs. In some instances progress has begun to be made, particularly when market participants, who have invested in and make use of NAMs, are able to engage with expert scientific assessors on a peer-to-peer basis. This process should be supported, widened and made more systemic. It should not be undermined by proposed changes to the governance of the EU's system of scientific assessment.

2.2.3. Use of Good Practices in Scientific Assessments

Good practices, such as those set out in the 2013 and 2016 Rules of Procedure for the Commission's independent scientific committees, suggest that **assessments of scientific studies should be based on a quantified and transparent methodology that weights individual studies on the basis of quality and relevance[15].** This allows all evidence to be assessed hence meeting legislative requirements whilst also ensuring that low quality or out-of-date science plays little part in informing assessments. It is also consistent with the scientific method.

When designing measures to strengthen the protection of consumers, scientific assessments should, wherever relevant, undertake risk-benefit analyses. These enable regulators to understand complex trade-offs, particularly in areas such as food and beverages, and cleaning products. An intended consequence of most consumer safety legislation is that interventions should ensure safe enjoyment of benefits.

2.3. Governance of Scientific Assessments

Good governance frameworks of scientific assessments have four distinct and mutually supporting characteristics. First, there are clear political, legal, and other binding commitments. Second, there is a formal institutional architecture that guides the decision-making process. This encompasses powers, responsibilities, and formal processes. Third, there are detailed policies that set out how critical processes will be carried out. Finally, there are principles and guidelines for scientific integrity, covering study quality, assessment of evidence, communication to regulators, and selection of experts.

When considering the governance of scientific assessments for consumer safety, there are a number of important issues. These include:

- Importance and role of governance (section 2.3.1.)
- Regulatory Principles – EU Governance of Consumer Safety (2.3.2.)
- Institutional Architecture – Good Practices (2.3.3.)
- Policies – Good Practices (2.3.4.)

2.3.1. Importance and Role of Governance

Governance of scientific assessments plays a major role in ensuring that regulation of consumer safety is of high quality. It provides **a political, legal, procedural, and structural framework within which decisions are made**, including assessment of the likelihood of harm and the management of mitigation measures. **Governance informs the culture and**

[15] European Commission *'Rules of Procedure of the Scientific Committees on Consumer Safety, Health and Environmental Risks, and Emerging and Newly Identified Health Risks'* (2013, and up-date in 2016).

behaviours of scientific assessors and regulators, contributing to the predictability, nature, and quality of decisions. It provides the context within which high quality decisions are made.

Finally, **good governance strengthens trust** in the overall decision-making process, enhancing **transparency**, legitimacy, and social acceptance. In turn, this facilitates consumer confidence.

A series of food safety crises in the late 1990s accelerated trends towards better governance of scientific assessments. In response, OECD governments separated institutionally processes for assessing the likelihood of harms (risk assessment) from those designed to develop mitigation measures (risk management); greater transparency was introduced; and independent agencies and scientific committees were set up. At EU-level, these reforms also included clear restrictions on the application of the Precautionary Principle. This is, the EU recognises, a measure for managing risk and should play no part in assessment of likelihood of harms (risk assessment).

2.3.2. Regulatory Principles – EU Governance of Consumer Safety

At EU-level, a high-quality governance framework has been established for the independent scientific committees supported by DG SANTE. This provides a clear model of good practice. The framework is derived from legislation, Commission Decisions, and Rules of Procedure. The regulatory principles for consumer safety are the most important part of the framework. These are set out in political, legal and other binding commitments. These principles guide and structure the processes of scientific assessment and mitigation measures.

Specifically, the EU-level principles require the following:

- Primary social aim is to **protect the consumer**;
- **High quality scientific advice** is the foundation of and justification for State action;
- **Independent experts** provide advice, using excellent, impartial, and transparent processes, and based on the best available scientific evidence, regardless of provenance;
- Assessments are based on the **likelihood of harm**, focusing on real world exposures, and meet the highest standards of excellence, impartiality, and transparency;
- Scientific assessments are undertaken by **formally organised groups of independent experts with deep relevant knowledge** of applications, usage, sectors, and technologies;
- Scientific opinions are based solely on scientific evidence: there are no other influences;
- Scientific assessment bodies are institutionally independent of regulators and EU Member States; and,
- Scientific experts collaborate with global and other EU bodies.

2.3.3. Institutional Architecture – Good Practices

Evidence from good practices within the EU institutions and in the OECD area suggests that **scientific committees should have significant powers to act flexibly and independently of regulators[16].** Good practices include powers to gain access to experts; set up working

[16] See for example, ERF Monograph *'Scientific Evidence and the Management of Risk'* (2016) and ERIF Highlights Note 17 *'Consumer Safety'* (2021).

groups; investigate potential future harms; use evidence from new ways of understanding safety and likelihood of harm; establish consultation processes; and, set rules of procedure. Assessors should also be involved, where appropriate, in the formulation of mandates from regulators, and should have the flexibility to identify other relevant unanswered questions.

Governance is also strengthened by the inclusion, within the institutional architecture, of a small number of critical processes. These include:

- **Peer review of significant opinions**;
- **Procedural rights for structured reassessment of findings of opinions**; and,
- **Administrative appeals procedures**.

The European Medicines Agency (EMA) has made an important contribution to the development of good governance practices. These include a clear focus on patient safety and the safe enjoyment of benefits; understanding of benefit-risk trade-offs; access to experts, regardless of affiliation; peer review of opinions; formal processes for the reassessment of opinions; and the use of Better Regulation principles to structure the development of substantive guidance.

It is important, however, to place the contributions of EMA in context. They reflect, in part, the highly salient role of the agency is ensuring that all of the EU's citizens have access to the benefits of safe medicines, and in matching or exceeding global standards of regulation of human and veterinary medicines set by the US FDA (a body that is significantly older than EMA).

In view of this, care needs to be taken in making comparisons between the EMA, a body based on Technical Working Groups of Member State experts, and the potential for governance reforms in other, similar bodies.

2.3.4. Policies – Good Practices

Membership of scientific committees should be based solely on excellence and relevance. Transparent processes should be used to select members. Formal commitments to act in the public interest must be made by all members and conflicts of interest, including non-financial conflicts, should be clearly identified and, wherever possible, managed.

There should also be clear policies for identifying and gaining access to additional expert knowledge, regardless of provenance.

2.4. Independent Scientific Committees

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 experts drawn from Member States – EMA and ECHA use this approach for example; and independent scientific committees controlled by specific Commission DGs and EFSA[17].

[17] The different models used at EU-level to develop scientific assessments as a basis 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).

A review by ERIF of the model of independent scientific committees used by the European Commission highlighted a number of issues. These include:

- Effectiveness of the independent scientific committee model (section 2.4.1.)
- Reasons for success (2.4.2.)
- Challenges (2.4.3.)

2.4.1. Effectiveness of the Independent Scientific Committee Model

The current regulatory framework for managing consumer safety, set out in well-designed legislation, implemented through scientific assessments provided by independent scientific committees and focused on the likelihood of harm, works well. Consumers enjoy a high standard of protection; citizens trust regulators, bolstering consumer confidence; and a predictable, evidence-based regulatory framework creates incentives for investment in new ideas, choice, and sustainability.

The EU's independent scientific committees are an example of a world-leading good practice for the governance and provision of scientific assessments.

Indeed, **scientific assessments developed by the independent committees are almost always of the highest quality.** Assessments are undertaken by scientists with relevant expertise and are based on likelihood of harm derived from real world evidence of exposures. 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. Where appropriate, 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.

2.4.2. Reasons for Success

The success of the independent committee model rests on a number of factors, including formal commitments to independence, transparency, and excellence set out in the Commission Decisions that provide the authority for their actions[18].

All actions of the committees are 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. As a result, 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.

Committees are independent. Committee members are selected from open application processes and are not nominated by Member States. There is institutional separation of scientific assessment of likelihood of harm and the development of mitigation measures. Assessment processes are designed to ensure impartiality.

A further aspect of the concept of independence is the degree of flexibility enjoyed by the scientific committees. For example, committee members have the institutional

[18] See Commission Decision 97/579/EC *'Setting up Scientific Committees in the field of consumer health and food safety'* (1997), and subsequent Decisions in 2004, 2008, and 2015.

independence to identify emerging issues (including potential harms), new assessment models, divergences from decisions by scientific assessment bodies in other parts of the world or the EU, and scientific advances in understanding the impact of technologies on consumers. Committees also have the authority to seek out experts, set up expert working groups and workshops, engage with stakeholders, identify and review emerging harms, and to assess new ways of understanding consumer exposures or carrying out risk assessments.

Moreover, **processes used to select committee members, manage conflicts of interest and undertake assessments of evidence are transparent ensuring that opinions are perceived to be impartial.**

Over time, members of committees have also **developed a culture of 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. This includes an increasing willingness to accept evidence generated through New Approach Methodologies (NAMs).

2.4.3. Challenges

Over time, the independent scientific committees have built a reputation globally for the quality of their scientific assessments, helping to build trust and market confidence and to deliver a high standard of consumer safety. They also provide 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.

However, **the independent scientific committee model used by the European Commission faces a number of threats.**

These threats are of two types:

- First, threats to the effective operation of the current model because of the progressive loss of expertise and difficulties in gaining access to the best available evidence; and,

- Second, threats to the continued existence of the model because of proposals to restructure the provision of scientific assessments at EU-level and basing future regulatory interventions on intrinsic properties rather than likelihood of harm. (These threats are considered in Section 2.5.)

Expertise is critical to the effectiveness of the independent scientific committee model. It must be relevant to the sector, application, technologies, and usage. Increasingly, the availability of suitably qualified experts is diminishing due to Conflict of Interest policies used by parts of the European Commission that exclude scientists with links to the commercial economy, and the impact of 'ad hominem' attacks on scientists who participate in the regulatory process.

Without access to the best, most relevant expertise the quality of scientific assessments may fall, posing threats to consumer safety and reducing the safe enjoyment of benefits. Action is needed by the European Commission to reverse this process, including challenging criticisms

against individual scientific advisers and recognising how knowledge is produced in modern economies.

Regulatory requirements and substantive guidance at EU-level continue to inhibit the use scientific evidence generated by NAMs, and too many regulators lack the expertise to interpret it appropriately. This needs to change, if scientific committees are to gain access to the best available science, thereby continuing to ensure that assessments are of the highest quality. Action is needed to encourage the use of such evidence and to support continued development of its application and potential.

2.5. Restructuring of Governance of Provision of Scientific Assessments

As part of the EU's Green Deal, proposals have been developed for restructuring the governance of scientific assessments. Ideas include greater emphasis on using intrinsic properties, rather than likelihood of harm, to legitimate regulatory interventions, and the absorption of the responsibilities of the independent scientific committees into other EU bodies organised on the basis of Technical Working Groups.

A review of these ideas identified a number of issues. These include:

- Rationale for Restructuring of Governance (section 2.5.1.)
- Potential Problems – Institutional Architecture (2.5.2.)
- Potential Problems – Regulatory Philosophy (2.5.3.)
- Opportunities (2.5.4)

2.5.1. Rationale for Restructuring of Governance

Two arguments have been used to justify restructuring the governance of the EU's independent scientific committees:

- First, the need to reduce administrative costs by absorbing the functions of the independent committees into other scientific assessment bodies;

- Second, the importance, for the protection of citizens, of speeding up the process of assessing and managing harms because of the slowness of existing decision-making and the presence of unmanaged dangers to health and the environment. This will be achieved, it is argued, by basing safety assessments on intrinsic properties rather than likelihood of harm: a change in the regulatory philosophy that forms part of governance of scientific assessments for consumer safety.

Both of these arguments are disputed.

For example, in a recent academic article, senior officials of **the German Federal Institute for Risk Assessment (BfR) argued that the existing framework of EU-level regulation worked well and that there was no robust scientific evidence of harms that were not being managed.** Policy proposals were based, they concluded, on social concern rather than scientific evidence. This is a weak logic for intervention[19].

[19] 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 Toxicology, 95 (2021).

Reflecting these expert concerns, all proposed reforms of the governance of scientific assessments for consumer safety, including changes in the regulatory philosophy for the management of harms or restructuring of institutional architecture, should be subject to the extensive requirements for public consultation and impact assessment set out in the Commission's Better Regulation policies and guidance. Any impact assessment carried out should, moreover, have a particular focus on identifying evidence of potential positive and negative impacts on consumer safety, and the Regulatory Scrutiny Board should assess the findings and process rigorously.

2.5.2. Potential Problems – Institutional Architecture

The existing legislative framework, and supporting implementation mechanisms, for consumer safety work well, delivering a high standard of protection and facilitating safe enjoyment of benefits, as well as supporting incentives for investment.

The independent scientific committees form part of a mature and effective eco-system of regulation of consumer safety. They are a model of good practice for governance and outcomes. There is no evidence of failure.

If the proposals are implemented then the responsibilities of the independent scientific committees may be taken over by existing Technical Working Groups (TWGs), possibly within an EU agency. TWGs comprise scientists nominated by Member States: they are not selected from the wider scientific community on the basis of excellence and relevance.

Research by ERIF identified a number of major problems with the effectiveness of the TWG model of scientific assessments[20]. These include:

- Inadequate expertise;
- Focus on compliance with procedure rather than science;
- Pursuit of national political goals;
- Lack of relevant and up-to-date scientific knowledge;
- Process delays and lack of compliance with deadlines;
- Inappropriate application of the Precautionary Principle in scientific assessments; and,
- Inequalities of scientific knowledge between Member States.

Moving the responsibilities of the independent committees would be a major change in governance. It would put at risk, unless carefully managed, a model for carrying out scientific assessments that is highly successful. A culture focused on expertise, exposures, and mitigation of the likelihood of harm would be threatened, without any obvious compensating benefits for consumer safety. Advances in the adoption of the most up-to-date scientific evidence would also be placed at risk, weakening the capacity of the EU to ensure consumer safety.

Arguably, the weakening of governance of the scientific committees will reduce rather than strengthen consumer safety. Scientific assessments will be based on a limited understanding of applications, exposures, and usage, rather than the mature and expert approach of the existing independent scientific committees. This poses a challenge to the achievement of the objectives of the legislative framework.

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[20] ERF Monograph *'Risk management and the EU's Administrative State: Implementing Law through Science, Regulation, and Guidance'* (2019).

2.5.3. Potential Problems – Regulatory Philosophy

Greater use of intrinsic properties as the principal regulatory philosophy for managing harms is frequently justified because it will, according to supporters, speed up decision-making and protect the public, leading, in turn, to the replacement of 'unsafe' materials with 'safe' ones. **Whilst this approach has an intuitive appeal, these arguments are controversial and are not robust**[21]. It is, for example, difficult to identify robust scientific evidence of harms that are not currently managed by the existing regulatory framework or any extensive evidence of the effectiveness or net positive impact on safety of 'forced' substitution of materials across large-scale value chains.

Intrinsic properties alone do not provide an appropriate basis for ensuring consumer protection and the safe enjoyment of benefits. Evidence of the properties of materials, without knowledge of the likelihood of harm when in use, is **insufficient to design the specific actions need to ensure consumer safety**. In most cases, it is **too far removed from everyday life**. To design effective interventions that deliver consumer safety, scientific assessments need to be based on an understanding of dose-response relationships, usage, and exposures. Without this, **interventions risk triggering unintended trade-offs that increase net harms or a loss of safe enjoyment of benefits, such as the health protection properties of cleaning products. Such actions do not improve consumer safety.**

Use of intrinsic properties to legitimate and shape harm mitigation measures poses a number of additional problems. First, it **does not provide the information needed to transparently assess trade-offs between different outcomes or harms (such as choices between harms or benefits for humans or nature), or to assess risk-benefit issues.** Second, it **fails to provide the information needed to demonstrate that benefits justify costs, that safety has been improved, and hence that the powers of the State have been used effectively.** This weakens trust and legitimacy.

2.5.4. Opportunities

A review, by the European Commission, of the governance of scientific assessments for consumer products could provide an opportunity to strengthen, rather than weaken, the effectiveness of the independent scientific committees.

Rather than dispersing the responsibilities of the existing committees, a better approach, and one that would be in the public interest and protect consumer safety, could be to create a new agency focused on non-food consumer safety. This could contain and support the independent scientific committees, as well as providing an institutional architecture that could be used to provide an implementing mechanism for a wide range of 'vertical' product safety legislation, as well as laws regulating the use of detergents and cosmetics.

This new agency would be a model of good practice, focusing on products that are essential to the quality of life of Europeans. It would sit alongside the other consumer safety agencies: EFSA for food and drink, and EMA for human and veterinary medicines.

Instead of seeking to base regulatory interventions on intrinsic properties, the review of governance should also be used to establish a clear **statement of the regulatory principles for consumer safety**, building on the model established in the late 1990s and confirmed in

[21] See for example ERF Highlights Note 2 *'Hazard-based Regulation. Acknowledging the Problems'* (2015).

2015[22]. This statement should include, amongst other requirements, a commitment to focus on consumer safety as the social objective of interventions and likelihood of harm as the principal regulatory approach.

3. CONCLUSIONS

Consumer safety depends upon assessments of the likelihood of harm carried out by relevant, eminent experts and based on an understanding of exposures derived from the best and most up-to-date scientific evidence. Science and expertise, regardless of provenance, protects citizens and ensures safe enjoyment of benefits.

The present EU-level governance of consumer safety is highly effective. It ensures that legislative objectives are delivered, protects consumers, facilitates safe enjoyment of benefits, and helps prevent regulatory failure.

Since the late 1990s, citizens of the EU have enjoyed a high level of consumer safety because of series of far-reaching and innovative governance reforms, including the establishment of **independent scientific committees** combined with risk management laws that focus on the likelihood of harm rather then intrinsic properties. This is a successful model of good practice and has made the EU a world leader in the effective regulation of consumer safety. Any changes that are proposed, such as those set out in the Commission's Chemicals Sustainability Strategy, must demonstrate not only that consumer safety will be improved rather than diminished, but also that the likely marginal benefits will be significantly higher than the expected costs. This will be a challenge.

There is no evidence that the existing approach based on independent scientific committees is failing or needs to be restructured. It continues to deliver high quality harm mitigation measures that are trusted, effective, and predictable. It has also been highly successful at keeping political debates away from the process of scientific assessments, thereby strengthening perceptions of its excellence and impartiality.

Looking to the future, the existing model of independent scientific committees can be improved in two critical areas: access to expertise and to the most advanced scientific evidence.

- **Access to expertise** – wider Commission policies that stigmatise scientists for their involvement with commercial society threaten to limit access to expertise, one of the foundations on which the success of the independent scientific committees rests. Such policies are both out-of-date, paying no regard to modern understandings of conflict of interest or to how knowledge is created, and pose a threat to consumer safety.

  A new policy approach is needed, reflecting the recommendations made to the Commission by the Group of Chief Scientific Advisers in 2019. If adopted, this new approach recognises the importance of expertise, regardless of its provenance, and seeks to ensure that all forms of conflicts of interest are identified and, wherever appropriate, the resultant potential for bias managed.

[22] See Commission Decision 97/579/EC 'Setting up Scientific Committees in the field of consumer health and food safety' (1997), and subsequent Decisions in 2004, 2008, and 2015.

- **Access to evidence** – action is also needed to accelerate the process of making greater use in scientific assessments of the most advanced science. EU-level regulators are understandably cautious in moving away from historic approaches but need to take steps to favour scientific knowledge over history, tradition, and bureaucratic compliance.

  New approaches to regulatory toxicology should be welcomed, strengthening the perception of Europe as a scientific leader. Amendments to regulatory requirements should be introduced, where appropriate. Work is needed to educate regulators in how to interpret evidence derived from new, non-animal methods, and to encourage producing companies to generate and submit such studies. Failing to do this weakens the quality of scientific assessments and ensures that the EU will become a global laggard rather than a leader in regulation of consumer safety.

Alongside these changes, the governance of scientific assessments can be improved further by the introduction of new processes encompassing peer review of significant opinions; procedural rights for structured reassessment of findings of opinions; and administrative appeals procedures.

However, the greatest threat to the future effectiveness of consumer safety regulation in the EU comes from the risk posed by inappropriate reforms of governance of scientific assessments. Specifically:

- **Basing interventions on intrinsic properties of materials, rather than the likelihood of harm, will weaken consumer safety.** In most instances, this regulatory philosophy is distant, abstract and, because it fails to consider fully toxicological knowledge, unscientific. It does not provide a basis for identifying specific and effective interventions. There is, moreover, no evidence of success. Instead, it triggers actions that reduce the safe enjoyment of benefits, including, for example, restricting access to cleaning materials and the health properties of certain foods, without increasing protection. Mitigation measures based on intrinsic properties also tend to create risk substitution, whereby unintended behavioural changes lead to an increase in the overall likelihood of harm.

- Another potent threat is posed by **proposals to absorb the functions of the independent scientific committees into other EU bodies, ostensibly to reduce administrative costs. If implemented, this would be a backward step. It would return the governance of scientific assessments in the EU to the situation of the mid-1990s**, destroying a highly successful model without compensating improvements in consumer safety. There is no evidence of current regulatory or governance failures to support this proposal.

Instead, there are opportunities to strengthen the use and governance of the independent scientific committees, and the high-quality opinions they produce, through the creation of new, dedicated agency and by setting out a statement of the regulatory principles that guide regulation of consumer safety.

Rather than absorb the functions of existing scientific committees into old agencies or Technical Working Groups, it would be in the public interest to **create a new agency**. Focused on non-food consumer safety and enveloping the existing independent scientific committees, this new agency would be a world-leading innovation that would strengthen the EU's Administrative

State and enhance consumer safety. This would complement the protections that citizens enjoy in the areas of medicines and food.

At the same time and as part of the review of governance, the European Commission should take the opportunity to issue **a formal statement of the regulatory principles that guide regulation of consumer safety**. It should, for example, emphasise the importance of basing decisions on likelihood of harm rather than intrinsic properties. It should also establish consumer safety as the sole purpose of regulatory interventions.

4. RECOMMENDATIONS

Drawing on the insights of participants and in-house research carried out over more than fifteen years, the European Regulation and Innovation Forum has identified a series of reforms that, if implemented by the EU institutions, will significantly improve the governance of scientific assessments used to protect consumer safety.

There are two groups of reforms: changes to the overall structure of governance of consumer safety assessments (section 4.1.); and improvements that strengthen the governance and effectiveness of the existing scientific committees (4.2.).

4.1. Overall Structure of Governance

Recommendation 1: The **EU Legislator** should establish a **new non-food consumer safety agency**. This will support the existing independent scientific committees and provide, initially, the implementation mechanisms for legislation regulating cosmetics and detergents. Over time, the agency could expand its activities to support the implementation of other risk management laws that seek primarily to ensure consumer safety for sectors not covered by the existing agencies for medicines (EMA) and food (ECHA).

Recommendation 2: The **European Commission** should set out, for instance in a new Decision, the **regulatory principles for consumer safety**. This is a fundamental part of the governance framework. It should emphasise:

- **Consumer safety as the primary goal**;
- **Scientific evidence** as the foundation for interventions;
- Decisions based on **likelihood of harm**, based on the best science and understanding of exposures;
- Assessments undertaken by **independent experts**, organised on the basis of expert committees, with relevant and up-to-date knowledge;
- Selection of experts primarily on the basis of eminence and relevance;
- **Transparency** and impartiality of assessment processes; and,
- Institutional separation of risk assessment and risk management

Recommendation 3: The **European Commission** should fully **apply Better Regulation mechanisms and tools, including scrutiny by the Regulatory Scrutiny Board, when assessing any proposed changes in the governance of scientific assessments for consumer safety**. All assessments should examine the impact of proposals on consumer safety. Only governance proposals that can demonstrate credibly that consumer safety will be improved should be put forward for adoption.

4.2. Governance and Effectiveness of Existing Scientific Committees

Recommendation 4: The **European Commission** should set out, for instance in a new Decision, the key **principles for the selection of scientific experts and the operation of scientific committees**, and the future non-food consumer safety agency, that reflect a comprehensive understanding of bias and the complex conflicts of interest that cause it, and the way in which knowledge is generated in modern economies.

Recommendation 5: The **European Commission** should develop and enforce uniform **guidelines for the selection of experts and functioning of committees**, and the future non-food consumer safety agency. Drawing from a new Commission Decision set out in Recommendation 3, the guidelines should set out ways in which conflicts of interest can be managed such that regulators gain access to the most eminent and relevant expertise.

Recommendation 6: The **independent scientific committees** should jointly draw up **substantive guidance designed to encourage the submission by regulated companies of scientific knowledge derived from New Approach Methodologies (NAMs)**. They should commit to utilising such knowledge whenever NAMs prove to deliver more accurate and reliable evidence. The guidance should also explain to regulators and scientific committees how to interpret appropriately these new forms of knowledge as they develop and evolve, such that exposures and the likelihood of harm can be assessed with the greatest possible accuracy. In addition, the EU legislators should introduce appropriate amendments to relevant legislation to ensure that knowledge derived from NAMs can be included in risk assessments.

European Regulation and Innovation Forum
March 2022

Appendix A

Scientific Excellence in Consumer Safety

Science-Based Decision-Making Workshop

Thursday 18 November 2021
09h30-12h45 CET
Online (via Zoom)

Programme

This ERIF workshop will contribute to the evolution of the EU's approach to the management of consumer safety. It will be held under The Chatham House Rule and will focus on identifying ways of ensuring scientific excellence and impartiality, considering two perspectives: scientists who undertake risk assessments and who strive to deliver high quality opinions; and, second, the framework of governance that fosters such outcomes.

Two distinguished panels will address these issues, focusing on scientific as well as institutional issues.

09h15 Opening of Zoom connection

Session I - Science Perspective

09h30 Welcome and Introduction: **Howard Chase**, ERIF Chairman

Logistics by Moderator: **Dirk Hudig**, ERIF Secretary-General

09h40 Lead Speaker
Sir Colin Berry, Emeritus Professor of Pathology, Queen Mary and Westfield College, London University

09h55 Panellists Interventions
Karl-Heinz Jöckel, Professor of Medical Informatics, Biometry, and Epidemiology at the University of Essen
Daniel Dietrich, Professor of Human and Environmental Toxicology at the University of Konstanz
Paul Carmichael, Endowed Professor of Next Generation Risk Assessment Approaches for Human and Environmental Health at Wageningen University and Senior Science Leader, Safety and Environmental Assurance Centre (SEAC), Unilever

10h20 Discussion and Q&A

11h00 Close Science Session

Session II - Governance Perspective

11h15 Introductions by Moderator: **Dirk Hudig**, ERIF Secretary-General ERIF

11h20 Lead Speaker
Richard Meads, ERIF Rapporteur

11h35 Panellists Interventions
Jim Bridges, Emeritus Professor of Toxicology and Environmental Health, University of Surrey and a former Chair of SCTEE, SCC, and SCHENIR committees
Sue O'Hagan, Director Scientific Affairs and Food Safety at PepsiCo and former regulatory toxicologist at the UK Department of Health
Angus Cameron, International Regulatory and Pharmaceutical Registration expert

12h00 Discussion and Q&A

12h40 Chairman's summation and comments

12h45 Close of Workshop

European Regulation and Innovation Forum
November 2021

European Regulation and Innovation Forum

The European Regulation and Innovation Forum (ERIF) is an expert-led and not-for-profit think tank with the aim of promoting high quality decision-making by the EU institutions through Better Regulation. The ERIF was known as the European Risk Forum until January 2021.

In order to achieve this, the Forum applies the expertise of a well-established network of experts to 'horizontal', cross-sectoral issues. In particular, it addresses regulatory governance, decision-making structures, tools, and processes; the risks and benefits of new and emerging technologies, and of lifestyle choices; obstacles and incentives for innovation, including the regulatory framework; and the importance of high-quality scientific evidence for better regulation. This approach is highly relevant at present, as the EU recovers from the COVID-19 pandemic and undertakes an effective and proportionate transition to the new economic and societal models pursued by the European Green Deal.

Better Regulation is one of the pre-conditions for delivering these goals. It seeks to strengthen consent to law-making and to the actions of the State needed to implement legal requirements. Accordingly, laws and regulations should be:

- Necessary, effective, and proportionate (resting on a rigorous definition of the policy objectives, as well as a clear and comprehensive description and assessment of problems and their underlying causes);
- Based on credible evidence, particularly science, that supports the use of the powers of the State;
- Informed by a robust and transparent understanding of costs and benefits, particularly dynamic impacts such as risk-risk trade-offs;
- Demonstrate that benefits justify costs;
- Developed using transparent and participatory decision-making processes; and,
- Reviewable over time and subject to appeals and redress mechanisms

High quality decision-making, notably risk regulation, should take place within a structured framework that emphasises a rigorous and comprehensive understanding of the need for public policy action (risk assessment), and a transparent assessment of the workability, effectiveness, costs, benefits, and legitimacy of different policy options (risk management).

Achieving these goals is likely to require extensive use of evidence (especially science); rigorous definition of policy objectives; clear and comprehensive description and assessment of problems and their underlying causes; realistic understanding of the costs and benefits of policy options; and extensive consultation.

These principles and requirements form part of the approach to regulatory decision-making set out by the OECD since 1995. The approach to risk regulation promoted by the WTO also makes explicit reference to these principles and practices.

The ERIF is supported principally by the private sector. The ERIF does not seek to promote any specific set of values, ideologies, or interests. Instead, it considers high quality risk assessment and risk management decisions as being in the public interest. An advisory group of leading academics supports the ERIF's work.

The Forum works with all EU institutions to promote ideas and debate. Original research is produced and is made widely available. As an expert group, the Forum brings together multiple sources of evidence (such as the experience of practitioners and policy-makers; non-EU good practices; and academic research) to assess issues and to identify new ideas. The ERIF directly engages in EU regulatory reform debates through targeted lunches and roundtables. The Forum also regularly contributes to public consultations launched by the EU institutions. A key feature of the ERIF's approach is its emphasis on expert-to-expert dialogue to share views and learn from good practice.

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