



HAZARD-BASED REGULATION – ACKNOWLEDGING THE PROBLEMS –

HIGHLIGHTS NOTE 02

HAZARD-BASED APPROACH: CONCERNS

Alongside the traditional risk-based approach, over the last decade the EU has experimented 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.

Based on a comprehensive 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 the 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** – Hazard-based approaches reject 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-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' itself 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** –

The EU Treaty imposes consideration of proportionality and the requirement for regulatory decisions to be informed by a thorough understanding of costs and benefits is integral part of the EU Better Regulation strategy. 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, 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 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** –

There is no clear rationale for government action Without evidence of a benefit from it, or of a clear causal link between the properties of a material and the likelihood of harm and damage. Without such evidence, 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.

ERF OBSERVATIONS

In a relatively short period of time, the hazard-based approach to risk regulation 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. Regrettably, the Better Regulation strategy has so far failed to consistently address the phenomenon. Indeed, many of the arguments advanced in support of the 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'. The basis of science is the scientific method, with its emphasis on properly formed hypotheses, credible methodologies, replication, openness, peer review and 'provisionality' (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 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.*

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Richard Meads, the European Risk Forum's Rapporteur, wrote this Highlights Note. However, the views and opinions expressed in this paper do not necessarily reflect or state those of the European Risk Forum or its members