Department
for Environment,
Food & Rural Affairs

Hazardous Substances Advisory Council Biannual Review

Updates on the work undertaken by the HSAC over the last six months

January 2025

Issue 1

We are responsible for improving and protecting the environment. We aim to grow a green economy and sustain thriving rural communities. We also support our world-leading food, farming and fishing industries.

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Chair's Welcome

As Chair of the Hazardous Substance Advisory Committee (HSAC) I am delighted to welcome you to this first biannual review showcasing the breadth and diversity of our activities and opinions over the past year.

I joined the HSAC in April 2022 and was appointed as Chair in April 2023, and am thus coming close to 2-years in this role, which has been fantastic! The complexity of the topics we are asked to give our opinion on, which reflects the diversity of the remit of the Chemicals, Pesticides & Hazardous Waste team at Defra - is enormous, covering all environmental compartments [air, soil, water (fresh and marine), urban and waste] and the whole spectrum of chemicals and pollutants – from plastics to pesticides, from suspected harmful and emerging chemicals to legacy pollutants that are embedded into products of all types and for which there are no easily available alternatives. The challenges are many and the pace at which data is emerging is accelerating, requiring increasing effort to be spent on "evidence synthesis" or compilation of available knowledge in order to draw meaningful conclusions regarding the safety or otherwise of chemicals.

It would be remiss of me not to acknowledge the enormous amount of preparatory work that goes into compiling, reviewing and interpreting the documents that we as HSAC comment – whether it is Defra's policy team themselves, the Chief Scientist's Group at the Environment Agency or consultants hired to synthesise evidence on a specific topic. The quality of the documents we review, and the commitment to excellence is evident in all documents that we provide an opinion on. It is easy to critique the work of others, and while we inevitably find something to suggest or clarify, we are always hugely impressed at the quality of work and the time invested by the policy teams involved.

In addition to the commissions that come from Defra and its agencies and arms-length bodies, we as HSAC also determine topics that we think are of strategic importance and thus that we think Defra should be preparing for. One example of this is the Brief on New Approach (or non-animal) methodologies (NAMs) where HSAC identified a number of opportunities for UK Inc. to take a leadership role in moving from the classical substance-by-substance hazard and risk assessment to an adaptive and progressive NAMs-based regulatory framework where chemicals can be grouped based on similar modes of action, for example, and where chemicals mixtures can be tackled meaningfully. During 2025, HSAC will build upon these initial recommendations through a set of case studies demonstrating how NAMs can be effectively used in regulatory decision making.

This first HSAC biannual review is part of the strategy defined in 2024 to increase the transparency of the work that HSAC does, without breaching confidentiality or disclosing sensitive information. Topics considered in 2024 included a review of the recent literature on oxy-biodegradable plastics, consideration of the human health impacts of flame

retardants, some initial discussions on the potential environment threats from unexploded ordinance (military waste) dumped into the ocean at the end of World War II that could be a ticking time-bomb, and considered some specific chemical types for further investigation. A lot of fascinating topics for us to consider, some of which will continue to be explored in 2025.

Together with my colleagues in the Chemicals Team at Defra and the HSAC members, I hope that you find this review useful, and an excellent complement to the HSAC meeting minutes, which are made available on the HSAC website once approved shortly after each meeting.

Iseult Lynch

University of Birmingham / Chair HSAC

Publications

Recommendations for the Adoption of New Approach Methodologies (NAMs) in UK Chemical Regulation

In 2012, Defra's Hazardous Substances Advisory Committee (HSAC) prepared an opinion on New Approach Methodologies (NAMs), which indicated that the scientific basis was not yet sufficiently advanced for NAMs to replace traditional animal tests. In 2024, Defra invited the HSAC to provide an updated opinion and recommendations on the adoption of NAMs for assessments of chemical safety in the UK. The HSAC evaluated the use of NAMs broadly and produced a high-level Brief focused on key recommendations for Defra regarding the adoption of NAMs for chemical risk assessment.

The key takeaways were as follows:

- The UK is well positioned to emerge as the global leader, and to achieve substantial economic benefits and high standards of human and environmental protection, in using NAMs to obtain findings that are useful for assessing and, when appropriate, regulating chemical exposures.
- NAMs are advancing, leading to better understanding of chemical modes of action and adverse outcome pathways. NAMs are presently viable for regulatory applications by improving the confidence that chemicals belong to defined groups because they induce similar biological responses as other members, as a basis for prioritisation.
- Although UK REACH currently provides a legal basis for applying NAMs, strategic implementation of a NAMs approach within UK REACH can significantly reduce, refine, and potentially replace the use of mammalian animals (the 3Rs) for chemical safety testing while improving hazard assessment robustness and efficiency.

The key recommendations were:

- Adoption of a technology agnostic definition of NAMs based on an understanding of chemical modes of action.
- Setting of criteria for NAMs to be considered within a progressive regulatory framework, beginning with criteria for their use in grouping and prioritisation.
- Application of a Progressive NAMs Regulatory Framework that utilizes NAMs for a wide range of regulatory applications as the certainty of the findings for hazard assessment increases. NAMs may already be used to support grouping of chemicals to prioritise higher-tier testing.
- Establishment of UK centres of excellence and a UK national reference laboratory for the development and validation of NAMs to ensure the uptake of technological improvements within the government and private sectors.

- Incentivisation of chemical registrants under UK REACH to provide NAMs data indicative of the modes of action of their substances to support the implementation of a “group first” approach to chemical safety assessment.

The full report can be found on the HSAC website under Publications.

Pro-oxidant Additive Containing Plastic

In 2019 the HSAC reviewed the available evidence on Pro-oxidant Additive Containing plastic (also known as PAC plastic or oxo-degradable / oxo-biodegradable plastic). The report concluded that "the literature as a whole suggests that current oxo-degradable plastics have not been demonstrated to provide a substantial improvement in terms of complete biodegradation or breakdown over existing standard plastics in the open environment”.

In early 2024, Defra's Chief Scientific Advisor asked the HSAC to undertake a review of the literature published since 2019 to assess whether sufficient evidence exists of the breakdown or biotransformation of PAC plastic under natural conditions. HSAC undertook a search of the available published literature using key search terms, restricted to papers published between 2019 and 2024. This data was supplemented with information submitted to Defra following a call for evidence in early 2024.

This report will be published on the HSAC website in Spring 2025.

The 2019 report can be found on the HSAC website under Publications.

Meeting Discussion Topics

The following topics were discussed at the July, October and December 2024 HSAC meetings.

The Effects of Flame Retardants on Human Health

Hazardous flame retardants were one of the five priorities under the UK REACH Work Programme 2022-23. The Environment Agency undertook a scoping project in 2022-24 with the aim of updating an original 2003 report, and including risk to human health via the environment. This identified several different areas for further investigation. The HSAC were asked to input their ideas on effective next steps, including consideration of how flame retardants may be grouped for action and the possible methods that could be used to determine and address potential risk.

In consequence the HSAC prepared a structured feedback document which provided advice on how to determine and characterise the level of risk to human health from flame retardants, what action is needed to address this risk, what data already exists, where the existing data gaps are and how prioritisation of different groups of flame retardants to investigate could be done.

Unexploded Ordinance - Legacy discussion on ecological effects of warfare/dumped munitions

The HSAC meetings present an opportunity for the Committee to bring topics of potential interest to Defra's attention. A recent presentation by a committee member to the Society of Environmental Toxicology and Chemistry (SETAC) on emissions from unexploded World War 2 ordinance in the Baltic Sea was prepared for the HSAC. Recent evidence has shown that the casings, which were previously preventing the release of pollutants from the inside, are now starting to degrade and the munitions are starting to release their contents into the sea. A study in the Baltic Sea has shown that these emissions are potentially causing issues in the marine environment. It is currently unclear whether this is a problem that is affecting the UK; currently there is little to no data for the UK.

The HSAC plans to revisit this topic at a later date.

Technical advice to the Environment Agency

A review of options to assess the “sufficiency” of environmental endocrine disruptor databases for regulatory purposes

The Environment Agency presented a report which sought to determine what constitutes sufficient data to allow a Predicted No Effect Concentration for endocrine disrupting chemicals to be derived for an adequate control assessment. The report concluded that there is sufficient data for this to be possible. Several approaches in the derivation of probabilistic or deterministic Predicted No Effect Concentrations were described for three data rich compounds; nonylphenol, octylphenol and 17α-ethinyloestradiol. The results were also validated against other compounds.

The HSAC provided written feedback on the report and suggestions for improvements, including further explaining the rationale behind some of the proposals for testing methodologies within the report. They also suggested that future work should consider the potential to use Non-Animal Technologies (NATs) and NAMs to align with the wider policy goals of reducing animal testing.

Screening prioritisation of benzotriazoles group

The Environment Agency commissioned a study to improve the evidence base on the Benzotriazoles group of chemicals, which are a class of organic compounds used in a diverse range of household, commercial, and industrial applications and products. The HSAC were asked to review the document and provide consolidated feedback to the Environment Agency on areas for improvement in the report.

The review identified 591 benzotriazoles across various UK and EU registers, of which 36 were identified for prioritisation based on the prevalence of use in the UK and potential hazard. These included screening for properties such as persistent, bioaccumulative and toxic (PBT), persistent, toxic and likely to be mobile in the environment, or endocrine disrupting (ED).

The report makes suggestions for further work to improve the understanding of the emissions, hazards and risk of benzotriazoles in the UK. The Environment Agency is considering the next steps.

The HSAC were impressed with the comprehensive nature of the report and its ability to consolidate a wide range of information into an easily readable format. They were supportive of the recommendation to conduct more targeted monitoring of exposure concentrations of benzotriazoles to determine the risk to the environment in the UK. They

also suggested adding an additional recommendation to continue to monitor scientific and patent literature for additional/novel uses of benzotriazoles in consumer and industrial products.