March 2019

Toxic Chemicals in Everyday Life

A response from the Royal Society of Chemistry to the House of Commons Environmental Audit Committee.

The Royal Society of Chemistry continues to advocate for a system of chemicals and products regulation that achieves a balance between nurturing innovation, protecting the environment and human health, and is harmonised with global regulations to enable the UK to trade internationally. Such a system is best implemented using a risk-based approach to regulation.

In this response, we focus on four overarching action points that relate to all of the questions posed in the inquiry and we believe require further investigation and consideration by government:

1) The need for **decision-making principles** for chemicals and products regulation
2) The need for effective and **independent scientific evaluation and advice mechanisms** to ensure consumer confidence in credible chemicals safety decisions
3) The need for **globally harmonised outcomes** for chemicals and products regulations
4) The **development of biomonitoring** of chemicals in humans and wildlife

5) We also provide a specific **response to Question 11** of the inquiry relating to substances of very high concern (SVHCs) and their management after EU exit and beyond.

1) Decision-Making Principles for Regulating Toxic Chemicals in Everyday Life

All chemicals, even water, can be toxic to organisms; whether or not adverse outcomes arise in an organism is dependent on the 'dose' of the chemical and the nature of its toxic effects. When chemical exposure and effects are considered together we can consider the risks of an adverse outcome arising. This is the fundamental scientific basis of how chemicals and products are assessed for their safety and then regulated. When the risks and the impacts of chemical exposure are explained to decision-makers then other factors, such as socio-economic aspects, the degree of precaution that society will accept and whether to harmonise with other decisions by trading partners, come into play.

We have produced a document 'Principles for the Management of Chemicals in the Environment' in which we outline a set of principles that our community advocate as being important for environmental policy and in the context of managing chemicals within the 25 year plan for the environment. These principles are also relevant for the management of chemicals in products and everyday life.

(http://www.rsc.org/globalassets/04-campaigning-outreach/tackling-the-worlds-challenges/environment/rsc_principles_for_chemicals_in_the_environment.pdf **)**

When it comes to assessing and managing the risks of chemicals in everyday life, and in particular managing the use substances of very high concern (SVHCs), balancing the following five decision-making principles as shown in Figure 1 is important, in as open and transparent way as possible. The Citizen's right-to-know (what chemicals are present in their environments and how they might be affected) is an important principle that we have advocated and we are pleased to see this reflected in the Environmental Principles and Governance draft bill.

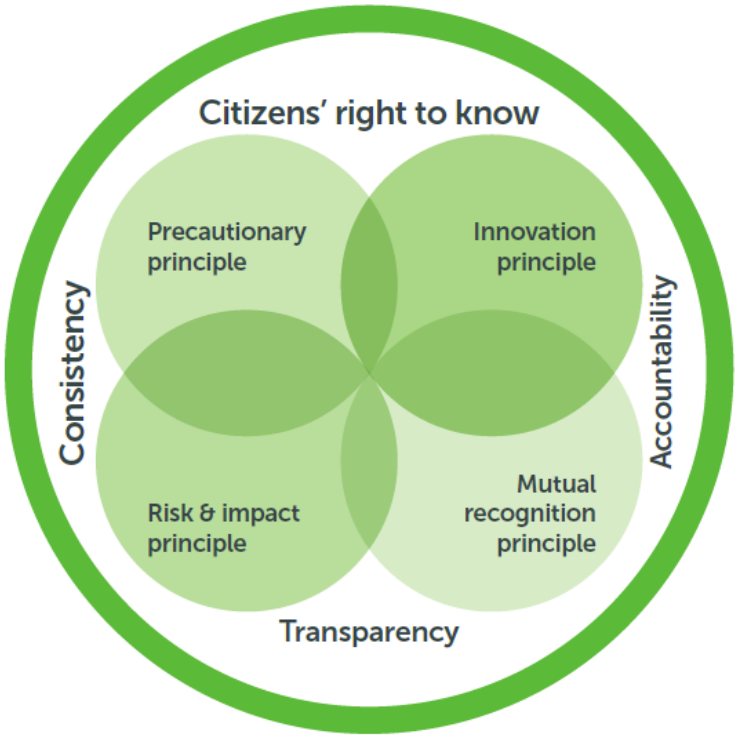

Figure 1 Decision-making principles for the management of chemicals in the environment and everyday life

a) **Precautionary principle**: Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation. (Rio principle 15; TFEU Article 191(2))
This principle requires significant discussion by governments as to how it is implemented in practice and in particular in relation to the full interpretation stated in the Communication from the EU Commission (EC) on the precautionary principle in 2000. An important point made by the EC is that 'The implementation of an approach based on the precautionary principle should start with a scientific evaluation, as complete as possible, and where possible identifying at each stage the degree of scientific uncertainty.' Full scientific certainty is rarely achieved, even with a large amount of scientific evidence, and uncertainty is often complex to communicate. The scientific community is integral to the implementation of the precautionary principle and assessing risk. The ultimate risk management decisions for chemicals and products are taken by policymakers based not only on the science but on societal acceptability of the degree of precaution desired in a given situation and should involve all relevant stakeholders, with experienced high calibre scientists as key contributors to decision-making.

b) **Risk & Impact Principle**: an environmental and human health risk and impact assessment shall be undertaken for proposed activities that are likely to have a significant adverse impact on the environment and are subject to a decision by the national competent authority. (Rio principle 17)

Risk assessment is performed for hundreds and thousands of substances by government bodies such as the Health & Safety Executive, Public Health England, the Environment Agency, the Foods Standards Agency and in EU by the European Chemicals Agency and European Commission Joint Research Centre. Risk assessment relies on a significant body of scientific data and high calibre expertise to interpret the evidence and inform policymakers on the risk and impact of potential adverse health and environmental outcomes. There is an opportunity to link environmental policy to health and wellbeing policies and a principle through which to do this, is via scientifically informed integrated risk and impact assessments. See also principles of risk assessment and risk management from the health and safety executive http://www.hse.gov.uk/risk/principles.htm]

c) **Mutual Recognition principle**: it should be considered as to whether the decision being taken is in agreement with the nature of decisions taken in other nations, where mutual interests require harmonisation e.g. for trading or collaboration purposes.
The principle of mutual recognition stems from Regulation (EC) No 764/2008. In the EU context it defines the rights and obligations for public authorities and enterprises that wish to market their products in another EU member state country. A similar principle could be developed to consider harmonisation in matters relating to environmental issues of mutual importance between collaborative partners in other parts of the world. The interpretation of the scientific data and technical approaches used act as a strong determinant in achieving mutual recognition.

d) **Innovation principle**: whenever legislation is under consideration, its impact on innovation should be assessed and addressed. (European Policy Strategy Centre; new principle based on EU developments)
*The Innovation Principle was introduced by the **European Risk Forum (ERF)**, a Brussels-based non-for-profit think tank, in October 2013. This principle has been discussed in the EU in 2016 by the European Political Strategy Centre*
https://ec.europa.eu/epsc/sites/epsc/files/strategic_note_issue_14.pdf
*We propose here that **the innovation principle should not be applied in isolation** but in concert with the precautionary principle, the mutual recognition principle, and the risk & impact principle.*

e) **Citizens 'Right to Know'/Transparency & Inclusivity principle**: multi-level and multi-sector stakeholder engagement, accountability and empowerment should underpin environmental and chemicals policy development, including involvement of citizens in decision-making. Local level buy-in and participation should guide decision-making, ideally at local levels where decisions impact. [Foundation EU policy – Citizens 'Right to Know']
http://ec.europa.eu/environment/basics/benefits-law/right2know/index_en.htm

It is important that these 'decision-making principles' should operate in a mutually inter-dependent way and not in isolation.

2. Independent Scientific Evaluation and Advice Mechanisms

Citizens are reassured, kept safe and there is broad 'confidence in chemicals' in society when decisions are transparent and based on an independent expert review of the latest scientific evidence.

To draw robust conclusions from scientific data, it needs to be evaluated and interpreted by scientific experts – data collation is most often done by industry scientists and consultants in the form of collating and interpreting a dossier of scientific data and evidence. Some expert academics focus their careers around investigating particular substances or mechanisms of toxicity in detail, but they are not usually the scientists who typically compile regulatory data.

Dossiers of data are complex and extensive, well into hundreds, sometimes thousands of pages of data that require significant resources, independent review and interpretation. Independent 'authoritative' committees linked to government bodies recruit typically academics but also independent consultants to take a higher level view around the proposed interpretations of the submitted data packages surrounding a substance or product safety dossier. This system of independent scientific review, where all real and perceived conflicts of interest are managed transparently, provides society with confidence that safety decisions have been arrived at in an independent and objective way, based on scientific evidence and knowledge, and not vested interests.

For example, in anticipation of the additional workload in the area of foods safety after Brexit, the UK Foods Standards Agency (FSA) is currently in the process of recruiting 40 more experts to their scientific committee structures (Committee on Toxicity (COT), Committee on Mutagenicity (COM), Committee on Carcinogenicity (COC), Advisory Committee on Novel Foods and Processes (ACNFP), and their subgroups etc.). These committees perform important scientific advisory functions into FSA regulatory decision-making and help to provide confidence that foods are safe (see the FSA video at https://www.food.gov.uk/about-us/scientific-advisory-committees). We have been actively involved in helping the FSA to source experts for this system of independent scientific review.

We would advocate that similar expert scientific advisory approaches are considered for wider implementation for the chemicals area e.g. to support decision-making in OPSS at BEIS and in Defra more broadly for REACH data evaluations, restrictions and authorisations post EU-exit. It could be useful to **build a register of specialists to support scientific committee structures for chemicals regulation**.

3. Globally Harmonised Chemicals and Products Regulation

In February 2019, we performed a survey of our members on our brexit priority themes of funding & collaboration, mobility of scientists and chemicals regulations. Almost 5800 people responded. In relation to the future of chemicals regulation:

Only 4% of respondents in our recent survey on brexit said the UK should prioritise developing its own rules and standards.

88% of respondents to our survey said the UK should prioritise harmonising regulations, globally or with the EU.

This outcome was also echoed strongly by participants in a recent meeting we held on 27 February 2019 jointly with the Interdepartmental Group on Hazards and Risks from Chemicals (IGHRC), on the topic 'Meeting the Challenges of Global Chemicals Regulation'. The programme, list of speakers and their presentations can be found on the RSC website at.

http://www.rsc.org/events/detail/36015/meeting-the-challenges-of-global-chemical-regulations

The UK has been a global player in driving forwards harmonised chemicals regulations to enable frictionless trade. The greatest success in this regard is the single harmonised EU system of chemicals regulations under REACH for the current EU single market. Post exit, if the UK is intending to strike new trade deals with new parts of the world, it should be understood that there are significant differences between the ways chemicals in products are regulated in different parts of the world e.g. USA, South Korea, Japan, Canada, Brazil etc. Such differences can adversely affect trade deals significantly and negotiations can become lengthy about mutually recognising each other's systems of chemicals and products regulation and the outcomes achieved by their respective regulations. For example, a trade deal between the USA and EU has proven difficult for many years, largely due to irreconcilable differences in how chemicals, foods and products are regulated.

Given we are members of the EU currently, the UK system of regulating chemicals in products starts off identical for the purposes of supporting UK-EU trade; however, after EU exit there is the potential for UK divergences to occur deal or no deal. Such divergences, particularly if new UK standards were to be lower than EU, would potentially damage trade between UK and EU. It is essential standards are not lowered and harmonisation is sought between UK and EU regulatory outcomes. This relies on achieving a **close working partnership between the UK and the European Chemicals Agency (ECHA**).

Trade deals with other parts of the world, taking a mid to long term view, could be based on a system of regulation that is globally harmonised or at least where outcomes are mutually recognised, and the UK and EU should continue to work together and lead on the global stage to achieve a strategic approach to international chemicals management (SAICM) through United Nations initiatives (http://www.saicm.org/).

4. The Development of UK & EU Citizens' Understanding of Human and Wildlife Biomonitoring Data

On 22 January 2019, we held a meeting at the Royal Society of Chemistry Burlington House, London, jointly with the Interdepartmental Group on Hazards and Risks from Chemicals (IGHRC), on the topic of biomonitoring of chemicals in the human body and in wildlife. The programme, list of speakers and their presentations can be found on the RSC website at http://www.rsc.org/events/detail/36014/biomonitoring-human-and-environmental-perspectives .

At this meeting the Project Coordinator Marike Kolossa-Gehring from the German Environment Agency shared a status update on the European human biomonitoring HBM4EU research project and also gave an overview on the German Human Biomonitoring System (GerES). She presented data on plastics additives (phthalates) and bisphenol A in the urine of children and on persistent perfluorinated compounds in adults. The presence of such chemicals in humans can present concerns for society and the real scale of risks will require assessing by qualified professionals.

A recent article from Chemical Watch (https://chemicalwatch.com/crmhub/74658/scientists-develop-multi-analyte-method-for-improved-biomonitoring?pa=true) highlights the developments from HBM4EU in the Czech Republic in the chemical sciences arena for determining concentrations of 80 organohalogenated chemicals in human serum: 40 flame retardants, 19 perfluoroalkylated substances (PFASs), 11 organochlorine pesticides (OCPs) and eight polychlorinated biphenyls (PCBs).

More data of this type will emerge in Europe and UK over the coming years on chemicals in humans and wildlife, and as citizens become more aware of these data, we will seek as a society to know whether the chemicals observed in our biofluids (blood and urine) are presenting significant harm to the quality and longevity of life. This will require significant scientific analysis and investment of time from those in our community with expertise to evaluate and interpret the data.

5. Response to Question 11 How should substances of very high concern (SVHC) be regulated after the UK leaves the EU? How should the Government manage risk from newly identified toxic chemicals after the UK has left the EU?

After EU exit, the **UK should aim to work as closely as possible with the EU** on SVHC hazard classifications and evaluations, authorisations and restrictions under REACH regulation. At the very least **the UK should seek 'observer' status** on the European Chemicals Agency's (ECHA) Risk Assessment Committee (RAC) and socio economic assessment committee (SEAC). Harmonisation is for the benefit of enabling frictionless trade.

If a no deal brexit occurs, then the UK cannot legally participate in EU decisions on SVHCs. In terms of negotiating a future partnership, the **UK should aim at securing as close a relationship as possible with the work of ECHA** and seek to harmonise on classifications, when they are based on sound scientific evidence.

The management of risk is a more challenging question and decision-making could deviate between UK and EU over time. One can follow the guidelines and procedures of the EU regulations as transposed into UK law from day 1 after exit, but doing so does not guarantee that the same risk management decisions will be made for managing the risks of a chemical for the UK society. The withdrawal agreement only assures the processes and procedures of EU chemicals regulations are transposed into UK legislation. It does not dictate how risk management and REACH authorisation and restriction decisions should be made, but the statutory instruments for chemicals regulation say decisions will be made by the HSE as the regulatory body and the Secretary of State. The management of risks from chemicals for UK citizens becomes a matter for UK government (and possibly devolved nations).

Scientists have an important role in illustrating the scale of the risk and options the government might have, but the government must take the policy decision on what is an acceptable risk for society. A transparent set of decision making principles are needed for doing so, coming back to point 1 above.

For new chemicals, the principles and guidelines of the EU REACH data generation processes should be followed. These guidelines are based on years of toxicological risk assessment work and based on OECD guidelines for chemicals testing that have stood the test of time and are accepted globally.

However, chemicals safety evaluation is on a path to disruptive change through scientific advancement. The years ahead will result in key developments of new science for chemicals regulation. New approaches to safety testing involving the chemical sciences are being developed for future implementation in chemicals regulation. For example:

- Adverse outcome pathways using in vitro input data (OECD, US EPA, EU)[1]
- Chemical read-across (OECD, US EPA, EU)[2]
- Exposomics (EU, USA research collaboration)[3]
- European Human Biomonitoring Initiative
  (26 countries, 170 EU organisations: including Horizon20:20 funding)[4]

The UK is active in all of these areas of science that will change the way safety assessment is performed. It is vital the UK continues to actively work collaboratively and internationally in these areas to stay at the forefront of chemicals regulation as a world leader.

About us

With approximately 50,000 members and a knowledge business that spans the globe, the Royal Society of Chemistry is the UK's professional body for chemical scientists, supporting and representing our members and bringing together chemical scientists from all over the world.

Our members include those working in large multinational companies and small to medium enterprises, researchers and students in universities, teachers and regulators.

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[1] Adverse Outcome Pathways, Molecular Screening and Toxicogenomics, OECD.org http://www.oecd.org/chemicalsafety/testing/adverse-outcome-pathways-molecular-screening-and-toxicogenomics.htm

[2] Cronin M, Madden J, Enoch S, Roberts D (2013) Chemical Toxicity Prediction: Category Formation and Read-Across. Book published by Royal Society of Chemistry, Print ISBN: 978-1-84973-384-7, PDF eISBN: 978-1-84973-440-0, DOI:10.1039/9781849734400

[3] Exposomics Project http://www.exposomicsproject.eu/

[4] European Human Biomonitoring Initiative (HBM4EU) https://ec.europa.eu/research/conferences/2016/hbm4eu/index.cfm

