March 2019

House of Lords Debate on Draft REACH etc. (Amendment etc.) (EU Exit) Regulations 2019

Briefing on proposals to transfer additional responsibilities to the Health and Safety Executive in the event of no deal

Summary

The Royal Society of Chemistry calls for chemicals regulation that achieves a balance between nurturing innovation, protecting the environment and human health, and enabling the UK to trade internationally. Should a no deal scenario arise, we call for pragmatic and evidence-based decision-making that is harmonised with EU outcomes in chemicals regulation.

The Draft REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 aim to correct inoperabilities in the EU REACH legislation, as it would be transposed into UK law. One of the main changes is who holds decision-making powers for restrictions and authorisations in REACH. Hence, this SI is not just to correct inoperabilities in process but the changes also shift decision-making responsibilities for chemicals entirely from the European Chemicals Agency to the Health & Safety Executive (HSE) together with the Secretary of State.

Scientific evidence and sound scientific advice lies at the heart of confident and harmonised regulatory decision-making for chemicals, but at present there is no clear plan to ensure this strong scientific evidence base will be present in a regulatory regime run by the HSE and Defra.

We have three primary asks regarding the additional responsibilities being transferred to the Health and Safety Executive:

- We ask that the government set out its plans to ensure HSE has **adequate scientific capability** to take on increased decision-making responsibilities and act as the national regulator.
- We ask that the government clarify how the UK will seek to aid **harmonisation of its scientific evidence base** with the EU in a no deal scenario.
- We ask that the government set out plans for a fully **transparent decision-making process, guided by clear principles.**

Ensuring the HSE has adequate scientific capability to act as the national regulator

1. Effective decision-making requires access to the most relevant and respected scientific expertise and resource. In order for the HSE to take on additional data-review and decision-making responsibilities, there must be a critical mass of scientific expertise within the organisation to evaluate chemical safety dossiers, and access to scientific advisors and experts in their fields when substance specific decisions are required.

2. There are currently no resourcing plans that are in the public domain for such critical capabilities at the HSE. Scientific advice cannot come for free, i.e. pro bono from willing academics. There must be a plan for adequate resourcing of scientific evaluation and the provision of independent advice for a UK REACH regime.

3. **We ask that the government set out its plans to ensure HSE has adequate scientific capability to take on increased decision-making responsibilities and act as the national regulator**, specifically:

    a. **Does the HSE have a plan for recruiting the required scientific skills** for its increased level of responsibility?
    b. **Does the HSE plan to continue working in a collaborative model with the EC Joint Research Centres,** or
    c. **Will Defra and HSE fund its own new scientific research programmes in areas that underpin chemicals regulation** in order to retain influence in bringing new and relevant science to the attention of both UK and EU decision-makers?

Harmonising the scientific evidence base for decision-making

4. In the event of no deal, UK and EU decision-makers would immediately lose access to each other's scientific networks and databases that provide data and information into regulatory decision-making. The UK will no longer have a place on the EU member state committees that make important decisions for chemicals such as the Risk Assessment Committee (RAC) and the Committee for Socio-Economic Analysis (SEAC) within the European Chemicals Agency (ECHA).

5. **Scientific research collaborations are at the heart of effective and harmonised chemicals regulation, which is critical for frictionless trade in the chemicals sector**. Scientists provide policy-makers with up to date scientific information on the risks and impacts of chemicals on health and the environment. Good science therefore influences the design of regulations and influences chemical safety decisions.

6. **We ask that the government clarify if and how the UK will seek to aid harmonisation in decision-making rather than divergence from the EU when it leaves RAC and SEAC, specifically:**

    a. **Will the HSE aim to harmonise UK decisions with EU decisions** for the benefit of UK-EU trade, or will there be a UK decision-making framework for chemicals that could lead to regulatory divergence?
    b. ECHA does not review every substance dossier submitted into EU REACH, even with its large budget and capability. **How will the HSE prioritise substance review and what proportion of dossiers would the HSE expect to review in full?**

Adopting clear, transparent decision-making principles

7. There is currently no clear set of principles that will guide chemical regulatory decisions made by the HSE and the Secretary of State as the national regulator. Furthermore, there is no guarantee that decision-making processes will be shared with the public.

8. Decision-making principles and a commitment to transparency are not present in the transposition of UK REACH regulation into UK law. It is clear that in a no deal scenario, the UK can take its own decisions, and divergence from the EU could arise from day one. We would advocate remaining harmonised with the EU as much as possible, for the purposes of frictionless trade of chemicals and goods.

9. We have produced a document 'Principles for the Management of Chemicals in the Environment'[1] in which we outline a set of principles that our community advocates as being important for decision-making.

10. When it comes to assessing and managing the risks of chemicals, and in particular managing the use of substances of very high concern (SVHCs), balancing the five decision-making principles as set out in **Appendix A** is important, in as open and transparent a way as possible in order to facilitate dialogue in the future with the EU.

11. The HSE will form its opinions based on available scientific data and translate that information for the Secretary of State to make the final decision. Transparency is essential. The Citizens' Right to Know (what chemicals are present in their environments and how they might be affected) is an important principle that we have advocated.

12. **We ask that the government set out a clear plan for the principles that will guide the Secretary of State and HSE when making decisions about chemicals regulation, and commit to a fully transparent decision-making process.**

[1] http://www.rsc.org/globalassets/04-campaigning-outreach/tackling-the-worlds-challenges/environment/rsc_principles_for_chemicals_in_the_environment.pdf

APPENDIX A: Decision-making principles for chemicals regulation

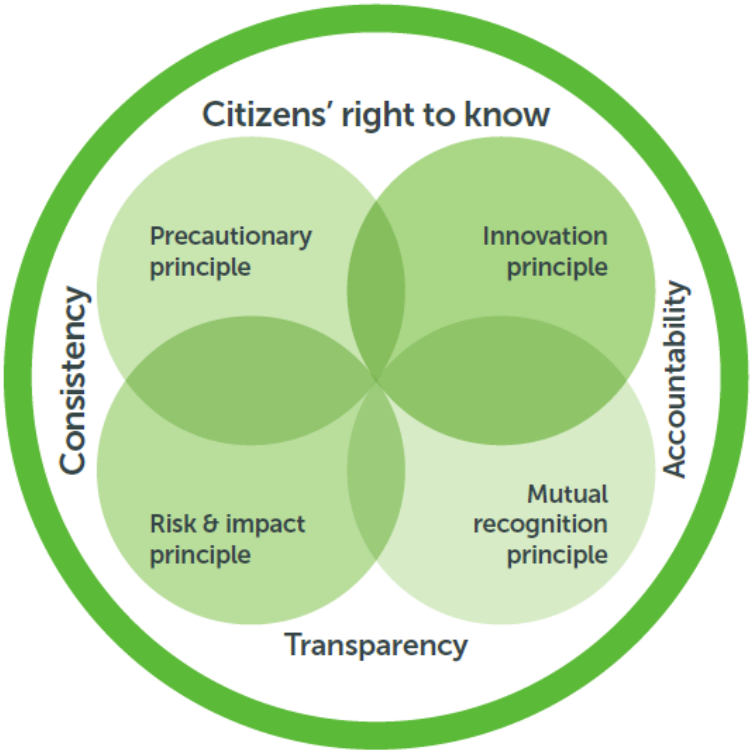

Figure 1: Decision-making principles for the management of chemicals in the environment

13. **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[2] (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.

14. **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 the 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

[2] https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2000:0001:FIN:EN:PDF

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[3]]

15. **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[4]. 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.

16. **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[5]. 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.

17. **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'[6]]

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

Contact

The Royal Society of Chemistry would be happy to discuss any of the issues raised in our response in more detail. Please direct questions to Camilla Alexander-White or Matt Davies at policy@rsc.org.

About the Royal Society of Chemistry

With about 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.

[3] http://www.hse.gov.uk/risk/principles.htm
[4] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32008R0764&locale=en
[5] https://ec.europa.eu/epsc/sites/epsc/files/strategic_note_issue_14.pdf
[6] http://ec.europa.eu/environment/basics/benefits-law/right2know/index_en.htm

