National Centre
for the Replacement
Refinement & Reduction
of Animals in Research

Unilever

Workshop report:

Opportunities for the UK to develop world-leading chemicals regulation

Workshop: 11 May 2023
Report published: 23 October 2023

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Pioneering Better Science

Background

1. Following EU-Exit there is a unique opportunity for the UK to consider the focus and approach of domestic chemicals regulation policy, including that related to assessing and assuring the safety of chemicals. This presents the prospect of harnessing forward-thinking approaches – ensuring that the policy and its implementation embraces the most up-to-date technologies and scientific thinking. It is critical that any future UK policy in this area maximises opportunities to apply the principles of replacement, refinement and reduction of animals (the 3Rs) in testing, whilst continuing to ensure the highest standard of protection for human health and the environment. Around the globe, more flexible approaches within chemicals regulations[1] demonstrate that the adoption of modern regulatory safety science can also benefit the 3Rs.

2. To support and inform the UK's future chemicals policy, a workshop was hosted in London by the NC3Rs and Unilever in May 2023. This brought together the government departments responsible for developing and implementing UK chemicals regulation policy post EU-Exit, as well as industry as end-users of the policy and UK-based academic scientists working in the area of chemical safety. The meeting was chaired by Ian Kimber, Emeritus Professor of Toxicology (University of Manchester).

3. Discussion centred on the opportunities to develop and implement chemicals regulation that is science-led and embraces recent scientific developments, is beneficial to the UK economy, and in line with sustainability goals. The discussions were focused on establishing a consensus five-year vision for UK chemicals regulation, a draft of which was circulated to delegates in advance. The draft vision can be viewed on pages 4 to 5 of this report.

4. The key objectives of the workshop were to:

    a. Establish whether there is general agreement across the UK science base on the principles set out in the vision and determine which aspects vary dependent on industry sector.
    b. Determine the main risks/challenges for realising the vision.
    c. Identify how the challenges could be overcome, and what next steps and resources are needed.

5. A copy of the workshop programme can be found in Annex 1. Presentations were given during the morning session by keynote speakers to set the scene. These covered:

    - A perspective on future needs for UK chemicals regulation by the current chair of the UK Committee on Toxicity.
    - Industry perspectives from UK trade associations representing the cosmetics/consumer products and crop protection sectors.
    - An overview of current relevant UK government activities.

[1] For example in Canada: https://www.canada.ca/en/health-canada/services/chemical-substances/canada-approach-chemicals/risk-management.html; and Australia: https://www.dcceew.gov.au/environment/protection/chemicals-management/national-standard/roadmap.

6. The draft five-year vision was also presented for discussion. The second part of the workshop involved focused breakout group sessions, with delegates discussing points related to the key objectives described above.

7. The workshop was attended by over 50 UK-based scientists drawn from large/multinational industry (across consumer products, industrial chemicals, food, agrochemicals, and pharmaceuticals; 31%), government agencies (19%), academic experts (19%), trade associations (11%), small and medium-sized enterprises (SMEs) and contract research organisations (CROs) (each with 7.5%), as well as consultancies and learned societies (6%).

8. This report summarises the main themes discussed at the workshop and provides a basis to inform future activities in this area, to shape and support the development of world-leading UK chemicals regulation that is based upon the most modern safety science.

Draft five-year vision for UK chemicals regulation shared with delegates ahead of the workshop

National Centre for the Replacement Refinement & Reduction of Animals in Research

Draft five-year vision for UK chemicals regulation

- This document forms the basis for discussions at the NC3Rs-Unilever workshop on *Opportunities for the UK to develop world-leading chemicals regulation* (11 May 2023). It was provided to all delegates in advance of the event.
- The goal of the workshop is to establish a consensus five-year vision for UK chemicals regulation.
- This document is centred on the vision for the development and implementation of domestic chemicals regulation and policy related to hazard and risk assessment for human and environmental health by 2028. Future work should also address defining a broader, long-term vision to transform the overall paradigm of chemical safety assessment beyond that time.
- The aim for 2028 is to establish a UK chemicals regulation that:
    a. Is science-led, embracing recent global scientific developments and technologies[1] and which maximises animal replacement opportunities.
    b. Provides a greater breadth and more relevant information on the potential risks posed by chemicals, to improve the protection of human and environmental health.
    c. Is beneficial to the UK economy, and resource efficient.
    d. Aligns with sustainability goals.

[1] This complements the Government's recently published plan to cement the UK's place as a science and technology superpower by 2030.

- To achieve this, there will be implementation of a tiered testing framework that exploits and allows for the early adoption of the latest scientific advances and technologies. This will enable wider generation and acceptance of data from new approach methodologies (NAMs)[2].

- A tiered approach will allow for the design of testing strategies that begin with initial considerations of (i) to what extent toxicity testing is needed (e.g. by incorporating exposure assessments); and (ii) what tailored data are needed to enable robust safety decisions to be made (e.g. following the generation of mechanistic information).

- Use and acceptance (from both a scientific and data quality perspective) of NAM data within weight-of-evidence and integrated approaches, as part of a tiered approach, will build familiarity and trust in the use and applicability of these methods. This will require a strong element of flexibility within the information requirements, to ensure that data generation is not restricted to "tick-box" lists of tests and can be adapted as approaches evolve. There will be sufficient confidence in the decision-making process that is transparent to the product end-users (i.e. consumers, workers, and the environment).

- The UK's approach will be informed by those adopted in other global jurisdictions and may influence that of regions where policy and regulation is being developed or is evolving.

- To meet the aims described, there will need to be:

    a. Establishment of dedicated capability and funding to support and lead development and validation of cutting-edge approaches within the UK.

    b. Support for innovation within the existing UK science-base (e.g. SMEs and academia), and the expansion of testing capacity within contract research organisations to meet demand.

    c. Sufficient expertise and ongoing training within decision-making agencies to enable more bespoke safety assessments to be conducted.

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[2] The NC3Rs definition of NAMs: non-animal-based approaches to provide information on chemical/drug toxicity and risk assessment; replacement with respect to the 3Rs.

General views and feedback on the draft vision

9. There was general agreement across the delegates on the premise of the vision and the principles it set out. The vision is currently relatively high level, and many aspects will need further definition, acknowledging that the initial draft was intended to provoke discussion and that there may be sector-specific differences not currently captured that are worthy of scoping in more detail. Delegates agreed that in addition to science, the vision and its implementation is also pertinent to UK economy/business and in addressing societal needs; and that improved protection of both humans and the environment must be its core aim.

Support for a transition to tiered, exposure-based approaches and ensuring the generic approach is applicable across all industry sectors

10. The prospect of the UK moving towards a risk-based paradigm for chemicals regulation, with the integration of information on levels of chemical exposure wherever possible, was supported along with the greater ability to waive (eco)toxicity testing based on exposure considerations. Although there are many ongoing conversations and activities within the wider safety assessment community focused on increasing the use of data from specific NAMs in regulatory safety testing, such discussions do not generally fully capture the utility of incorporating exposure information upfront as part of a tiered approach to assessment, nor the inclusion of innovative *in vivo* approaches (that are reduced/refined compared with current methods) in sectors where this is still permitted and where there remains a lack of confidence in NAMs. A greater emphasis on exposure-based approaches will affect specific sectors differently and will accordingly present different challenges – for example, for chemicals that have unknown or multiple uses and/or varying exposure levels depending on how they are used, or when planning for scenarios such as accidental release. Other sector differences include the extent to which risk:benefit relationships can be considered, and also how the current regulatory regimes operate – for example whether the chemical requires pre-marketing approval with all safety data provided upfront (such as for pharmaceuticals or agrochemicals), or if there is a registration process in place for substances already in use to identify and manage any risks (as is the case for most industrial chemicals). The advantage of a tiered approach that begins with a problem formulation step[2] and includes consideration of exposure is that it allows for one generic approach to safety assessment to be employed that will utilise the best available data to inform decisions depending on the scope of the assessment and the intended use(s) of the chemical. The key is formulating and articulating the specific data needs to answer the relevant scientific questions, and for innovation to be driven by the regulatory agencies themselves to ensure new methods are fit for purpose (e.g. products developed through the NC3Rs CRACK IT scheme such as the SAFE – innovative Safety Assessment of Fish adverse Effects – project); see section 4.3).

[2] The problem formulation step of any human health or environmental safety assessment seeks to define the scope of the assessment to best determine the data, tools, and procedures required to complete the evaluation. This ensures that the assessment is “fit for purpose” and meets the overall (risk) management goal (Solomon *et al.*, 2016) so that the data generated add value to the decision-making process and support the selection of studies, in line with 3Rs considerations.

Recognising the global nature of testing and marketing

11. Considering that most products are developed for a global market, and given the need to ensure global harmonisation wherever possible in the generation and regulatory acceptance of (eco)toxicity data, it was agreed that it would not be prudent for the UK's future legislation to be completely divergent or separate from those used in other regions. A pragmatic level of coordination with activities and practices used in other jurisdictions will be required but this does not preclude the UK from being visionary or leading in certain aspects, employing modern scientific approaches within the scope of existing legislation. There may be specific areas of testing where the UK has the expertise and capability and is prepared to take a leadership role, to be the first to adopt non-traditional approaches and act as an exemplar despite continued requirements for traditional approaches to be used elsewhere in the world. With use in practice over time, confidence in a new approach will grow and this could in turn influence changes to regulatory requirements in regions outside of the UK. It will be paramount that there is sufficient UK representation on relevant international groups and committees (e.g. as leaders and participants in Organisation for Economic Co-operation and Development (OECD) projects) to ensure maximal international influence. At the same time, to ensure that the most up-to-date practices are being adopted by the UK, it is necessary to better understand the approaches currently being taken globally that vary from the legacy EU regimes, and how these are being used in practice. Examples include the waiver process being used within the US Environmental Protection Agency (EPA) and tiered/exposure-based approaches being applied by Health Canada.

Determining what can realistically be delivered in five years

12. There was some discussion on what can be realistically achieved in the timeframe set out by the vision, recognising that transformation of the chemical safety assessment paradigm in its entirety is a much longer-term aim for various reasons, including aspects related to the varying state of the science in different areas of testing, and the relatively slow pace of legislative change.

13. In the short to medium-term, there could be a focus on taking examples from the cosmetics/consumer products sector (where consumer safety assessments are now made without the use of new animal testing, and with information on chemical exposure incorporated) and translating these approaches to the testing of chemicals produced for other uses, where possible. For example, considering whether the approaches used to assure consumer safety of cosmetic ingredients (where the UK Cosmetic Products Enforcement Regulations prohibits the use of animal tests) could also be used to assure the safety of workers in the UK using the same ingredient within an occupational setting.

14. There may also be opportunities to exploit flexibility that already exists with the current regulations – for example within the UK Registration, Evaluation, Authorisation and Restriction of Chemicals (UK REACH) regulation applicable to most chemical substances that are manufactured in or imported into Great Britain, there are opportunities under Annex XI for registrants to adapt the standard testing regime if animal testing does not appear scientifically necessary. Indeed, registrants are legally obliged only to conduct animal testing as 'a last resort' (Article 25, UK REACH). Annex XI provides opportunities to use scientific approaches to address the registration requirements without the use of animals, for example if read

across to data from other substances can be performed; there is sufficient existing data; information indicating negligible human or environmental exposure is available; or where weight-of-evidence from several independent sources of information leads to the assumption/conclusion that a substance has or has not a particular dangerous property. There is a clear opportunity for the UK to lead the way and set a precedent for best practice in areas of testing where there will be forthcoming regulatory requirements for safety assessment but for which the current paradigm would not be suitable, for example in the testing of polymers and per- and polyfluoroalkyl substances (PFAS).

15. The sharing of case studies demonstrating the use of waivers or non-traditional approaches in practice for decision-making and their consideration/review by expert committees will be instrumental in providing the scientific understanding, rigour, and awareness needed for such approaches to be applied more widely and with higher confidence, along with the provision of clear guidance. Ultimately, perfection is the enemy of progress, and it is critical to determine which areas are ready now for the application of novel approaches, and how these can be used in practice – along with a good understanding of the limitations. This will enable safety decisions to be made based on the best available data at the time – acknowledging that the data currently being generated using traditional animal tests are also not perfect.

What is needed to realise the vision

16. Several areas were identified where further work is needed to move the UK closer to adopting the principles set out in the vision, and some suggestions were put forward as to how this could be achieved.

17. The main areas were related to a need for:

    i. A clear understanding and description of the incentives and benefits over the existing regulatory system.
    ii. Accountability for and ownership of the vision, in conjunction with the necessary political will to drive a “top-down” change.
    iii. Dedicated resource in terms of expertise, personnel, and associated funding at the implementing/decision-making agencies.
    iv. Establishment of a UK centre of excellence and committed investment to sustaining this in the long-term.
    v. Training and continuing professional development in the use of NAMs, their data interpretation and integration across all stakeholders.

Further information on each of these points is given below.

Clear definition of the benefits over the existing regulatory system

18. More information is needed within the vision on the key drivers for the changes in overall approach, including what the added value is compared with continuing with the current regimes, and clearly articulating all the potential benefits that could be brought to science, the economy and society. The level of funding needed to enable delivery of the vision is not insubstantial and the benefits must be shown to significantly outweigh this, acknowledging that this may only become evident in the longer-term.

19. This would be supported by providing clear and specific examples of the potential benefits such as case studies demonstrating where current tools and approaches have not satisfactorily addressed safety concerns but where the use of NAMs (in conjunction with exposure information where appropriate) has or will be critical in solving these issues. Key to this will be specification of the vision's overall aim as positioning the UK at the forefront in the adoption of NAMs and the use of exposure science to improve the scientific rationale of safety assessment for better protection of humans and the environment, whilst reducing animal use and maintaining public confidence. The vision should be directly aligned with the ambitions set out in the recently published UK Science and Technology Framework.

20. All chemicals regulations ultimately aim to provide a framework to ensure that the chemicals humans and the environment are exposed to do not cause harm. It should be noted that defining what is an acceptable or adequate "level of protection" (i.e. to compare how well this is achieved currently, versus what *could* be achieved) is extremely challenging, as often our current levels of protection are not accurately defined. It is more feasible to seek to improve protection by being more accurate, through ensuring that new approaches are more fit-for-purpose from a scientific perspective than those used currently used. This could include better integration of exposure and hazard characterisation information along with an increased human/environmental relevance of the test systems used. Arguments around a questionable economic benefit of transitioning towards these new approaches could be outweighed by the positive societal impact. This needs to be seen as a long-term investment where the benefits will increasingly become realised over time, as the expertise and leadership in modern safety science in the UK builds and becomes an exemplar to other geographies (see paragraph 11).

Accountability/ownership and the need for political will to drive a "top-down" change

21. While the vision is intended to be representative of the broader UK science base, there is currently a lack of clarity on who will be responsible for driving its delivery. There have been many separate events, activities and discussions related to the use of NAMs and moving the science of chemical safety assessment forward both nationally and internationally in recent years. Development of policy and implementation of information requirements under the varying chemicals regulations are the remit of several different UK government departments (including the Department for the Environment, Food and Rural Affairs, the Health and Safety Executive, the Environment Agency, the Foods Standards Agency, and the Office for Product Safety and Standards). This adds to the challenge of establishing and implementing a broad UK approach to ensuring chemical safety. Raising awareness of this vision as a priority area at the government level needs harmonisation across a dedicated consortium of the key players from UK academia and industry as well as professional bodies and learned societies, to ensure a consolidated message and gain political and public buy-in. This workshop is a first step toward this end, and development of a policy paper for presentation to relevant government ministers and departments is a logical next step.

22. Delivery of the vision needs to come from the top-down and be the responsibility of government, and there must be the associated will (and dedicated funding) to prioritise and drive its delivery. There will need to be direct and sustained interactions with the relevant members of government and civil service

(e.g. ministers and chief scientists within the relevant government agencies) to gain the necessary political interest and confidence to act, and ensure that its delivery is not affected as a result of any discontinuity across government (for example due to elections, reshuffles or staff changes). Public perception and messaging around the topic should be considered from a political perspective, and a communication plan developed that ensures continued engagement with all relevant stakeholders.

23. Any subsequent changes made to UK legislation or data requirements must be sufficiently flexible and future-proofed due to the constant evolutionary nature of science and to ensure that regulation can keep pace with new developments, as opposed to specifying tick-box lists of standardised tests that must be conducted. This will also require further empowering decision-makers (see paragraphs 24 to 25). Here, gaining a greater insight into how more flexible approaches to regulatory science are successfully being applied in other jurisdictions such as Canada and Australia will be useful. If more bespoke approaches are permitted, the broader science-base will be in a better position to embrace the best new science for problem-solving.

Dedicated resource at implementing agencies

24. It is critical that the needs and challenges currently facing UK regulatory agencies are understood, as there is often a lack of resource to enable the consideration of new tools and data streams, considering the huge increase in the volume of UK-specific safety assessments being conducted following EU-Exit (where previously this burden was shared across all the member states). A tiered approach to providing information for chemicals regulations should allow the regulators to concentrate their limited resource on those materials of highest concern rather than on evaluating inert materials that happen to be produced in large tonnages. In addition to dedicated capacity to support the implementation of forward-thinking approaches, it would be beneficial if more information were provided to the regulatory agencies by companies submitting NAM data that is easy to understand, outlines how the approaches have been used for decision-making, and specifies what the benefits are over the use of traditional approaches. Even where NAM data inform safety assessment in a way that is comparable to the use of data from animal studies, this should always be used as a replacement in line with the requirement under the UK Animals (Scientific Procedures) Act 1986[3]. Ultimately, framework changes within the agencies will be necessary to enable the practical processes needed to realistically move towards a more flexible approach, for example through routine provision of workshops and via continuous dialogue with scientists from relevant advisory committees (e.g. Committee on Toxicity, and the Hazardous Substances Advisory Committee).

25. There is value and incentive now for increased collaboration across and between the relevant agencies responsible for implementing the various different chemicals regulations across food, cosmetics, industrial chemicals and agrochemicals, and although this is already starting to happen through activities such as

[3] Where paragraph 2(A) line 2 specifies that “a scientifically satisfactory method or testing strategy not entailing the use of protected animals must be used instead of a regulated procedure”.

the cross-Whitehall New Approaches to Chemical Risk Assessment in the Regulatory Space (NACRARS) group, there would be benefit from concerting efforts further to ensure progress.

Establishment of a UK centre of excellence and associated investment

26. There is currently a general lack of coordination between development of new methods for safety assessment and their application/implementation for regulatory purposes. Traditional research programmes in the UK fund fundamental academic research, but there is no set mechanism to resource evaluation/validation of methods or translation to their use in practice. Establishment of scientific confidence in NAMs is an evolving area (e.g. van der Zalm *et al.*, 2022) and one where the UK should be looking to input into the development of relevant frameworks. Prior to EU-Exit, as recommended in regulations such as EU REACH, the UK joined the rest of the EU in seeking advice from organisations including the EU Reference Laboratory for Alternatives to Animal testing (EURL ECVAM) on the appropriate use of non-animal approaches, although there is now a lack of a central body to provide advice in the UK. Rather than the creation of a UK-based centre that solely focuses on the validation, it was suggested that a centre of excellence should be formed that joins up the work of academic and industry scientists with regulatory (cross-government) needs. There are already examples of successful schemes that fund innovative scientists to solve challenges set out by regulatory agencies thus allowing for “co-discovery”, for example the public private platform PEPPER in France dedicated to the pre-validation of endocrine disruptor characterisation methods, the US EPA’s Challenges and Prizes scheme, plus CRACK IT Challenges from the NC3Rs (although the scope of this scheme is far broader than the area of safety assessment). There are also examples in other regions where regulatory agencies have their own dedicated research groups to support regulatory science and decision-making, such as the Office of Research and Development at the US Environmental Protection Agency.

27. A dedicated centre of excellence that crosses government, academic and industry sectors could also be a main point of contact for partnerships with other global regions looking to implement similar approaches and provide expertise for national and international collaborations that advance the field, and feed into consortia such as the International Cooperation on Alternative Test Methods (ICATM). The centre of excellence could take a lead domestically in setting out the goals of validation, in terms of ensuring that scientific confidence is built in using specific NAMs or combinations of NAMs in decision-making, and that the data from these methods are fit-for-purpose and therefore as protective of humans and/or the environment as possible (see paragraph 10). Dedicated funding and resource as well as backing from government will be vital to achieve the aspiration of setting up and maintaining this centre.

Continuing professional development of all stakeholders

28. There will be benefits in increasing professional development in the use of NAMs, raising awareness of new developments in the field and the interpretation/integration of the associated data across all stakeholders, and for ensuring the retention of expertise within organisations. Ideally there will be more open dialogue between the method developers, industry as submitters of the data, and regulatory agencies as end-users of the data, and such dialogue should not be driven by individual companies or committees; this could be a role for the centre of excellence described above. In the shorter-term, those

generating data from animal studies as a last resort should be incentivised to also generate and submit NAM data to build confidence and experience in using this type of data and help determine where improvements are needed. This would more likely be done in practice by companies with the resource and appetite to generate data for which there is currently no set regulatory requirement, given that NAMs are not necessarily inexpensive to run (e.g. due to the cost of accessing assays or reagents or associated analytical aspects, and the time and expertise associated with building weight-of-evidence approaches). There may also be concern that decisions made on the basis of NAM data could deviate from decisions made on the outcomes from animal tests, and there is uncertainty regarding how this would be considered by regulators and could add to industry cautiousness. Another consideration is ensuring that capacity is sufficient within the UK's CROs conducting NAMs to keep up with demand, so that availability of new technology is retained domestically and benefits the wider economy.

Key messages from the workshop and concluding remarks

29. There is undoubtedly a unique opportunity at the present time for the future of UK chemicals regulation to be informed and shaped by the nation's science base. These workshop discussions reflect the appetite and support for the UK taking a forward-thinking approach to chemical safety assessment. This involves utilising a tiered approach to determine the true data needs and exploiting the latest scientific advances, with incorporation of exposure information and data from NAMs where there is sufficient confidence. This will involve the UK potentially being the first in some areas to adopt and accept new approaches but will also require a large degree of international collaboration and harmonisation given the global nature of production and marketing. The core aim of any change to the current regime in the UK must be that it confers more accurate and relevant protection to both humans and the environment, although there will also be a need to ensure alignment with subsidiary aims including those related to maximising the 3Rs opportunities, economic growth, and sustainability. The UK has limited resource, and such a tiered approach to assessments would enable most resource to be aligned to evaluating the chemicals of highest concern.

30. It is important to understand and plan for what is realistically achievable in the short to medium-term, for example what is permissible within the current regulations without the need for legislative change considering that this is a lengthy process, and that the science underlying safety assessment is continually evolving. For example, a first step could take the learnings from the cosmetics sector where consumer safety must already be assured without the generation of new animal data (to comply with UK cosmetics regulations) and applying the approaches used here to other sectors/other regulations where possible; further, ensuring that case studies of the successful use of tiered and integrated approaches are shared widely and transparently to support wider and confident adoption of approaches would be valuable. Ultimately, to ensure the next steps that are needed to deliver the vision (as described in paragraphs 16 to 17) happen in practice, there needs to be the political backing to drive this from the top-down, as well as the associated funding and resource that is prioritised as a long-term commitment from government. To harness this political will there must be a clear and detailed value proposition, be that from a scientific, economic, and/or societal perspective; and there are arguments that realisation of the vision could tangibly benefit all three, looking at a future where the UK harnesses the best new science to

improve the safety of the UK's residents and environment whilst decreasing reliance on the use of animals for this purpose, and potentially boosting the UK economy by being a major global player in providing the most cutting-edge approaches.

31. This workshop was a first step towards building a consolidated message on the future direction of UK chemicals regulation across key stakeholders representing the various relevant facets of the UK science base. It will now be followed up by the preparation of a policy paper later in 2023. Led by the NC3Rs with a subgroup of experts present at the workshop, the paper will outline a vision for UK chemicals regulation, capturing the key discussion points and actions required, to gain the necessary political buy-in to realise the vision and ensure that the potential opportunities for the UK can be harnessed.

Acknowledgements

The NC3Rs and Unilever are grateful to the participants of the workshop for the insightful discussions.

References

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Annex 1: Workshop agenda

Time	Session content
10.00 – 10.10	**Welcome, introductions and aims of the meeting** *Professor Ian Kimber (University of Manchester; Chair)*
10.10 – 10.20	**Opening remarks** *Dr Julia Fentem (Unilever)*
10.20 – 10.30	**Chemical regulation: designing a better mousetrap** *Professor Alan Boobis (Imperial College London; Chair of UK Committee on Toxicity)*
10.30 – 10.50	**Industry perspective 1: cosmetics/consumer products** *Dr Emma Meredith (UK Cosmetic, Toiletry and Perfumery Association - CTPA)*
10.50 – 11.10	**Industry perspective 2: crop protection products** *Dr Dave Bench (CropLife UK)*
11.10 – 11.30	**Current relevant UK Government activities** *Dr Olivia Osborne (UK Food Standards Agency - FSA)*
11.30 – 12.00	**Presentation of the draft five-year vision, followed by initial feedback from delegates** *Dr Natalie Burden (NC3Rs)*

Time	Session content
13.00 – 13.10	**Introduction to discussion sessions** *Professor Ian Kimber*
13.10 – 14.30	**Breakout discussion session 1** ▪ Is there general agreement on the vision? Are there specific aspects with conflicting views, and are these sector-dependent? ▪ What are the main risks/challenges with realising the vision?
14.30 – 15.00	**Feedback from breakout groups and discussion in plenary**
15.15 – 16.35	**Breakout discussion session 2** ▪ How could the challenges identified be overcome, what steps are needed? ▪ What else will be needed to realise the vision, and how will this be secured?
16.35 – 17.05	**Feedback from breakout groups and discussion in plenary**
17.05 – 17.30	**Discussion on next steps; sum up and meeting close** *Professor Ian Kimber*