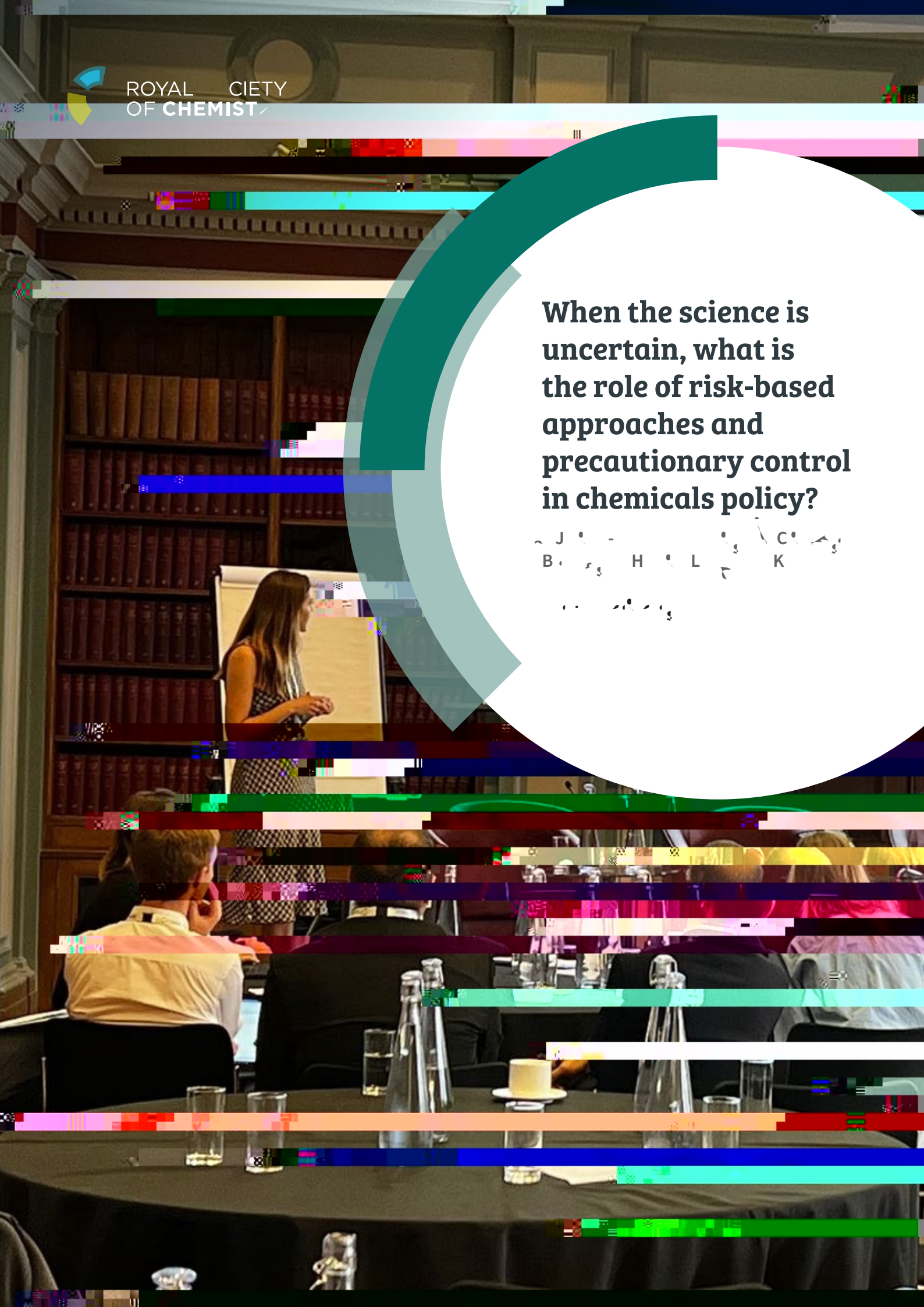
ROYAL SOCIETY OF CHEMISTRY

When the science is uncertain, what is the role of risk-based approaches and precautionary control in chemicals policy?



Contents

The precautionary principle and essential use criteria

The precautionary principle states that neither a lack of information nor scientific certainty should delay action or regulation when there are potential severe and irreversible consequences. This principle underpins why the concept of essential use has been proposed by some as a possible pragmatic risk management solution when faced with potentially large numbers of data-poor chemicals, for which a substance-by-substance approach to regulation can be slow and impractical. The essential use concept involves identifying the applications of chemicals and allowing their use when 'essential' but prohibiting other uses to limit exposure and potential harms. The concept was introduced in the Montreal Protocol, where a substance qualifies as 'essential' only if:

"1. it is necessary for the health, safety or is critical for the functioning of society (encompassing cultural and intellectual aspects); and

2. there are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health"[6]

The Montreal Protocol was narrow in scope, regulating select ozone depleting substances. If the essential use concept is to be applied to a wide-ranging group of data-poor substances, there are important methodological and practical questions to be further defined, such as

- which applications qualify a substance as 'essential,'
- when the concept should be applied,
- how it compares with other possible approaches to regulation,
- who makes these important decisions.

In the workshop 'When the science is uncertain, what is the role of risk-based approaches and precautionary control in chemicals policy?', around 60 attendees were brought together from academia, industry, NGOs, policy and professional bodies from the UK and EU to share and discuss this question.

The workshop was co-sponsored by the Royal Society of Chemistry (RSC), the Department for Environment, Food and Rural A□airs (Defra) and the Chemicals Industry Association (CIA). We invited the speakers below to set the scene, prior to an a□ernoon of breakout discussion groups on the practicalities of using risk-based regulation, precautionary control and

Workshop details

The following persons are thanked for chairing and speaking during the workshop sessions.

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- Professor Ragnar Lofsted (Kings College London)
- Catherine Gunby (Fidra)
- Silvia Segna (Chemicals Industry Assocation)

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- Stavros Georgiou (Health & Safety Executive)
- Dr Camilla Alexander-White (Royal Society of Chemistry)
- Edward Latter (Defra)

- Geo□rey Podger (Kings College London)
- Professor Frederic Bouder (University of Stavanger)
- Professor Nick Pidgeon MBE (Cardi□ University)
- Andrew Fasey (Mayer Brown)
- Professor Ian Cousins (Stockholm University)
- Dr Anna Watson (CHEM Trust)
- Dr Silke Gabbert (National Institute for Public Health and the Environment, Netherlands)
- Dallas O'Dell and Woong-Ki Lee (The London School of Economics and Political Sciences)

Workshop presentations

Risk and precaution

Opening the workshop, [illegible] observed that the role of scientists is to present options to politicians. He warned that in some cases politicians "are very much welcoming of scientific advice, provided it agrees with what they've already decided to do". Therefore, he called for transparency and accountability, proposing that when publishing a decision, politicians also publish the scientific evidence it is based on, or the justification for why it is not based on scientific evidence. He also stressed the importance of defining terms such as 'hazard', 'risk' and 'essential' so that no one party can take advantage of them being unclear.

Mr Podger also voiced concerns around the diminished inclusion of science and evidence in EU decision-making in recent years, particularly as the UK develops its post-Brexit chemicals strategy following EU exit. Due to international trading, pressure will come from industry for new UK regulation to follow EU regulation. Mr Podger suggested that the EU Chemicals Strategy for Sustainability (CSS) will be largely determined by EU politicians, who are driven by their own political agendas, and that there would be opportunities for the UK to have science and risk-based regulation. However, he recognised this would lead to divergence between EU and UK regulatory regimes, which would bring challenges.

[illegible] presentation explored how to define important terms. Professor Bouder noted that academics and governments usually define 'precaution' in similar terms: as something that is justified when there is a significant threat comia1 31dm being unclear.

Professor Cousins shared aspects to consider when applying the essential use concept. First, the substances for consideration need to be identified and the concept should only be applied to the 'most harmful substances' for which traditional risk assessment approaches may not be appropriate for their safe management. The essential use concept can be made more e□icient by regulating chemicals as groups. Second, there are di□erent ways the function of a chemical can be substituted. For example, Bisphenol-A (BPA) in thermal paper receipts can be substituted by a di□erent chemical (chemical function), thermal paper receipts can be created using di□erent materials (end use function), or electronic receipts can be used instead (service function). Third, to be 'essential' substances must be critical for the health and safety of society and have no acceptable substitutes. Professor Cousins shared that more clarity on what defines 'essential' will be available soon when the Wood Report, commissioned by the European Commission to define criteria for essentiality, is published.

D A presented insights from the **UK Chemicals Stakeholder Forum's** working group on essential use. The purpose of the working group was to discuss how the essential use concept has been used in the past and is proposed to be used to regulate hazardous chemicals. The stakeholders viewed the essential use concept as a pragmatic way of reducing pollution and speeding up chemical regulation. They agreas a . Theehol 74.173Ɛ4376 Tm(UK)T/Lan10 0mipy agreas a . Theen (opos n6g14T1Csl)13eced insights from th

Breakout sessions

To understand how risk assessment and precautionary control could be used to regulate data-poor chemicals, we asked participants to discuss four questions. The key points from these discussions are summarised below.[11]

Breakout one: risk and precaution

- There are di□erent types of uncertainty depending on what data is available. Therefore, whether a risk-based approach could provide e□ective protection di□ers on a case-by-case basis.
- Grouping allows data from representative chemicals to be used via the concept of read-across to e□iciently regulate multiple similar chemicals for which data may be insu□icient.
- REACH legislation has data requirements to deal with uncertainty. Issues arise from situations that were not considered when the legislation was made, such as mixtures and persistence without proven harm. Lessons must be learnt if there are evidenced cases where risk assessment has failed before.
- When regulating chemicals for which the science is uncertain there are factors to be considered:

1. Acceptability
   - The public's appetite for risk should be gauged.
   - The risk to workers di□ers from risk to the public.
   - The public has delegated authority to regulators to make decisions in their interest.

2. Transparency
   - Uncertainty is intrinsic to science.
   - Communication to the public should be done in a way that is understandable (e.g. likelihood of being struck by lightning).
   - Communication to the public should be done by scientists.
   - Policymakers are not required to follow scientific advice but must be transparent when they do not.
   - Transparency from industry makes more data available.

3. Flexibility
   - Legislation must be prepared to adapt to new scientific approaches and data.
   - A timescale is needed for review and revisions to regulations.

4. Prioritisation
   - A framework is needed for prioritising chemicals for further research.
   - Methods could include modelling, machine learning, toxicokinetics, New Approach Methods (NAMs).

Recurring themes in presentations and breakouts

The following is a summary of the major themes that emerged from the workshop. These are not recommendations, but rather a starting point for further discussions about risk-based decision-making, precautionary control and the essential use concept, and important considerations for their application.

1. D of relevant terms are needed so that it is clear what e□ect proposed regulations would have. Key terms include:
   - hazard
   - precaution
   - acceptable
   - uncertain
   - essential
   - sustainable
   - necessary
   - critical for the functioning of society
2. Apply the essential use concept as an for substaT10 0 09an/ActualTextFEFF0007BDC 1Tm /Lang (en-GB)/MCID 830BDC Bo7BDC 10 0 0 1

References

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[2] A chemicals strategy for a sustainable chemicals revolution (rsc.org)

[3] Persson et al (2022) Outside the Safe Operating Space of the Planetary Boundary for Novel Entities. *Environmental Science and Technology*

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