Department for Environment, Food and Rural Affairs

Minutes of the 33rd Hazardous Substances Advisory Committee (HSAC) meeting

Meeting date: 15 July 2021

1. Welcome and approval of the draft agenda

The Chair, Professor Chris Collins welcomed all attendees to the meeting (see annex a for Attendance List)

The draft agenda was approved with no additional items added under any other business.

2. Brief updates on the HSAC work programme

HSAC response to the consultation on the revised national action plan for the sustainable use of pesticides

Actions

- Chris Collins to collate comments from members on national action plan on sustainable use of pesticides into bullet points which will then be circulated to the committee members

Developing a horizon scanning exercise to identify chemical issues of emerging concern through a Delphi Method.

Chris Green from Defra provided an update on the drafting of a scientific paper on the horizon scan for future chemical issues that members of HSAC had participated in. He took suggestions from members on structuring the introduction.

Committee members agreed the introduction should start out at a high level starting with the three planetary crises - pollution, climate change and biodiversity loss as it encourages deeper thinking about how individual issues fit into a larger picture which has been difficult to achieve so far.

They suggested incorporating concepts such as ‘One Health’, planetary boundaries and late lessons from early warnings. It was suggested that the importance of chemicals for society should be caveated with discussion of their ‘essentiality’ in specific applications.

John Colborne highlighted the publication of an update to the 2017 Lancet Commission on Pollution and Health later this year which will likely be of relevance to this work.

Actions

- HSAC panellists redrafting issues are requested to complete the task by Friday 23 July. Chris Green to develop the introduction, requesting a few lines on the history of science and Late Lessons from Early Warnings from Susan Owens
- an update on the Horizon Scanning exercise should be prepared ready for the next HSAC meeting

HSACs feedback on the Environment Agency's draft per- and polyfluoroalkyl substance (PFAS) evaluations

At the 32nd HSAC meeting in May 2021, the committee was asked to give feedback to the Environment Agency on their Draft PFAS evaluations. They were requested to revisit the issue to provide more detailed answers to the Environment Agency's key questions by 23 July 2021.

Actions

- the committee agreed to look again at the questions posed by the Environment Agency regarding their draft PFAS Evaluations and to provide more detailed answers by Friday 23 July

3. An assessment of the challenge presented by copper in the UK natural environment

This was a progress report on the joint analysis conducted by the Defra's HSAC and the Expert Committee on Pesticides committees**.**

Andrew Johnson provided the committee with an update on the progress of the joint Defra HSAC and ECP assessment into the challenges presented by copper in the Natural Environment.

The committee was pleased with progress on the work. It was suggested that the work could be suitable for publication in a peer reviewed scientific journal as well as the Defra facing report.

It was felt that the section on future policy recommendations required some additional work and that the implications of a shift to green energy technologies could be discussed.

Actions

- the report should undergo editing for basic grammar and spelling issues. Susan Owens is requested to advise Andrew Johnson on policy implications of report with a deadline of 12 August
- the secretariat is to set up a meeting between Andrew Johnson and Defra pesticides team to discuss potential policy implications

4. HSAC PFAS recommendations paper

At their 32nd Meeting in May 2021, the Defra Chemicals Policy team invited the Hazardous Substances Advisory Committee to develop a Recommendations paper on the future of PFAS policy in the UK.

HSAC agreed that a succinct 2 page recommendations paper will be written. A final draft has been requested by November 2021.

The committee discussed the PFAS issue included:

- the need for any HSAC recommendations to consider the direction being taken by the Environment Agency's Risk Management Options Analysis (RMOA)
- the lack of a coherent view on the most effective way of grouping PFAS from the committee at this point
- the need for engagement with industry professionals to make any significant progress on PFAS management
- a suggestion that progress could be made in managing PFAS by identifying and regulating the top 10, 20 or 100 most environmentally damaging chemicals as it is too time consuming and difficult to independently assess all 6000+ of these chemicals
- the potential health impacts of PFAS should not be underestimated and concern was raised about the limited available data on potential impacts of long-term exposures for human and wildlife health
- the recent PFAS Statement from the Committee on Toxicology was highlighted and the importance of accounting for this in an HSAC recommendation was noted
- the need for manufacturers to provide transparent data to prove the safety of PFASs before they are used
- there was debate over the ultimate need of society for non-reactive, water repellent chemicals that would inevitably be difficult to break down in the environment and their 'essentiality'
- the question was raised about whether there is sufficient concern to ban PFASs or whether more research and data was needed
- there were comments on the direction of travel for PFAS regulation and feel that due to their persistence that they would likely be heavily restricted in the future anyway. The broad ban of PFAS in Maine, USA was highlighted
- there was debate over the need for swift action with clear restrictions to incentivise industry innovation to develop alternatives vs the need for alternatives to be available to enable regulation and the concern for regrettable substitution and limited safety data on the new compounds
- it was suggested that PFAS should be used as a 'model compound' to help set the stage on how HSAC responds to these similar chemical challenges. The question was posed: 'What can we learn to change our ways of working going forward?'

Defra provided an overview of the PFAS situation relating specifically to policy implications and notes that the Environmental Agency is still carrying out Risk Assessments.

They stated that the Risk Management Options Analysis would be published in 2022 and explained that future policy decisions will be guided by the outcomes of the RMOA after further engagement with industry leaders to discuss potential issues.

A meeting will also be held with the Royal Society for Chemistry on 14 July 2021 with industry figures to discuss work currently underway. A brief mention was made of the European Union's plans to bring in broad restrictions of PFAS chemicals.

Actions

- Chris Collins to collate comments from the topic discussed into a document to circulate to members of HSAC prior to the next meeting on 16 September. This will then be reformatted into a 2 page HSAC document

5. Input to the Environment Agency's development of a UK PFAS Risk Management Options Analysis (RMOA) scoping discussion

There was some concern from members that the committee did not have the relevant expertise to adequately debate this issue.

The Environment Agency was seeking HSAC's views on the scope and approach of their Regulatory Management Options Analysis (RMOA) for PFAS.

Richard Dean explained that RMOA is a tool to be used by UK REACH (Registration, Evaluation, Authorisation, and restriction of Chemicals) that can develop regulatory approaches for managing PFAS risks in the UK context. RMOA was described as a 'technical assessment' which the UK government is not obligated to follow.

They set a series of questions for discussion:

What is HSAC's view on the RMOA excluding consideration of occupational exposure to PFAS, or risks from direct consumer exposure via cosmetics and personal care products, pharmaceuticals, DIY activities?

It was HSAC's view that these should be included in the RMOA.

What is HSAC's view on the RMOA including consideration of environmental emissions of PFAS used in pharmaceuticals, PPPs, and veterinary medicines, such as substances regulated outside the REACH regime?

It was HSACs view that PFAS's outside of the REACH regime should not be excluded.

Does HSAC agree with the proposed approach to PFAS definition and grouping?

HSAC questioned whether the Environment Agency is confident that grouping by structural similarity will capture problems? Do we know enough about their properties?

Does HSAC have any other comments on the approach or scope of the RMOA?

The Environment Agency may wish to consider the use of a risk ranking system for presenting information in the RMOA (see Donnachie et al, 2014).[1]

It was suggested that consideration of risk should include the pathway of exposure and not just the magnitude of emissions or production tonnage.

It was suggested that the Environment Agency could also consider the analysis of human and wildlife biobanks to demonstrate which PFAS are most abundant or of most concern and assess changing trends over time.

HSAC highlighted the need for international cooperation on PFAS due to their high persistence and mobility. They are not an isolated problem.

Centre for Environment, Fisheries and Aquaculture Science (Cefas) shared a series of Canadian case studies on PFAS 'case studies to demonstrate how omics can inform regulatory decision making' from the Organisation for Economic Co-operation and Development (OECD), including a case study on grouping which maybe of relevance to the RMOA and the HSAC recommendations.

It was noted that the concept of 'essentiality' will not be in scope of the RMOA and that this will be within Defra's remit. Defra noted that the RMOA is a technical document designed to be combined with other work as part of a management process, but that this is a work in progress.

Actions

- the secretariat is going to collate HSAC's feedback and circulate it to the committees' members for edits before it is returned to the Environment Agency by Monday 26 July

6. Long Chain Chlorinated Paraffins (Environment Agency)

Pippa Curtis-Jackson of the Environment Agency's Chemical Assessment Unit sought HSAC's opinion on whether they can conclude on the bioaccumulation of long chain chlorinated paraffins (LCCPs) with carbon chain lengths in the range C18 to 32 at all chlorination levels (30 to 70% by weight) based on evidence from the scientific literature.

Advancements in understanding has led to a need to re-evaluate the data and amend their initial conclusions to consider whether LCCPs should be classified as bioaccumulative or very bioaccumulative.

[1] Donnachie et al. (2014) sets out a rational approach to selecting and ranking some pharmaceuticals of concern for the aquatic environment and their relative importance compared with other chemicals (Environmental Toxicology and Chemistry 35 (4) pages 1021 to 1027)

Four studies from scientific journals were shared with the committee which identified high concentrations of LCCPs in higher trophic level terrestrial species. HSAC were asked to consider the validity of the conclusions drawn by these studies:

- Du, X. et al. (2019) Tissue-Specific Accumulation, Sexual Difference, and Maternal Transfer of Chlorinated Paraffins in Black-Spotted Frogs. Environmental Science and Technology 53 pp 4739-4746 https://doi.org/10.1021/acs.est.8b06350
- Du, X. et al. (2018) Short-, Medium-, and Long-Chain Chlorinated Paraffins in Wildlife from Paddy Fields in the Yangtze River Delta. Environmental Science and Technology 52 pp1072-1080 https://doi.org/10.1021/acs.est.7b05595
- Yuan, B. et al. (2019) Accumulation of Short-, Medium-, and Long-Chain Chlorinated Paraffins in Marine and Terrestrial Animals from Scandinavia. Environmental Science and Technology 53 pages 3526-3537 https://doi.org/10.1021/acs.est.8b06518

The reliability of the statistics in the Du et al. studies was questioned due to high standard deviations. It was felt that the data were insufficient to draw conclusions from as presented in the paper. It was recommended that the Environment Agency contact the authors to access the raw data sets.

The study from Yuan et al. was considered to provide more reliable evidence of high levels of LCCPs in birds of prey whilst those in mammals were much lower, indicating biomagnification through the food chain in support of the Environment Agency's concerns.

It was recommended to contact a research group in Japan who have been studying brominated chemicals in aquatic birds using a non-targeted screening approach who may have some useful insights.

Benchmarking LCCPs against known POPs, focusing on data from European biota, was also recommended.

Ioanna Katsiadaki (Cefas) also agreed to discuss the possibility of conducting some testing at their laboratories to support Environment Agency decision making on these chemicals.

Actions

- overall, the committee felt that more work would be needed to conclude on bioaccumulation of LCCPs. It was recommended that the Environment Agency reach out to a Japanese group who recently conducted non-targeted screening of organohalogens in wild birds for advice (Tue et al. 2021). [2]

[2] 'Tue, N.M. et al. 2021. Nontarget screening of organohalogen compounds in the liver of wild birds from Osaka, Japan: specific accumulation of highly chlorinated POP homologues in raptors. Environmental Science and Technology 55, 8691-8699.' https://doi.org/10.1021/acs.est.1c00357

7. Advanced Materials (AM) updates from OECD and UK workshops

The OECD has recently held workshops on Advanced Materials to provide a platform for stakeholder engagement on potential challenges of advanced materials regarding risk assessment and safe use, and their potential implications with regards to circular economy.

Gary Hutchison attended alongside the UK delegation on behalf of HSAC and provided a summary.

It was noted that improving sustainability of Advanced Materials is made more difficult by their complexity.

Further work is required to lay a framework for future classifications as regulators are not prepared for the pace of change. There needs to be clarity on what is defined as ‘hazardous waste’ and an ‘advanced material’.

Gary set out ways in which the UK can prepare for future issues with advanced materials through the development of early warning systems, and recommended the UK follow Germany’s approach to set up a dedicated inter-agency group assigned to AM.

The European Commission have shown themselves to be keen to develop a framework for Safe and Sustainable Design (SSD). There is also set to be a review of Networked European Software and Services Initiative (NESSI) protocols. There is to be an effort made to bring together the existing approaches to improve risk assessments.

The next steps will be to create model case studies that can be used to guide future thinking on early warning systems, risk assessments and regulation. There is an opportunity for major amounts of cooperation and discussion at all levels that we should not pass up.

Fatima Nasser (Defra) presented an update on a UK workshop on Advanced Materials.

This was part of the creation of a UK knowledge sharing community to share views on the benefits of this new technology, including the societal benefits that may arise from them and the potential obstacles to their wider adoption.

This was led by an organising committee of Defra, National Physical Laboratory, Health and Safety Executive, Public Health England, BREC Solutions and British Standards Institute.

Fatima highlighted several discussion points from the workshop:

- future EU funding and priorities will be centred around Advanced Materials and not uniquely on nanomaterials. The sustainability and possibility of a circular economy with advanced materials and nanomaterials are high priorities

- advanced materials and nanomaterials take 10 years to develop and a further 10 years to exploit them in applications. The speed of development and innovation remains

ahead of attempts at regulation and potentially toxic substances are being created in the µm-nm ranges

- further research must go into assessing the life cycles of advanced materials. Those being created will be outside of existing regulations and there has not been enough consideration for the potential exposure pathways and the potential consequences. Developing methods to detect and monitor emissions should be encouraged

The committee questioned the sustainability of nanomaterials. Fatima noted that there are currently no recycling solutions available for advanced materials and that a national initiative may be required to make progress on this issue.

Incentives could be offered to encourage industry to incorporate sustainability into its business model. A drive to increase consumer knowledge of these sustainability issues to create a natural demand regarding sustainability of these materials.

The committee expressed some concerns about the potential risks associated with advanced materials due to their complexity. But also noted that we cannot ignore the issue climate change poses and innovation will be crucial for adaptation.

The importance of biomonitoring in understanding impacts on wildlife and human health was discussed. Susan Owens asked what work is being done currently to encourage public engagement. Well-designed public engagements in these areas can help inform innovation and noted that this had been conducted for nanomaterials in the past.

Fatima noted that a second workshop would take place in February 2022 with an aim to include case studies from industry professionals that would enable more open discussions with regulators.

Copies of the OECD and UK Workshop Reports are included in the meeting pack

Actions

- HSAC members to be invited to the second UK Advanced Materials workshop in February 2022 which will feature presentations from lawyers, industry professionals and other regulatory bodies to further discuss what work needs to be done

8. New Approach Methodologies (NAMs) and the future role of animal tests in chemical regulations

In 2012 HSAC produced a Statement on the Use of Animals in Chemical Testing (PDF). Since then, there has been significant innovation in the development of non-animal methods internationally.

In this session HSAC discussed some of their perspectives on hazard assessment and considered how they could conduct future work in this space. A series of presentations were given which were included in the meeting pack:

- Chris Green (Defra) provided initial policy context highlighting the HSAC's 2012 statement, the UK's new chemical regulations the call from the Royal Society for Chemistry for the UK to become a world leader on New Approach Methodologies (NAMs) in its paper on the drivers and scope for a UK Chemicals Strategy

- Peter Matthiessen gave perspectives from his work as the co-chair of the OECD's Validation Management Group on Ecotoxicity (VMG-eco) - He described the increasing number of In Vitro and In Silico methods that are being integrated to develop new approaches to testing with an aim to integrate results from multiple methods for greater accuracy

- Peter discussed OECD Test Guideline 249 (the defined approach to skin sensitisation) as an example of new non-animal necessary Test Guidelines and outlines advantages of a harmonised Integrated Approach to Testing and Assessment (IATA) approach. Peter called on committee to recognise the increasing number of non-animal methods that will be used in the future

- John Colborne and Stewart Owen discussed how the 2012 HSAC Statement could be updated and what has changed since. They felt it could be updated to incorporate NAMs, use more positive language and set an ambition to raise the 3Rs (Replacement, Reduction and Refinement) up the agenda

- they discussed New Approach Methodologies and different definitions from European Chemicals Agency, the UK's Committee on Toxicology, and the US Environmental Protection Agency (EPA). There is an opportunity to work internationally through the US EPA's Accelerating the Pace of Chemical Risk Assessment (APCRA) initiative and the EU Horizon 2020 Precision Toxicology project (2021 to 2026)

- Olivia Osborne from the Food Standards Agency (FSA) described the NAMs roadmap developed by the FSA for the UK Committee on Toxicology and how it will be compliment other scheduled work

There is a belief at FSA that the science has already been completed and there is now a need for progress these methods within regulatory systems. There is also a belief that this progress will not be publicly accepted without a concerted extra push for transparency from agencies.

The committee agreed that an update to the 2012 HSAC Statement would be timely, general comments from the committee included:

- that there is an opportunity for the UK to take a leading role internationally on NAMs
- the need to build a trusted database on use of NAMs to start a progressive change to their uptake in risk assessment that can bring other nations on board
- the application of tiered approaches to risk assessments with grouping based on mode of action and testing of class representative compounds
- the need for clear guidance in any HSAC recommendations must be 'ecological realism' and clarity on what new methods can and cannot do (their limitations). The ability of NAMs to identify chronic toxicity with potentially major ecological implications, for example effects on behaviour, reproduction or olfaction was questioned
- the potential for a cross-research council initiative, perhaps involving the Biotechnology and Biological Sciences Research Council, Natural Environment Research Council, and others. It was asked whether the Defra Chief Scientific Advisor could support this
- the importance of engaging the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs) in work on this topic

The Environment Agency expressed support for tools that reduce animal testing. However, they highlighted the need for a global perspective. Dossiers on chemical risk are produced for an international community.

If one country needs an animal test for their regulations, then it will be carried out. It is then prudent for other regulators to use this data when it is available.

They felt that regulators need assurances on how well the new approaches work and highlighted the importance of OECD validation (for example, for defined approaches and by developing quantitative adverse outcome pathways).

It should be recognised that existing testing and assessment approaches also carry their own (sometimes quite high or unknown) levels of uncertainty and variability, it is just that regulators have gotten used to dealing with these.

NAMs therefore only really needed to be as good as or ideally better than existing approaches in terms of minimising uncertainty and variability and it would be useful to explore such comparisons in greater detail. The Environment Agency offered to send HSAC some further thoughts on the regulatory acceptance of NAMs.

The FSA suggested considering the One Health approach when considering this challenge.

They also informed the committee that they would be running a workshop on their roadmap in October 2021 and would invite HSAC members. This intends to discuss future challenges and understand the need for policy changes.

Actions

- the committee agreed to produce an update to the 2012 Statement on the use of animals in chemical testing. John Colborne, Stewart Owen, and Peter Matthiessen will lead the work
- a skeletal draft is requested in advance of the meeting on 16 September. The secretariat will set up a short meeting with Defra policy officials to discuss the pathway to impact for the paper with regards to new UK regulations and the Chemicals Strategy

9. Discussion on climate change, biodiversity loss and how pollution can be brought up this agenda

A 12 person scientific steering committee was assembled by the Intergovernmental Science and Policy Platform on Biodiversity and Ecosystem Services (IPBES) and the Intergovernmental Panel on Climate Change (IPCC).

They participated in a 4 day virtual workshop to examine the synergies and trade-offs between biodiversity protection and climate change mitigation and adaptation which published a report in 2021.

This represents the first ever collaboration between the 2 intergovernmental science and policy bodies. In the absence of a science to policy interface organisation for pollution, this additional global challenge was secondary.

The United Nations Environment Programme's (UNEP) Making Peace with Nature report has described biodiversity loss, climate change and pollution as three interlinked planetary crises.

HSAC discussed the need to bring pollution up the agenda domestically and internationally and felt it was time it was recognised as a global challenge.

They highlighted that climate change was not synonymous with environmental concern alone and that if biodiversity loss was a high priority, then pollution must be as well.

They noted that there had been a lot of progress in reducing gross pollution issues but that we were still challenged by more complex, insidious chemical challenges.

Andrew Johnson's paper on the British River of the Future was discussed as an example of how climate change could impact 2 contrasting river ecosystems in the UK.

Ioanna Katsiadaki (Cefas) recommended contacting the Woods Hole group in the US to discuss their One Health approach for pollution and their international agenda.

Actions

- the committee agreed that pollution should be elevated up the agenda alongside climate change and biodiversity loss and that they should draft a short statement asserting its importance as an issue

- Iseult Lynch will lead and collate the comments from committee and bring them together in some bullet points in a skeleton draft before the meeting on 16 September. to the secretariat will find out how HSAC could engage with COP26 (12 November 2021)

10. Thank you to Gary Hutchison

Gary is leaving the committee after 2 terms and additional extensions having joined the committee in 2013.

He was thanked by the committee and Defra for his efforts and public service over the years in pursuit of high quality independent scientific advisory on chemicals the value of his perspectives and expertise on nano and advanced materials was particularly noted.

Annex A

Attendance list

HSAC members

1. Christopher Collins
2. John Colborne
3. Michael Depledge

4. Gary Hutchison
5. Iseult Lynch
6. Andrew Johnson
7. Peter Matthiessen
8. Stewart Owen
9. Susan Owen
10. John Sumpter

Secretariat

- Chris Green (International Chemicals Team)
- Fatima Nasser (International Chemicals Team)
- James Kearney (Stakeholder Engagement Team)
- Jamie Comer (International Chemicals Team)

Defra policy officials

- Kay Williams (International Chemicals)
- Ellie Bates (International Chemicals)
- Gintare Masiulyte (Chemicals Strategy)
- Mary Tomlinson (Chemicals Strategy)
- Ruth Coward (Chemicals Policy Team)
- Edward Latter (Chemicals Policy Team)
- Gersh Rai (Chemicals Policy Team)
- Rachel Mumba (International Chemicals)
- Julia Sussams (Evidence Team)
- Liz Lawton (Persistent Organic Pollutants and Chemicals in Waste Team)

Defra agency representatives

- Ioanna Katsiadaki (Cefas)
- Simon Hoy (Environment Agency)
- Richard Dean (Environment Agency)
- Pippa Curtis-Jackson (Environment Agency)
- Amelia Charles (Environment Agency)
- Morne Van Der Mescht (Environment Agency)

Other government department and agencies

- Ovnair Sepai (Public Health England)
- Olivia Osborne (FSA)

Devolved administrations representatives

- Adam Wadding (Welsh Government)
- Adriana Kiss (Welsh Government)
- Martin McVay (Welsh Government)
- Eloise Procter (Welsh Government)

- Peter Reid (Scottish Government)
- Caroline Barry (Northern Ireland Government)
- Siobhan Fitzpatrick (Northern Ireland Government)

Observers

- Camilla Alexander-White (Royal Society of Chemistry)