

# Identifying methodologies for prioritising chemical issues and substances for further controls

Briefing for HSAC and health-focused scientific committees (CoT etc) to consider methodologies and processes for prioritising chemical issues/substances for further regulatory interventions.

## Introduction

For an overall strategic approach to identifying and acting on emerging chemical risks, we need to consider a number of areas depending on the amount of information available and extent of emergence. Broadly this can be set out by considering 3 main questions:

- A. How could we identify problems before they happen?
- B. How do we act on early warnings?
- C. How do we prioritise regulatory actions when emerging risks have been identified?

This paper is focussed on the 3<sup>rd</sup> question. (Further advice may be sought on other questions in due course. This will be dependent on the direction of government policy post general election.)

A number of horizon-scanning methodologies (e.g. PEWS, Delphi method) currently allow us to identify and monitor a 'long list' of existing and emerging chemical risks. However, setting a bar for regulatory action, and assessing priorities for further controls, presents a number of challenges.

We often may have a good understanding of the hazards (e.g. whether a substance is classed as carcinogenic, or Persistent, Bioaccumulative and Toxic), but limited use and exposure evidence for GB, often extrapolated from EU REACH dossiers (which may not identify the tonnages manufactured or imported into the UK). In the absence of robust exposure data, we cannot accurately assess the specific risks posed by hazardous substances in GB, but there may be sufficient concern to suggest regulatory action in some form may be warranted.

Filling evidence gaps around exposure is time and resource-intensive, and cannot be done for every substance of concern. We need a way of determining which substances should be prioritised for further evidence gathering or regulatory controls, including grouping approaches to aid risk assessment and reduce regrettable substitution.

There are existing generic provisions which allow the rapid ban of substances identified as Carcinogens, Mutagens or Reprotoxicants (CMRs) from consumer uses such as cosmetics. However, hazard data and generic risk assessments alone

can still leave unmanageably large groups of substances to address, which we need to further narrow down in order to target proportionate action.

In addition, the types of issues we are trying to assess often have very different endpoints, modes of action and timelines for impacts, making comparison and prioritisation challenging. For example, some substances may primarily affect human health, while others may impact on the environment; effects may occur in the short term, or over many decades. Some factors such as likely exposure at vulnerable life stages (e.g. during pregnancy, or childhood) are commonly accepted as relevant, but the numbers of substances that may fulfil the same criteria may be unmanageable and require further prioritisation in order to achieve appropriate and proportionate regulation. It is recognised that chemicals provide benefit to society (in sociological, cultural and economic ways that can be values driven and difficult to clearly determine). Overly precautionary approaches in response to uncertain human health or environmental risks may result in overall lower net benefit to society.

## **Case study: current process for identifying priority substances and issues to address under the UK REACH Work Programme**

For the annual UK REACH Work Programme (WP), we identify priority substances deemed to require further investigation or controls through UK REACH levers such as restriction.

To identify these priorities, we currently monitor global concerns, the EU's pipeline of REACH restrictions and additions to the Candidate List and Annex 14, and invite proposals from a range of internal and external stakeholders. We also consider GB-specific data such as the outputs of PEWS, and the recommendations emerging from the UK's own pipeline of Regulatory Management Options Analyses (RMOAs).

Since leaving the EU, a key source for identifying UK WP priorities has been the list of substances for which the EU is considering further controls. However, the priorities identified by the EU are not based on a systematic assessment of relative risk of all possible hazardous substances, but on a range of factors including priorities of Member States emerging from specific expertise developed by their respective Competent Authorities, political priorities, and the objective of creating a level-playing field across the EU Single Market.

In the UK, we have worked with stakeholders to develop broad principles for prioritisation. Proposals are given higher priority where there is an evidence-based risk of either:

- human exposure to hazardous substances within Great Britain, and risk management action through UK REACH would provide the greatest positive impact compared with other proposals
- long-lasting or damaging impact on the environment, and risk management action through UK REACH would provide the greatest positive impact compared with other proposals

In addition, for proposals to be given higher priority, both of the following must apply:

- appropriate risk management action is not already being taken in Great Britain or at an international level to address the risk (for example, through the Stockholm Convention, which the UK is a party to)
- there are no other risk management measures (regulation or other control measures) which already adequately address the risk identified

We publish the [rationale](#) used by Defra, the Welsh and Scottish Governments to agree priorities for regulatory action under the UK REACH WP, and to deprioritise some substances for which the EU is considering restrictions.

If a hazardous substance is identified as a potential priority, HSE, supported by the EA, may begin a restriction process, or produce a Regulatory Management Options Analysis (RMOA). An RMOA assesses the potential human health and environmental risks associated with the use of a substance or group of substances, alongside the existing regulatory framework and any specific controls relating to them. RMOAs help refine our understanding of GB-specific risks, and may make recommendations which can include filling evidence gaps, and risk management actions under UK REACH or other mechanisms. We may also commission research projects to fill evidence gaps and help establish GB risks, and determine appropriate next steps to manage them.

## Questions

We are interested in exploring systematic, evidence-based criteria or mechanisms to weigh up and compare risks, and options for developing a more robust and transparent process, potentially involving independent scientific or other relevant input such as deliberative methodologies or multi-criteria decision analysis.

1. What existing methodologies (for chemical prioritisation or other relevant disciplines) could help assess and compare the relative risks of very diverse chemical issues, with a view to better targeting further evidence gathering or regulatory action?
2. Is there scope for developing any modelling for assessing priorities based on varying levels and types of evidence (hazard, use, exposure, socio-economic etc), when severity, timing of impacts and exposure routes may be uncertain?

And ways of extrapolating relative benefits of further evidence gathering before taking action, compared with prompt action based on less comprehensive and conclusive evidence?

3. In the absence of a robust evidence-based prioritisation methodology, what opportunities are there to increase the validity and transparency of our prioritisation process?
4. What models might we consider for creating a new process with independent scientific advice to support prioritisation of chemicals issues? What role might existing scientific committees such as HSAC/CoT/SAG etc play in an improved prioritisation process?
5. Given the pace of research and developments in the field, how frequently should a prioritisation exercise be carried out?

## Outputs

Would the group be interested in formulating proposals for robust and transparent prioritisation processes that would be suitable to support UK policy-making?