EUROPEAN RISK FORUM – POLICY NOTE 31

MANAGING POTENTIAL HARMS, PROTECTING CITIZENS, FACILITATING PROSPERITY – HAZARD OR RISK?

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EXECUTIVE SUMMARY

For more than 100 years, public management of the possible threats posed by technologies has focused on the likelihood of harm, using evidence from high quality science. This is a risk-based approach by governments to managing harms. It accepts that the dose makes the poison; it identifies the degree of realistic exposure; and it highlights likely effects on health and the environment. Its consistent application has delivered significant benefits to Europe and its citizens.

Over the last decade, the European Union has embarked upon a major risk governance experiment. Alongside the traditional risk-based approach, the EU has adopted a new strategy, combining hazard characteristics with the "substitution principle" to force the removal of so-called 'unsafe' products and processes and their replacement by 'safer' ones. Known as hazard-based regulation, this approach maintains that harms are best regulated on the basis of intrinsic properties of substances, rather than through their normal use or degree of exposure. This approach does not seek to consider the likelihood of harm (or of unintended consequences) and is not informed by the costs and benefits of individual decisions. It is based on a belief that industry can and will always develop 'safer' alternatives. In a relatively short period of time, this new approach has become the dominant means of managing at EU-level the harms posed by crop protection products, biocides, and most uses of chemicals and metals.

The effectiveness and workability of the hazard-only approach in one of the world's largest economies remains unproven. Its use is, moreover, designed to achieve ill-defined goals whilst risking extensive unintended consequences.

After nearly a decade of experimentation, it is appropriate to review the strengths and weaknesses of this new risk governance strategy. Within this context, the ERF has identified a series of recommendations. Specifically:

- Expand the mandate of the Chief Scientific Adviser to include the organisation of risk governance and scientific advice in EU decision-making;
- Create an Inter-committee Group on Risk in the European Parliament, and expand the risk analysis capacity available to MEPs;
- Launch a comprehensive review of risk governance that examines critically the use of hazard and substitution to manage harms;
- Undertake an independent evaluation of the consequences of using the substitution principle by the EU institutions to manage harms and consider legislative amendments;
- Adopt a formal Innovation Principle in EU risk management and regulatory practice;
- Adopt an EU Law of Administrative Procedures that applies the four principles of good administration to all forms of implementing measures;
- Develop new forms of mutual recognition, based on the concept of equivalence of regulatory outcome, and informed by a "common scientific space" to ease trade tensions between the EU and the USA;
- Expand the scope of the Commission's IA process to include non-legislative decisions which ban, restrict or stigmatise on the basis of hazard characteristics;

- Establish mandatory standards and principles that define the quality of studies, information, and data to be used in scientific assessments;
- Require all significant risk assessment opinions to be independently reviewed;
- Draw up specific mandatory scientific standards for assessing hazards;
- Strengthen the application of existing legal requirements for determining hazard classifications;
- Require all substitution decisions to be based on a case-by-case comparative risk assessment; and,
- Regulate the potential harms posed by products on a case-by-case basis, rather than on the basis of technologies.

1. BACKGROUND

From the middle of the nineteenth century onwards, public management of potential harms has been one of the most important functions of governments. At EU-level, it encompasses the possible damage to human health, public safety or the environment posed by technologies and, increasingly, by lifestyle choices.

Until the late 1990s, management by governments of potential harms was based primarily on a robust risk-based approach, which relies on high quality science to identify the likelihood of harm. Government action focused on identifying specific threats, gathering evidence of the likelihood of damage, and imposing measures designed to limit risks so that benefits exceeded costs. Interventions by government were targeted, proportionate, science-based, and, in most cases, predictable.

This approach is consistent with the principles of evidence-based policy-making promoted by the OECD since 1995, and supported by the EU and its member states.[1] It complies with WTO rules as well.

Risk-based regulation, the policy strategy for management of harms that has emerged from this approach, seeks to manage potential harms through an expert assessment the scale of exposure needed for adverse effects, the likely exposure (based on real world considerations) and the expected impact of realistic exposures on health or the environment. It is, anchored in the toxicological principle identified by Paracelsus, namely that the dose makes the poison.

Within this risk governance framework, it is assumed that acceptance of some level of risk is beneficial and that a "risk-free world" is neither possible nor desirable. For Europe and its citizens, the benefits of using this science and risk-based policy framework have been considerable. It has contributed to safer products, less harmful production processes, enhanced longevity, higher living standards, and improved environmental quality. Innovation has been encouraged too. High quality, evidence-based decision-making by governments provided certainty and predictability for investors; strengthened user confidence; built markets and supported demand; and encouraged experimentation, creating new opportunities for products and services.

At EU-level, things have begun to change, and **the traditional way of managing potential harms has been replaced,** in part, by a new approach. Rather than basing decisions on assessments of the likelihood of harms of specific substances or processes (the "risk-based approach"), the new method **focuses solely on the intrinsic properties of materials, encouraging or mandating substitution whenever certain properties are considered to be 'unsafe' or 'undesirable**' (the "hazard-based approach").[2]

Using information about the hazardous properties of materials or processes when governments seek to reduce the threat of harm is not new. Protection of occupational health and safety has relied upon hazard characteristics of materials, as a means of triggering mandatory changes in operating practices or equipment, for decades. Developed over a long period of time, this well-proven means of protecting workers recognises technical progress,

[1] OECD 'Recommendations of the Council of the OECD on Improving the Quality of Government Regulation' (1995); OECD 'The OECD Report on Regulatory Reform' (1997; OECD 'OECD Guiding Principles for Regulatory Quality and Performance' (2005); OECD 'Recommendations of the Council on Regulatory Policy and Governance' (2012)

[2] This new risk governance strategy combines decisions about hazardous properties with substitution, either through mandatory bans or, through the use of public blacklists to encourage stigmatisation.

works within technological 'frontiers', and limits the scale of negative regulatory impacts to predictable additional operating and capital costs.

Similarly, hazard characteristics are one of the principal ways of prioritising the review, by government scientists in most OECD countries, of potential harms posed by chemical materials, supporting subsequent detailed, science-based assessments of risk. One example of this approach is the strategy used in the EU and the USA to manage the potential harms posed by pharmaceutical products. On the basis of their safety profile, most new pharmaceutical products are required to undergo a formal, mandatory pre-market approval process, during which experts assess the likelihood of potential negative side effects, along with potential benefits.[3]

In contrast, **the new, hazard-only approach to managing harms excludes any consideration of the likelihood of harm, or of the costs and benefits of individual decisions.** Instead, supporters have a different perspective. Rather than limiting the risk posed by specific threats, they believe that public policy should be used to deliver a different, social goal: a 'safer', toxic free world. Supporters argue that any exposure of citizens or the environment to harm is socially and morally unacceptable, and that the only way to prevent this is for governments to ban substances on the basis of hazard characteristics alone.

In advocating such action, supporters assume that there are always safer alternatives; that businesses will be willing to invest in the EU to replace 'unsafe' materials or processes; that the costs of using substances with hazardous properties always exceeds any benefits; and that, as a result, innovation will be stimulated rather than hamstrung.

Alongside the surviving elements of the traditional risk-based method, this hazard-only approach now forms one of the cornerstones of the EU's strategy for managing the potential harms posed by technologies. It is, for instance, deeply embedded in EU laws for managing crop protection products, materials used in electrical and electronic equipment, biocides, and uses of chemicals and metals.

Yet this new strategy has been adopted without a major, formal debate about its potential benefits or its weaknesses. Its assumptions and goals have not been reviewed nor have they been subject to rigorous challenge.

This paper examines the use of hazard, combined with the substitution principle, to manage harms. It sets out some of the reasons why this strategy has been adopted (section 2), and begins the process of highlighting a series of concerns (section 3). It finishes with brief conclusions (section 4) a small number of initial policy recommendations (section 5).

2. HAZARD-BASED DECISION-MAKING

When making decisions based on hazard, regulators follow a three-stage process. In the first stage, there is an assessment of the intrinsic properties of materials. At its best this uses high quality science and excludes a priori, hypothesis-forming or poorly conducted research. The second stage of the process culminates in a regulatory decision, based solely on intrinsic properties of the material, as to whether a material might be harmful to humans or the environment ('hazardous'). Robust consideration of normal handling and use is a best practice during this stage of the process. If the material is deemed to be 'hazardous' then, in the final stage of the process, producers and users are required to replace the material with

[3] This is also an example of the prudent use of precaution in risk governance.

'safer' alternatives – the substitution stage. In some cases this may be a mandatory requirement (bans or restrictions); in other situations substitution may be achieved through stigmatisation, employing public blacklists to amplify social concern and to trigger changes in behaviour by users and producers.

An important characteristic of this approach is that there is no consideration of exposure or of the likelihood of harm or of the costs and benefits of individual decisions.

The adoption of this new strategy by the EU is, in part, the result of political pressure, primarily from a small number of Member States, environmental and health activists, and influential MEPs. Supporters argue that the new approach, based on combining hazard characteristics with the substitution principle, is needed for a number of reasons:

- **Speed** – because of the large number of complex technologies and substances used in a modern economy, and the lack of information about the risks posed by many of them, traditional ways of managing potential harms take, it is argued, a long time and consume considerable state resources. Delays are allegedly also morally unacceptable: citizens should not be exposed to harms without their full consent.

  Hazard characteristics, as a simple means of identifying potential harm, are said to provide regulators with a way of speeding up the process of delivering a 'safer' world for citizens, supporters argue. A faster process of decision-making also allows politicians to claim that decisive action is being taken to resolve social concerns, maintaining public trust in government.

- **Health fears** – some citizens, politicians and interest groups are concerned about the possibility of links between involuntary exposure to dangerous substances and the prevalence of difficult to explain medical conditions, such asthma, allergies, cancer, behavioural problems, and learning difficulties. In the face of such concerns, a hazard-based approach appears to offer a quick, simple, and efficient way of removing exposures, thus improving health.

- **Gaps in understanding** - opponents of the traditional, risk-based approach argue that, because of the complexity of modern exposures to man-made chemicals, all risks cannot be adequately or credibly foreseen, and hence cannot be controlled. Potential threats posed by low dose and chemical cocktail exposures, for instance, cannot be fully understood. In the light of this, they argue that the only way in which risks can be managed is through the elimination of all hazardous substances: if there is no exposure, there is no possibility of harm.

- **Conceptual flaws** - another critique of the traditional system argues that risk assessments are biased and should not be seen as 'truth'. Rather, they are the product of human, and hence biased, scientists Outcomes of risk assessments are thus little more than opinions: a reflection of the social and political values of the scientists who drew them up. These weaknesses are, it is argued, of particular relevance when scientists need to develop assumptions to deal with uncertainties. Not only are scientists merely expressing opinions, they may also be wrong. As such, they should not enjoy a privileged position in the governance of risk: the views of scientists are no more relevant to public policy decisions than lay opinions or social concerns. Taking these concerns together, critics argue that risk assessments are deeply flawed conceptually, biased, and misleading.

- **Exclusion of politics** - some politicians, regulators and activists are uncomfortable with traditional methods of managing harms because, it is claimed, they limit scope for political involvement and administrative judgement. Whereas, scientific evidence places boundaries on politics and enhances transparency and accountability, experience shows that decisions about hazard characteristics are more easily adjusted to reflect social concerns or hypothesis-forming research.

For some opinion-formers and policy-makers these arguments make a compelling case for adopting a new strategy for managing the threats posed by technologies to humans and the environment. Indeed, they have persuaded the EU's institutions to adopt a hazard-based approach in a number of major policy areas.

3. HAZARD-BASED APPROACH – CONCERNS

For more than five years, the European Risk Forum (ERF) has observed and reviewed the use of hazard-based decision-making by the EU institutions. It has held a number of risk forums, policy lunches, and informal consultations involving leading academics scientists, lawyers, officials from the European Commission and the EU agencies, MEPs, and a wide range of experts from the business community. ERF experts have also reviewed recent academic research.[4]

Based on this process of consultation and research, the ERF has identified a number of possible problems with the use of hazard characteristics, combined with the substitution principle, to manage potential harms.

Possible problems include:

- **Trade frictions** – WTO agreements, covering technical barriers to trade and phyto-sanitary requirements, do not permit the use of hazard characteristics alone to justify barriers to trade. Instead, trade restrictions must be based on good quality science and assessment of risk. In other words, they must take into account exposures, likelihood of harms, and real world usage, and must be based on scientific evidence that meets international standards. Decisions based solely on hazard may, if they create barriers to trade, lead to the EU breaching its international obligations.

- **Scientific scepticism** – the new approach to decision-making, based solely on hazardous characteristics, rejects toxicological science in general, and the insights of Paracelsus in particular. It discards the well-established toxicological principle that the dose makes the poison and replaces it with a new, unscientific belief that all exposures are harmful, no matter how small or improbable. There is no scientific evidence to support this: it is unscientific. Much of our prosperity is based on science and technical progress, which requires acceptance of risk. Historical evidence suggests that societies that reject or restrict the use of science experience lower growth and enjoy fewer freedoms.

- **Irreversible damage** – if a product or process is banned because of its hazardous properties, then, for the user or owners, this is probably irreversible. It is unlikely to re-

[4] See for example, Lofstedt R. 'The Substitution Principle in Chemical Regulation: a constructive critique' (Journal of Risk Research, October 2013); Lofstedt R. 'Risk versus Hazard – How to Regulate in the 21st Century' (European Journal of Risk Regulation, 2/2011); and, Nordlander K., Simon C-M., and Pearson H. 'Hazard versus Risk in EU Chemicals Regulation' (European Journal of Risk Regulation' 2/2010).

enter the market, even if new scientific evidence emerges and the regulator reverses the decision (the "false positive" scenario). The damage is done. In view of this and taking into account the growing number of discredited claims of harm derived from poor science, it would be expected that regulators would seek to raise scientific quality standards when basing decisions primarily on hazard characteristics. There is, as yet, no evidence of this.

- **No reduction in harm** – when applied to real world situations, the operation of hazard-based processes tends to trigger a complex process of substitution. There is no simple shift from 'unsafe' to 'safe'. Instead, producers and users switch to the next best economic option, regardless of its intrinsic properties or its potential hazards. This is because laws and regulatory processes tend, in practice, to target only selected substances or hazards individually, ignoring other materials. So the shift away from known substances with well-understood properties to unknown ones often creates new hazards, a process of risk-risk. If this occurs then the EU's hazard-based strategy may not lead to any overall reduction in harm.

- **Loss of economic and social benefits** – hazard-based decision-making takes no account of the likelihood of harm or of the benefits of risk-taking, including the use of products with hazardous properties. In view of this, it is likely that products that generate significant economic or social benefits will be unnecessarily banned or restricted, whilst posing no realistic threat of harm, creating welfare losses for Europe's citizens. A "toxic free world" would, for instance, deprive citizens of treatments for human parasites, such as lice or ticks, as well as eliminating rodenticides and treatments for diseases transmitted by mosquitos and tsetse flies. Many household cleaning products would also be lost with serious implications for public health.

- **Questionable workability** – the "substitution principle", one of the building blocks of the new approach, rests on assumptions that may be flawed. Evidence from Sweden and Germany suggests that it is unworkable when used on any significant scale: 'safer' alternatives do not exist in most cases, and companies are unwilling to invest to develop them. It is a critical assumption of the substitution principle that 'safer' alternatives always exist, but all toxic materials cannot be substituted, some have unique properties and toxicity itself, as a characteristic of certain materials, has a high value to humans. It protects life and health.

- **Undermined evidence-based decision-making** – OECD guidelines, accepted by the European Union and embedded in its Smart Regulation strategy, require regulatory decisions to be informed by an understanding of costs and benefits. This is not possible if decisions to ban or restrict or to stigmatise are taken solely on the basis of hazard characteristics. Unless exposure and the likelihood of harm are assessed, using real world assumptions, then decision-makers have no evidence of the scale of the threat that government action aims to prevent, and hence the benefits of intervention to society, measured in improvements in life, health or environmental gains, cannot be identified. Without evidence of benefit it is, moreover, impossible to determine whether or not there is a net gain to society, that benefits exceed costs. The application of hazard-based approaches to risk management may well undermine the EU's capacity to meet its internal and international commitments to base decisions on evidence.

- **Undermined legitimacy** - without evidence of a benefit from government action, or of a clear causal link between the properties of a material and the likelihood of harm and damage, then there is no clear rationale for government action. Without evidence of

the likelihood of harm, and hence an assessment that the benefits of action exceed costs, regulators cannot explain why they have acted, in any specific case. This weakens consent, undermining legitimacy. Citizens cannot judge the possible gains from the use of government power. Due process is undermined as well, because property is lost without substantial evidence of likely harm. Arguably, this undermines the rule of law.

4. CONCLUSIONS

The European Union has embarked upon a major experiment in risk governance. Alongside the traditional risk-based approach, the EU has adopted a hazard-only strategy, combining hazard characteristics with the 'substitution principle' to force the removal of so-called 'unsafe' products and processes and their replacement by 'safer' ones.

This new strategy does not consider the likelihood of harm (or unintended consequences) and, because it does not assess risks, it is not informed by the costs and benefits of individual decisions. It is based on a belief that 'safer' alternatives will always be developed.

In a relatively short period of time, this new approach has become the dominant means of managing at EU-level the potential harms posed by the application of a number of technologies. Its use spans crop protection products, biocides, materials used in electrical and electronic equipment, and most uses of chemicals and metals. In contrast, risk management decisions in other parts of the economy continue to be made on the basis of a scientific assessment of risk that encompasses the likelihood of harm, and an understanding of costs and benefits.

The EU has revised its approach to risk governance without a fully informed debate about the potential costs and benefits of a hazard-based strategy for managing harms. Indeed, many of the arguments advanced in support of this new approach are misleading or incorrect, and others rest on beliefs, for which there is little credible supporting evidence.

Science, for instance, is not the same thing as scientists. It is misleading and wrong to elide science with scientists. It is not the same. The basis of science is the scientific method, with its emphasis on properly formed hypotheses, credible methodologies, replication, openness, peer review and 'provisonality' (all findings are provisional).

Speed of action, another argument used to support the hazard-based approach, does not guarantee regulatory effectiveness nor is it a substitute for it. Without effectiveness, policy action lacks legitimacy. Continued consent of the governed, it is widely accepted, depends on good government. In turn this requires the use of government power to be properly justified, to follow due process, and to be effective. If speedy decision-making undermines due process or leads to major social or economic loss or even creates additional harms, then legitimacy is undermined and consent is lost.

The effectiveness and workability of the hazard-only approach in one of the world's largest economies is unproven. Its use is, moreover, designed to bring about goals that are ill-defined and probably unattainable ('a safer world' or a 'toxic free environment'), whilst risking enormous costs and extensive unintended consequences, including increased harms, poor governance, economic disruption, less innovation, fewer jobs, and further economic stagnation.

After nearly a decade of experimentation, it is appropriate to begin to examine the effectiveness of this new risk governance strategy, to review its strengths and weaknesses, and to identify recommendations to improve the quality of risk management at EU level.

5. RECOMMENDATIONS

Over the past two decades, the European Commission, influenced by the OECD and others, has established well-respected standards for regulatory decision-making, supported by clear policies, extensive guidance, and strong institutions.

This commitment to better regulation in general, and to evidence-based decision-making in particular, provides a framework within which action can be taken by the EU institutions to shape the future use of hazard characteristics and substitution to manage harms, and to reduce the negative impacts of existing hazard-based laws. To achieve this, the ERF has identified a series of recommendations. Specifically:

- **Expand the mandate of the Chief Scientific Adviser to include the organisation of risk governance and scientific advice in EU decision-making.** Within this wider role the CSA should also have responsibility for co-ordinating and defining the Commission's communications on risk and science to opinion-formers and decision-makers.

  This will raise the profile of risk governance within the EU's institutions and improve the quality of evidence used to inform decisions throughout the policy cycle.

- **Create an Inter-committee Group on Risk in the European Parliament, and expand the risk analysis capacity available to MEPs.** The new group should be based on the existing Working Group on Risk, whilst the additional scientific capacity could be added to the existing EP Directorate-General for Parliamentary Research Service.

  This will strengthen the focus on risk and science amongst MEPs and contribute to better informed legislative decisions.

- **Launch a comprehensive review of risk governance that examines critically the use of hazard and substitution to manage harms.** Specifically, the review should consider the arguments used to support hazard-only management of harms; the weaknesses of the hazard-only approach; and the claimed inadequacies of the risk-based approach. It should also consider the organisational and procedural arrangements currently in place, as well as the tols deployed.

  This review should subject the arguments used by proponents of each form of risk management to public comment and debate, requiring beliefs, opinions, and assertions to be backed up by evidence. It should take into account the recognised strengths of the traditional, risk-based approach to managing harms, and should make use of the findings of an ex post evaluation of the precautionary principle and an independent evaluation of the use of the substitution principle.

- **Undertake an independent evaluation of the consequences of using the substitution principle by the EU institutions to manage harms and consider legislative amendments, if appropriate.** The evaluation should focus on the application of the principle, including its interaction with hazard characteristics; key

assumptions embedded within it; workability (in major economies) and effectiveness; and, unintended consequences, costs, and benefits.

This will provide an opportunity to test fully the claims of proponents and to develop findings to inform the wider review of risk governance.

- **Adopt a formal Innovation Principle in EU risk management and regulatory practice.** This will ensure that whenever precautionary legislation is under consideration, the impact of innovation should also be taken into full account in the policy and legislative process. Application of the principle will help decision-makers better understand the potential costs of decisions.

  Bans and restrictions based solely on hazard characteristics are, because there is no evidence of the likelihood of harm, precautionary. All fall within the scope of an Innovation Principle.

- **Adopt an EU Law of Administrative Procedures that applies the four principles of good administration to all forms of implementing measures, including technical guidance, agency decisions, and 'new' comitology.** The principles are transparency and consistency; public participation; public record; and accountability.

  This will ensure that all implementing (non-legislative) decisions to ban, restrict, or stigmatise on the basis of hazard characteristics must meet mandatory due process standards, requiring regulators to demonstrate evidence of the likelihood of harm.

- **Develop new forms of mutual recognition, based on the concept of equivalence of regulatory outcome, and informed by a "common scientific space" to ease trade tensions between the EU and the USA.** Policy-makers should assume that existing frameworks of risk regulations deliver a similar level of protection for citizens and the environment on both sides of the Atlantic.

  This will limit the potential negative impacts on Trans-Atlantic trade of the EU's hazard-based approach to managing harms in a number of areas.

- **Expand the scope of the Commission's IA process to include non-legislative decisions which ban, restrict or stigmatise usage of substances, products or technologies on the basis of hazard characteristics**, ensuring that all such decisions must demonstrate likelihood of harm, need for government action, benefits of action, and benefits in excess of costs. Any assessment of costs should also consider risk-risk outcomes.

  If overseen by the IAB and supported by appropriate technical guidance, this will raise governance standards, ensuring better informed decisions that are based on evidence and that limit the negative impacts and logical absurdities of hazard-only legislation.

- **Establish mandatory standards and principles that define the quality of studies, information, and data to be used in scientific assessments** by the European Commission's scientific advisers and committees (including EU-level risk assessment agencies, Technical Working Group, independent scientific committees and Rapporteur Member States).

  These principles should have a presumption favouring peer reviewed data and results, and require sufficient transparency to facilitate reproducibility. They should also require studies, information, and data to be based on widely-accepted and objective practices (the "scientific method").

This will increase confidence and public trust in the excellence of science used to inform risk management decisions at EU-level. It will also highlight the importance of the scientific method for public policy, rather than the opinions of individual scientists.

- **Require all significant risk assessment opinions to be independently reviewed.** Such peer reviews should be characterised by scientific and process integrity that maximises excellence and transparency, whilst providing substantial opportunities for public comment.

  This will ensure that the EU's use of risk assessments meets best practice standards, helping build confidence in their utility, excellence, and objectivity.

- **Draw up specific mandatory scientific standards for assessing existing hazards and identifying new ones.** These should be based on accepted science and the main principles of toxicology, and should require thorough science-based evaluations, using robust well-established methods and internationally accepted definitions.

  This will ensure that hazard assessments are based on credible evidence, increasing transparency and improving the quality of decision-making.

- **Strengthen the application of existing legal requirements for determining hazard classifications, specifically rules that demand the consideration of "normal handling of use".** Legislators have included these provisions to ensure that hazard classifications respect toxicological science, take account of exposure and consider the likelihood of harm.

  This will limit the implicit adoption of a precautionary approach to hazard classification whereby any exposure to intrinsic hazardous characteristics, no matter how unlikely, is deemed to pose a threat to safety, health or the environment. It will also limit the use of anti-scientific practices in public policy.

- **Require all substitution decisions to be based on a case-by-case comparative risk assessment,** recognising that, in practice, such decisions involve trade-offs between different types of hazard.

  This will help improve the quality of decision-making by making risk-risk trade-offs explicit.

- **Regulate the potential harms posed by products on a case-by-case basis, rather than on the basis of technologies.** Stigmatisation of technologies should be avoided. The emphasis of risk management measures should be on specific harms.

  This approach will help improve the quality of regulatory outcomes by making risk-risk trade-offs more transparent and limiting obstacles to innovation.

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European Risk Forum

The European Risk Forum (ERF) is an expert-led and not-for-profit think tank with the aim of promoting high quality risk assessment and risk management decisions by the EU institutions, and raising the awareness of the risk management issues at EU-level.

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 decision-making structures, tools and processes, as well as the risks and benefits of new and emerging technologies, of climate change, and of lifestyle choices.

The Forum believes that:

- High quality risk management decisions 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, cost, benefits, and legitimacy of different policy options (risk management);

- Risk management decision-making processes should ensure that outcomes are capable of meeting agreed social objectives in a proportionate manner;

- Risk management decisions should minimise negative, unintended consequences (such as new, unintended risks, economic losses, reduced personal freedoms, or restrictions on consumer choice); and

- The way in which risk management decisions are made should be structured, consistent, non-discriminatory, predictable, open, transparent, evidence-based, legitimate, accountable, and, over time, subject to review.

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.

The Forum works with all of the EU's institutions to promote ideas and debate. Original research is produced and is made widely available to opinion-formers and policy-makers at EU-level. 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. Indeed, direct engagement with opinion-formers and policy-makers, using an extensive programme of conferences, lunches, and roundtables, is a feature of the Forum's work.

The ERF is supported principally by the private sector. The ERF 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 ERF's work.

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