Chemicals policy and regulation update

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1. Broad policy issues

1.1 Chemicals Strategy

The government's 25 Year Environment Plan committed to a new strategy to tackle chemicals of concern and help ensure the levels of harmful chemicals entering the environment are significantly reduced. The commitment to publish a Chemicals Strategy was reiterated last week in the Environmental Improvement Plan (EIP) published on 31 January, where the government committed to publishing a Chemicals Strategy in 2023.

To help develop policy thinking across a range of chemicals issues and inform a strategy, we ran a series of workshops across 2022. These workshops explored a range of policy themes, including actions to address priority chemicals issues, international, managing chemicals in waste, effective regulation, and driving innovation and sustainable chemistry. Feedback included (but was not limited to) the importance of transparent and evidence-based decision making, the importance of the UK taking a leading role in science and regulatory expertise, and an emphasis on greater uptake of New Approach Methodologies (NAMs). Summary papers of the workshops were circulated with attendees on 31 January.

If you have not already received a copy and would like to, contact us by emailing: chemicals.strategy@defra.gov.uk.

Building on this valuable engagement, we are establishing a sub-group of the UK Chemicals Stakeholder Forum that will act as an advisory group on the developing Chemicals Strategy. This will allow government to test emerging thinking and seek feedback on the strategy content ahead of publication. The Defra team will introduce plans for this sub-group in more detail at the February CSF meeting.

1.2 Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS)

PFAS CSF Working Group

To inform our policy development on PFAS, Defra have convened the newly formed PFAS CSF Working Group. The group gives NGOs, figures within industry that are involved with the use of PFAS and others, such as experts on innovation, to share their knowledge and experiences of transitioning away from the use of PFAS. The first meeting took place in November 2022. It provided some background on the scientific context for PFAS and the challenge of regulation. Discussion centred around sharing different views or experiences of PFAS use and key factors to consider when developing policy options within different categories (circular economy, innovation, education and regulation).

The group is currently developing short policy papers that articulate:

- the common barriers and challenges of moving away from PFAS, for example, demonstration that alternative PFAS products provide the required performance level and meet standards
- the policy options available to government to accelerate leadership by industry users in moving away from PFAS and to address the most critical risks of specific PFAS
- how government can support innovation for cost-effective alternatives to PFAS

The working group currently has a life span of 12 months, which will be reviewed to see how useful the group continues to be as we near the end of 2023. The aim by the end of the 12 months is to have a set of policy options that we can take forward for further consideration and analysis. The next meeting will take place in March 2023.

PFAS is a global issue in terms of markets and transboundary risks, so we continue to look to understand the impacts of significant action happening in other jurisdictions on UK stakeholders and learn from other countries to inform our approach to PFAS in the UK. Notable in this regard is the EU's restriction dossier on PFAS. This will apply in Northern Ireland as it is still covered by EU REACH owing to the requirements of the Northern Ireland Protocol, but we would also welcome thoughts from stakeholders on what the impact of this, or other PFAS policies globally, may be for UK stakeholders recognising significant trade between Great Britain and the EU in the chemicals industry.

Send your views by email to: Fredric.Barratt@defra.gov.uk.

1.3 Unintentional mixtures

Work is ongoing to develop policy options to account for the risk from unintentional mixtures. In December 2022 Defra hosted a workshop on unintentional mixtures as part of this process. This included a presentation from the Environment Agency and the UK Health Security Agency on their recent report (Evaluation of the potential approaches to risk assessment of unintentional chemical mixtures for future UK REACH assessments), and discussions with stakeholders on potential policy options. This included consideration of applying a mixture assessment factor (MAF) in UK REACH.

The discussions helped inform our assessment of the pros and cons of this approach and allowed for discussion of alternative approaches to address the risk from unintentional mixtures. Presentation slides and a summary of the discussion are due to be circulated to participants.

If you were unable to participate but would like to receive the slides and summary, email us at jack.brown@defra.gov.uk.

2. Update from the Devolved Administrations

2.1 Scotland

Scottish Chemical Policy Network (SCPN)

The delayed seventh meeting of the SCPN took place on 29 September 2022 and included a presentation from Environmental Standards Scotland on this new body and their work.

Anyone interested in participating in the SCPN, with any issues they wish to present to the Scottish Government should email them at chemicals@gov.scot.

Analysis of responses to last year's consultation on Scotland's proposed Circular Economy Bill was published on 30 November 2022.

2.2 Northern Ireland

DAERA continues to develop Northern Ireland's first Clean Air Strategy. A synopsis of consultation responses to the Clean Air Strategy Discussion Document was published in June 2022 and a cross departmental stakeholder group, the Clean Air Strategy Interdepartmental Steering Group, has been established to further develop the scope of the strategy and specific actions. A public consultation on the draft Northern Ireland Clean Air Strategy will require approval from the Northern Ireland Executive to proceed.

2.3 Wales

The Environmental Protection (Single-use Plastic Products) (Wales) Bill continues to make its way through the Welsh Parliament. The bill makes it an offence for a person to supply or offer to supply (including for free), a range of commonly littered and unnecessary single-use plastic products to consumers in Wales and provides local authorities with enforcement powers.

The Welsh Government has just launched a consultation on a mandatory licensing scheme for acupuncture, body piercing, electrolysis and tattooing. This consultation closes on 19 April and may be of interest to anyone involved with the proposed UK REACH restriction on hazardous substances in tattoo inks.

3. UK REACH: Update from Defra

3.1 Transitional registrations

In December 2021, Defra committed to consulting on extending submission deadlines, to allow time to develop an alternative model for transitional registration, and if the decision is made to proceed, to develop and pass the necessary legislation. It is also necessary to allow industry time to comply with any new arrangements.

Defra carried out a public consultation last year on extending the current deadlines for transitional registrations, seeking views on:

- two options to extend the current deadlines for transitional registration
- extending the dates for the Agency (HSE) to carry out compliance checks on 20% of registration dossiers

Defra published the summary of responses and government response on 29 November, indicating that the submission deadlines would be extended to 2026, 2028 and 2030 depending on tonnage and hazard profile.

3.2 Additions to the authorisation List

The UK Agency , The Health and Safety Executive (HSE) provided its final recommendation of priority substances to be included on the Authorisation List (Annex 14 – the list of substances subject to authorisation) in December 2021.

Defra, Scottish Government and Welsh Government held 2 joint calls for evidence on the proposed 2 substances. We published the summary of responses to the calls for evidence of dicyclohexyl phthalate and disodium octaborate on 16 December 2022. The Defra Secretary of State will make a decision on whether these substances should be included on the authorisation list in due course. any decision to update the authorisation list would require consent from Scottish and Welsh ministers.

3.3 Decision-making on applications for authorisation

Defra has received four final UK authorisation application opinions from the UK Agency. Defra's Secretary of State has made decisions to grant authorisation on 2 of these applications and will make decisions on whether to grant the remaining applications in 2023. Consent from the Scottish ministers and Welsh ministers is required for decisions where the matter relates to areas of devolved competence.

Defra ministers have made decisions, with consent from the Scottish and Welsh ministers, on 9 transitional applications for authorisation. These applications were from Great Britain - based companies for which ECHA had adopted a final opinion, but the European Commission had not made a final decision before the end of transition period. Details of these applications and the decisions made are available on GOV.UK.

2.4 UK REACH Work Programme

In November 2022, Defra held a workshop with stakeholders to collate views on draft principles for prioritisation, and on priority chemical issues to address. The workshop was attended by 20 external stakeholders, comprising a mix of representatives from trade associations, individual businesses, consultancies, academics and NGOs. Key themes included:

- transparency in decision-making
- an evidence-led approach to prioritisation
- prevention of public health impacts and long-term, irreversible damage to the environment

Following the workshop, Defra is meeting with other government departments and regulators involved in chemicals regulations, and with HSE, the EA and Welsh and Scottish governments to determine priorities for the 2023/2024 UK REACH Work Programme, subject to agreement from the Defra Secretary of State, Welsh and Scottish Ministers.

PFAS Regulatory Management Options Analysis (RMOA)

As part of the UK REACH Work Programme for 2021 to 2022, Defra asked the EA and HSE to examine the risks posed by PFAS and develop an RMOA. HSE have been working with the Environment Agency to finalise the RMOA after the call for evidence closed in January 2022. HSE are aiming to publish the RMOA in Spring 2023. Defra and the Devolved Administrations will carefully consider its recommendations to inform future PFAS policy.

3. UK REACH – Update from the UK Agency (HSE)

4.1 UK REACH Independent Scientific Expert Pool (RISEP)

HSE published the RISEP list on 12 October 2022. HSE have recruited 36 experts who advise on the safety of chemicals and support the agency's scientific opinions.

4.2 UK Agency's Accredited Stakeholders

Since April 2021, stakeholders have been invited to apply for Accredited Stakeholder Organisation (ASO) status.

HSE has recruited 54 ASOs from industry and NGOs. The accredited stakeholders have been able to attend all formal meetings of RISEP and any relevant challenge panels to date.

There is no closing date for the ASO process and stakeholders can apply at any time. Details on how to apply can be found on the Get involved in UK REACH page.

4.3 UK REACH restriction proposals

HSE announced the extension to the lead in ammunition restriction process by 6 months on 5 January 2023. This decision follows the public consultation receiving 2,759 responses, including many detailed and technical submissions that need to be worked through.

The restriction proposal for tattoo inks and permanent make-up, which was also published on 6 May 2022, will follow their original timescales.

4.4 UK REACH Authorisation Applications

HSE is currently working through the thirteen applications for authorisation received from May to June 2022. RISEP challenge panels will be held for these later in the year.

Five new applications were submitted to HSE in December 2022 to January 2023, consultations on alternatives will begin in due course.

A further 23 applications are expected by the end of April 2023.

Final agency opinions were sent to the appropriate authorities in December for 2 of the substances (AFA005 and AFA007) and a third (AFA006) will be completed in the coming months.

Further information on the applications can be found on the HSE website.

4.4 Environmental Audit Committee (EAC)

In November 2022, Dr Richard Daniels, Director of Chemicals Regulation Division, gave oral evidence alongside Rebecca Pow MP and Gabrielle Edwards (Defra), to the EAC with regards to progress in implementing UK REACH.

4.5 Public Accounts Committee (PAC) response

In December 2022, HSE provided a response to the PAC recommendations following the committees report into regulation after EU Exit.

4. International Chemicals: Multilateral Environmental Agreements (MEAs)

The Triple Conference of the Parties (COP) to the Basel, Rotterdam and Stockholm (BRS) Conventions will take place from 1 to 12 May 2023. Parties will consider standard joint agenda items related to programmes of work and budgets and elections of officers, in addition to substantive agenda items related to the implementation of each individual convention.

5.1 Rotterdam Convention – Prior Informed Consent (PIC)

The Rotterdam Convention creates legally binding obligations for the exchange of information between Parties when certain hazardous chemicals and pesticides are traded internationally. This is known as the PIC procedure.

Triple Conference of the Parties (COP)

Parties will consider the listing of 7 chemicals in Annex III of the convention. These include terbufos and iprodione, which are being proposed for listing for the first time, in addition to carbosulfan, chrysotile asbestos, fenthion, paraquat, and acetochlor, which have all been deferred from previous meetings due to a failure to reach consensus. Any chemicals listed in Annex III of the convention become subject to the convention's PIC procedure.

Parties will also consider a proposal to amend the Rotterdam Convention. The proposal aims to address the COP's inability to agree to list several chemicals in Annex III of the Convention, despite the Convention's scientific body, the Chemical Review Committee (CRC), determining that they have met the scientific criteria.

5.2 Stockholm Convention – Persistent Organic Pollutants (POPs)

The UN Stockholm Convention on POPs agrees global bans of substances that fulfil the POPs criteria and requires all stockpiles and waste containing POPs to be identified and disposed of so that the POPs are destroyed or irreversibly transformed.

Triple Conference of the Parties (COP)

Parties will consider the listing of 3 substances to Annex A (elimination) or B (restriction) of the Stockholm Convention: UV-328, Methoxychlor, and Dechlorane Plus. They will also consider amendments to Low POPs content limits (LPCL) in waste such as, 'waste concentration limits,' as given in the technical guidelines of the Basel Convention, which Parties to the Stockholm Convention must consider, for several POPs, including some that do not yet have agreed international limits. The EU introduced new waste concentration limits into their legislation in late 2022, and it is anticipated that they will be pushing for these limits to be agreed internationally by the COP.

Public consultation

We intend to launch a public consultation in Spring 2023, seeking views and evidence regarding proposed changes to the retained POPs Regulation (2019/1021 - as amended by 2020/1358 and 2022/1293). Responses to this consultation will be used to inform decisions on future changes to the regulation for a number of different POPs in relation to waste concentration limits, specific exemptions, and exemptions for unintentional trace contaminants.

Further details and deadlines will be published on GOV.UK and shared with the CSF.

Persistent Organic Pollutants Review Committee (POPRC) 19

The POPRC is the science-facing arm of the Stockholm Convention process and considers technical criteria for whether substances meet the criteria for listing as POP.

The three substances that were considered at the risk profile stage at POPRC18 last September - long-chain perfluorocarboxylic acids (LC-PFCAs), chlorpyrifos, and the UK-led nomination MCCPs - will also be considered by POPRC at the next meeting in October 2023, following recent evidence-gathering. MCCPs and LC-PFCAs will be considered at the risk management evaluation stage (socioeconomic considerations), but chlorpyrifos will again be considered at the risk profile stage (scientific criteria).

These documents are currently being drafted by POPRC parties, led by the UK in the case of MCCPs, and there will be an opportunity to comment on these draft documents in March to April 2023. Further details and deadlines will be published on GOV.UK and shared with the CSF.

POPs in Soft Furnishings Waste

The research report by the Environment Agency that involved analysis of nearly 1,000 samples of waste soft domestic seating was released to stakeholders in October 2021. Defra continue to work with a stakeholder group (including representatives from the waste industry, furniture industry, charity sector, local authorities, and devolved administrations) as waste managers implement changes to ensure they are compliant with existing regulations on POPs.

In December 2022, the Environment Agency published guidance on how to comply with the legal requirements in managing soft furnishings waste containing POPs.

Alongside the guidance, the Environment Agency also provided 3 Regulatory Position Statements (RPSs) that are designed to help local authorities dispose of this waste appropriately whilst they work on fully compliant solutions. The Environment Agency also sent a second letter providing clarification to the first letter sent in August 2022.

We are monitoring a number of risks, including the potential for disruption to waste services. Where there is temporary disruption, the Environment Agency has worked rapidly and closely with the local authority and waste contractor to support them in finding compliant waste management solutions. The Environment Agency have set up a resolver group of technical experts to solve emerging issues with complying with the guidance.

Our consultant-led research project has been working to develop a deeper understanding of how organisations will achieve compliance and the longer-term socioeconomic impacts of that. This project is now in data analysis phase, and we expect to discuss headline figures of the report at our next working group meeting in February 2023.

5.3 Basel Convention – Control of Transboundary Movements of Hazardous Wastes and their Disposal

The overarching objective of the Basel Convention is to protect human health and the environment against the adverse effects of hazardous wastes. The convention aims to control movements of hazardous waste between nations, preventing the transfer of hazardous and other problematic wastes from developed to less developed countries and protecting human health and the environment from adverse effects from these wastes.

Open Ended Working Group (OEWG-13) and Triple COP

The OEWG-13 meeting, which will be held from 21 to 23 February, is an important technical gathering of regulatory and policy experts, during which discussions will be held to advance texts that will be negotiated and agreed at the subsequent Triple COP in May 2022.

All discussions at OEWG-13 will feed into the development of UK negotiating positions for the Triple COP, where it is likely the following four issues will continue to be our priorities:

1. Progressing work on the technical guidelines for environmentally sound management (ESM) of plastic wastes, which is a priority for the UK given the current high profile of plastic waste and our role as a co-lead country in developing the guidelines.

2. Progressing work on developing the technical guidelines on the ESM of wastes consisting of, containing or contaminated with POPs.

    a. These guidelines provide supporting guidance to parties on specialist disposal of all POPs. The updating of these guidelines (and others) is a regular process under the convention, ensuring new technologies, science or approaches are reflected.

    b. We anticipate the focus of discussion at OEWG-13 will be around Low POP Concentration Limits (LPCLs). Agreement of LPCLs has been challenging, with developed countries favouring higher limits and the African Union (amongst others) favouring lower ones.

    c. The UK supports most of the technical updating of the guidelines, but we are not yet able to agree specific LPCLs in the document as we are in the final stages of collecting and reviewing evidence to inform a negotiating position at the Triple COP. At OEWG-13 we intend to share our expertise and emerging evidence and assess the positions of other parties on the key issue of LCPLs.

3. Ensuring progress on the development of a clear, achievable and time-bound set of metrics in the new Strategic Framework.

4. Increasing our understanding of the issues around proposed amendments to annexes of the Convention and potential impacts on UK business and regulators.

There will also be discussions on other technical guidelines, such as the ESM of waste lead acid batteries and used and waste tyres, which are currently being updated. However, work on these documents is at a much earlier stage and we do not anticipate that these guidelines will be subject to substantive negotiations until COP-17 in 2025.

Once adopted by the Basel COP, technical guidelines establish the internationally accepted best practice for the environmentally sound management of a particular waste. Although they are not legally binding, our position is to ensure guidelines that are aligned with the legislation, policy and practise of all four UK jurisdictions, and which do not go further than the convention’s legally binding obligations.

6.International Chemicals: Voluntary international initiatives

6.1 The Strategic Approach to International Chemicals Management (SAICM) and the Beyond 2020 framework on chemicals and waste

After a successful meeting of the first part of the fourth meeting of the Intersessional Process (IP4.1) for the Beyond 2020 (B2020) framework, a continuation of SAICM, in September 2022, we are now preparing for its second part (IP4.2) that will take place from 27 February to 3 March in Nairobi, Kenya. Its aim is to finalise preparation of a single text for adoption at the fifth meeting of the International Conference on Chemicals Management (ICCM5) which is scheduled to place 25 to 29 September 2023 in Bonn, Germany.

In our preparations, we have been focussing on the UK's negotiating positions on the 28 draft, politically binding targets on the table, which will support delivery of the B2020 framework's goals. Defra has led extensive engagement with other government departments and industry and other external stakeholders.

On 23 November, the CSF B2020 sub-group met to discuss targets and resource mobilisation and finance. The group reflected on the importance of ensuring targets balanced ambition with realism such as, a target which seemed too aspirational in nature could fail to prompt any specific action against it.

There were doubts raised over the realism of 2030 targets for all countries, and over the number of targets, with 28 considered too many. Another broad reflection was of the importance of downstream engagement in the process, including small and medium sized enterprises, as the eventual customers of chemicals companies and with potentially greater agility to implement change.

Going forward, international negotiators will also be finalising a process for nomination and review of so-called 'Issues of Concern,' developing indicators, agreeing a high-level political declaration and drafting further resolutions for adoption at ICCM5.

6.2 Science-Policy Panel (SPP)

In March 2022, a resolution at the United Nations Environment Assembly (UNEA) 5.2 was passed to establish an independent, intergovernmental science-policy panel (SPP) to further contribute towards the sound management of chemicals and waste, and to prevent pollution. The intention is that the panel will be of similar stature to the Intergovernmental Panel on Climate Change (IPCC) and the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services (IPBES) increasing the public and policy profile of chemicals and pollution.

The first stage in the negotiations of the new Panel will consist of several adhoc Open Ended Working Groups (OEWG). The SPP OEWG1.2 is taking place from 30 January to 3 February, discussing the panel's scope and principal functions. An update on progress and next steps will be given at the February CSF meeting, with opportunities shared to feed into later negotiations.

6.3 Partnership for the Assessment of Risk from Chemicals (PARC)

PARC is a research and innovation programme under Horizon Europe to support EU and national risk assessment and risk management bodies with new data, knowledge, methods, networks, and skills to address current, emerging, and novel chemical safety challenges.

Work on PARC started in May 2022, and we have UK teams (from government and academia) who are active in all the work packages. Our structures for UK coordination of PARC activities are now fully up and running. This includes a steering group (with one representative from each UK partner) and the national hub (with all those in the UK working on PARC invited).

The steering group met ahead of the PARC Governing Board meeting to agree UK points to make at this highest level of PARC governance. Defra represents the UK on this board and attended in November. Main items discussed were to review reporting outputs so far and the strategic forward look for the programme.

A recently published article explains more details of the work packages and tasks that PARC will deliver (Marx-Stoelting, P., Rivière, G., Luijten, M. et al. A walk in the PARC: developing and implementing 21st century chemical risk assessment in Europe. *A*rch Toxicol (2023).), and there are dedicated plans that look to establish "a strategy to ensure timely and effective communication and dissemination of PARC outcomes to research communities and all stakeholders, including the general public, regulators and policy makers".

7.OECD's Environment, Health, and Safety (EHS) Programme

The Organisation for Economic Co-operation and Development's (OECD) EHS programme covers the safe use of chemicals, nanomaterials, pesticides, biocides, and products of modern biotechnology. It aims to protect health and the environment, while avoiding duplication of effort, ensuring that efficiencies are made and barriers to trade avoided. Defra continues to have oversight of the EHS programme, co-ordinating collective input from across UK government and external stakeholders.

Work on New Approach Methodologies (NAMs) – innovative non-animal chemical testing methods – is accelerating within the EHS programme, with the aim of providing methods with enhanced speed, efficiency, robustness and, human- and species- specific, relevance for chemical assessment that will best protect human and environmental health, meet increasing assessment demands, and reduce reliance on animal testing. The UK is an active participant within these programmes of work, including on the Test Guidelines Programme (TGP), where the UK continues to lead and contribute to development of test methods.

In December 2022, the Working Party for National Coordinators of the TGP (WNT) held a closed workshop to identify where TGP practice and process could evolve to best meet the new challenges posed by emerging science and technologies and remain relevant and useful to support country chemicals regulations. Preparatory webinars and previous discussion identified 6 priority issues relevant to NAMs development, which formed the basis for the workshop. These included:

1. Evaluating test method readiness for validation and regulatory application
2. Evolving the concept of Performance standards
3. How to handle non-stand-alone methods on the TGP
4. Developing guidance on validation of batteries of assays
5. Recruiting laboratories for validation studies
6. Better reporting of validation and TG study results

The outputs of the workshop, including recommendations for evolution of the programme and recordings of the preparatory webinars, will be published and made publicly available (expected early to the middle of 2023).

The next meeting of the WNT will be held 25 to 28 April 2023, with the UK being represented by UKHSA and Defra. Countries will provide updates for current test guideline projects, and national coordinators will vote on admission of proposed projects to the programme and adoption and publication of completed test guidelines and guidance documents.

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