# The Agency for UK REACH
## *Work programme*
## *2021/22*

**The Agency for UK REACH Work Programme 2021/22**

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# Contents

## Acronyms

| | |
|---|---|
| 2,3-DBPA | 2,3-Dibromo-1-propanol |
| APCRA | Advancing the Pace of Chemical Risk Assessment |
| BEIS | The Department for Business, Energy and Industrial Strategy |
| BMP | 2,2-Bis(bromomethyl)propane1,3-diol |
| CAU | Chemicals Assessment Unit |
| CLP | Classification, labelling and packaging of substances and mixtures |
| CRD | Chemicals Regulation Division |
| DAERA | Department for Agriculture, Environment and Rural Affairs |
| DAs | The Devolved Administrations |
| DEFRA | Department for the Environment, Food and Rural Affairs |
| DEHP | Bis(2-ethylhexyl) phthalate |
| DfE | Department for the Economy |
| EA | The Environment Agency |
| ECHA | European Chemical Agency |
| ELG | Enforcement Liaison Group |
| FTE | Full-time equivalents |
| GB | Great Britain |
| HSE | Health and Safety Executive |
| ISA | Independent scientific knowledge and advice |
| IUCLID | International Uniform Chemical Information Database |
| LADs | Latest Application Dates |
| LAs | Local Authorities |
| NAMs | New and alternative methodologies |
| NGOs | Non-governmental organisations |
| NPEO | Nonylphenol ethoxylate |
| NRW | Natural Resources Wales |
| OECD | The Organisation for Economic Co-operation and Development |
| OPEO | Octylphenol ethoxylate |
| OR | Only representative |
| PBT | Persistent, bioaccumulative and toxic |
| PDDP | Phenol, alkylation products (mainly in para position) with C12-rich branched or linear alkylchains from propene oligomerisation, covering any individual isomers and/ or combinations thereof |
| PEWS | Prioritisation and Early Warning System |
| PFAS | Polyfluorinated alkyl substances |
| PIC | Prior Informed Consent |
| POPs | Persistent Organic Pollutants |
| PPORD | Product and process orientated research and development |
| RAP | Rolling Action Plan |
| REACH | Registration, Evaluation, Authorisation and Restriction of Chemicals |
| RISEP | REACH Independent Scientific Expert Pool |
| RMOA | Regulatory Management Options Analysis |
| SEPA | Scottish Environment Protection Agency |
| SVHC | Substance of very high concern |
| TBNPA | Tribromo derivative, 3-bromo-2,2-bis(bromomethyl)-1-propanol |

| | |
|---|---|
| UN | United Nations |
| vPvB | Very persistent and very bioaccumulative |

## Part 1 General Context: Policy, Strategy and Organisation

### *1. Introducing UK REACH*

UK Registration, Evaluation Authorisation and Restriction of Chemicals (UK REACH) is part of the UK's independent chemicals regulatory framework, enabling decision-making that best reflects the UK's needs, while maintaining some of the highest standards in the world. UK REACH regulates the use of chemicals to protect human health and the environment. Until the end of the Transition Period (31 December 2020), the European Union-wide REACH regulation (EU REACH) applied in the UK. At the point that the Transition Period ended, EU REACH became retained law as "UK REACH" in the form it applied as at 31 December 2020, subject to any changes that were necessary to enable the legislation to continue to operate in Great Britain.

UK REACH retains the same basic principles as EU REACH namely:

- To ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances, while enhancing competitiveness and innovation;
- Lay down provisions on substances and mixtures applying to the manufacture, placing on the market or use of substances on their own, in mixtures or in articles; and
- Is based on the principle that manufacturers, importers and downstream users must ensure that the substances that they manufacture, place on the market and use do not adversely affect human health or the environment. It is underpinned by the precautionary principle.

UK REACH regulates the access of chemicals to the GB market. Under the Northern Ireland Protocol, EU REACH continues to regulate substances for the Northern Ireland market[1].

### *2. Roles and responsibilities*

HSE is the Agency for UK REACH and has responsibility for the majority of the regulatory functions under UK REACH, including the drafting of this work programme. In the delivery of these functions, HSE is supported by and/or reportable to a number of other government organisations as shown in the table below.

*Table 1: The governmental organisations that support HSE to deliver UK REACH.*

| Organisation | Role and function |
|---|---|
| The Appropriate Authorities (defined as the (Defra) Secretary of State and the Scottish and Welsh Ministers) | Can request information and propose that HSE undertake various activities under UK REACH, including asking HSE to prepare a dossier to identify a substance of very high concern (SVHC) and to prepare a restriction proposal. |

[1] Provisions have been introduced as part of UK REACH in the form of a simple notification system which facilitates the movement of chemicals from Northern Ireland into Great Britain

| | |
|---|---|
| Department for the Environment, Food and Rural Affairs (Defra) | The (Defra) Secretary of State is responsible for making regulatory decisions under UK REACH and making legislation in UK Parliament to give these decisions legal effect. |
| Scottish and Welsh Ministers | The Defra Secretary of State decisions (and legislation) are made with the consent of Scottish and Welsh Ministers when the decision relates to a matter of devolved competence of their respective Governments. |
| The Environment Agency, the Scottish Environment Protection Agency (SEPA) and Natural Resources Wales (NRW) | The Environment Agency has a statutory role as environmental advisor to HSE. In this role, HSE must seek the advice of the Environment Agency on relevant environmental issues . The Environment Agency in turn must collaborate with SEPA and NRW when advising HSE. |
| Department for Agriculture, Environment and Rural (DAERA) and Department for the Economy (DfE) – Northern Ireland | As UK REACH does not apply to Northern Ireland, DAERA and DfE do not have a statutory role in UK REACH. Nevertheless, DAERA and DfE maintain a strong interest in UK REACH and participate in governmental discussions related to UK REACH at all levels. |

## *3. UK REACH activities*

UK REACH covers several key activities including:

- **Registration/notification:** Manufacturers and importers of substances must provide HSE with information about the substances they are supplying to GB. These businesses also need to communicate information about safe use of their substances down the supply chain;

- **Evaluation:** Dossier evaluation assesses the adequacy of the information provided through registration and any testing proposals submitted. Substance evaluation informs decisions over whether any uses of substances need to be controlled through an authorisation requirement;

- **Authorisation:** When a substance is made subject to an authorisation requirement, businesses cannot generally use that substance for the specified use beyond the sunset date, unless they are granted an authorisation. There are three main steps:

    a. *Substance of Very High Concern (SVHC) identification*: to formally identify that a substance meets one of the criteria to be a SVHC. Identified SVHCs are added to the Candidate List.

    b. *Additions to the authorisation list*: the Secretary of State moves substances from the Candidate List to the Annex 14 Authorisation List.

    c. *Applications for authorisation*: a business can be granted an authorisation by the Secretary of State.

- **Restriction-related activities:** A mechanism for controlling substances that present an unacceptable risk to human health and/or the environment. Restrictions can be tailored to specific uses that cause concern or all uses, as needed;

- **Enforcement:** UK REACH is enforced by a number of different GB enforcing authorities who cooperate to ensure the entirety of UK REACH is enforced effectively. Details on UK REACH enforcement can be found in Annex I;

- **Using independent scientific knowledge and advice (ISA) in the development of opinions on restriction and applications for authorisation:** HSE has developed a new approach for UK REACH to ensure ISA is taken into account when developing opinions – this has involved the recruitment of a pool of experts to work with HSE and the Environment Agency, providing expertise, challenge and scrutiny in the process;

- **Supporting stakeholders:** HSE maintains information on its website to help stakeholders understand UK REACH. As well as this, HSE also maintains a helpdesk to provide advice to dutyholders; and

- **Engagement of stakeholders:** Stakeholders can input information and views into the functioning of UK REACH in a range of ways, including consultations, accredited stakeholder participation and informal engagement.

## *4. Context for the 2021/22 UK REACH Work Programme*

This work programme sets out the activity that HSE, supported by the Environment Agency, and other relevant agencies, will carry out in Financial Year 2021/22 and beyond to operate UK REACH.

The critical focus is to ensure the long-term operation of UK REACH, as a GB-only regulation – operating independently of EU REACH. HSE's role as the Agency for UK REACH represents a significant increase in responsibility from its previous role as UK Competent Authority under EU REACH. HSE has invested significant resource into building capacity to enable the new role to be discharged effectively – and will continue to do so in 2021/22 and beyond. In preparation HSE have:

- Recruited new staff, such that there are around 3 times as many scientists available for REACH work in HSE's Chemicals Regulation Division (CRD) compared to last year;

- Implemented training and capacity building within this year and developed plans for the future years, focussed on developing staff into the key roles required in UK REACH;

- Focussed on support to business via the helpdesk, development of guidance and working with Defra and other key stakeholders to run events and give presentations to help dutyholders;

- Supported the ongoing development of an IT system ('Comply with UK REACH') to support registration;

- Developed systems and approaches to deliver evaluation, authorisation and restriction; and

- Developed a statement on how to obtain and use independent scientific knowledge and advice (ISA) for UK REACH (which can be found in Annex III).

The Environment Agency's Chemical Assessment Unit will almost double its technical capacity in 2021 to support HSE in the delivery of UK REACH.

HSE is committed to ensuring that a high-quality service is delivered. This includes proactive and reactive work. In the first year of UK REACH when upskilling delivery capability, HSE will ensure that the amount of work is proportionate to resource and allows flexibility within the many areas of UK REACH. HSE has worked closely with Defra, the Scottish and Welsh Governments and the Environment Agency to identify the most immediate priorities for proactive risk management in the first year of UK REACH operation.

## *5. Multiannual priorities*

HSE, supported by the Environmental Agency, will work with the Appropriate Authorities to ensure that UK REACH achieves its objectives. In addition to its own analysis, HSE will monitor the global activities, priorities and work of other chemical regulatory regimes, including EU REACH. This will provide HSE with valuable insight to support the development of policy and new regulatory activity in the UK, prioritised on the UK's needs and requirements

This work programme describes operational work that will be taken forward over the next financial year. In many cases, work beginning during 2021/22 will continue into future years. As well as this, analysis and priority setting in this financial year will inform priorities for future years.

HSE will support the authorisation process, particularly through producing technical opinions on applications for authorisation. HSE expects the submission of future applications for authorisation to be largely guided by Latest Application Dates (LADs) and review dates

HSE has used a range of sources of information to identify substances and issues that warrant further investigation and will continue to do so. We will develop a Rolling Action Plan (RAP) of substances for evaluation. As well as this, further analysis, such as via Regulatory Management Options Analysis (RMOA), will be used to characterise risks and identify the most appropriate tools to manage any identified risk. Within UK REACH, these tools can include making a substance subject to authorisation (by adding it to the Candidate List and, eventually, the Annex 14 Authorisation List) or introducing a restriction.

HSE's approach to using independent scientific advice will ensure that the relevant experts are engaged. The *REACH Independent Scientific Experts Pool* (RISEP) will be used in the assessment of applications for authorisation within the workplan activities and will first support the formation of opinions on restriction in in 2022/23.

HSE will review and improve the effectiveness of UK REACH in achieving its objectives on a continuous basis. One way this will be done is through the reviews and reports that are required by UK REACH (this is summarised in Annex II).

## Part 2 Workplan

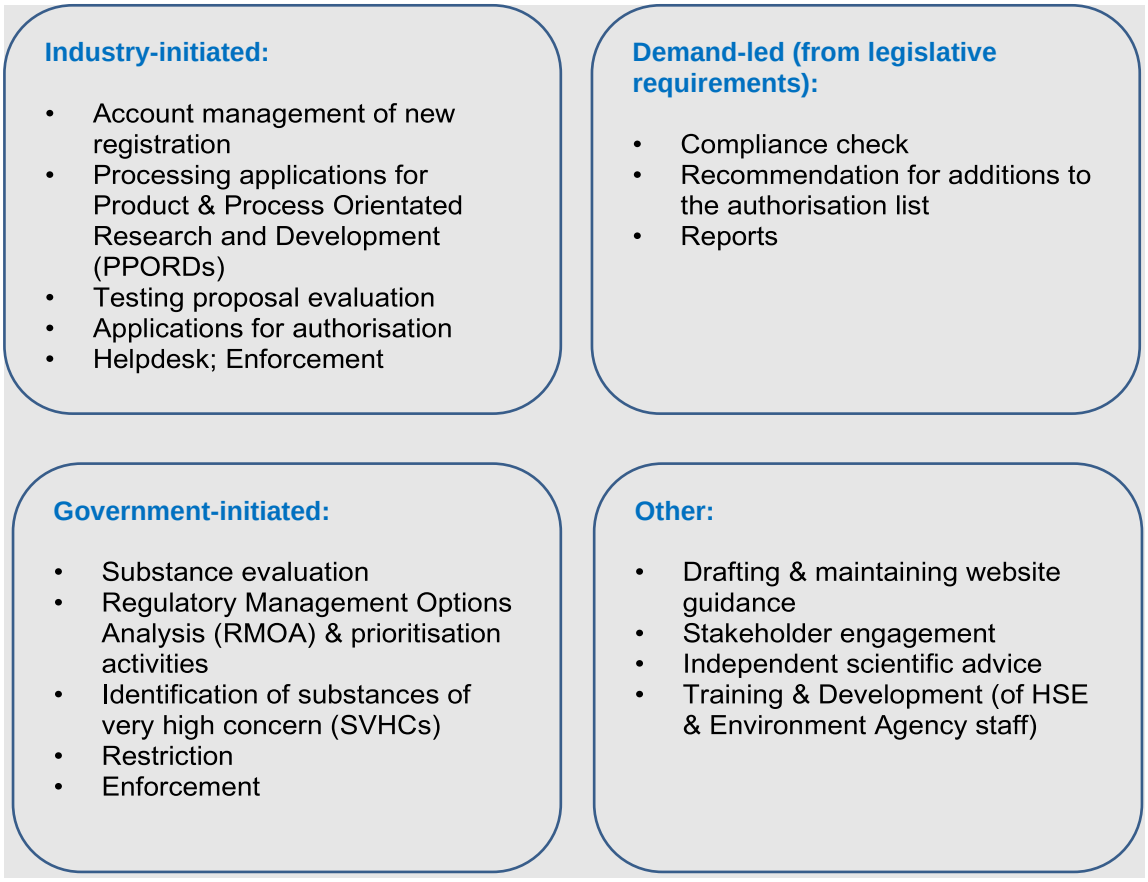
### *6. Introduction to the Workplan*

This workplan details the operational activities we (HSE, supported by the Environment Agency), will undertake in 2021/22. It aims to provide a comprehensive picture of all activities conducted under UK REACH. Within each subject theme, the workplan also provides early perspectives on the nature or scale of work anticipated in future years.

There has been a significant increase in the number and type of functions and responsibilities held by HSE since the end of the transition period following the UK's exit from the EU.

As illustrated below, our work will be directed by activities within industry and government, and by specific legislative triggers. We will also continue to develop our website, engage and consult stakeholders, secure independent scientific advice, and continue to develop the capacity and capability of our staff resource.

**Figure 1. Activities undertaken by the Agency for UK REACH**




We have identified the following objectives as being particularly important for the effective delivery of UK REACH.

*Table 2: Key delivery objectives*

| Objective | Target |
|---|---|
| Complete the processing of UK REACH authorisation applications within the statutory deadline. | 100% |
| Complete the processing of UK REACH registrations for previously unregistered substances within 3 weeks of submission (i.e. technical completeness check). | 100% |
| Produce UK REACH Annex 15 restriction dossiers. | 2 – (tattoo inks and lead ammunition), due in Q4 |
| Helpdesk - provision of high-quality advice to helpdesk enquiries; answering 90% within 10 working days of receipt. | 90% in 10 days |
| Produce a draft Annual report for 2021/22 and a draft Work Programme for the operation of the Agency for UK REACH in 2022/23. | 31st March 2022 |

Matters relating to strategic policy and further development of the UK REACH framework are addressed by Defra and the Scottish and Welsh Governments. They are outside the scope of this plan. However, we will assist Defra and the other Appropriate Authorities by providing technical support as required.

## *7. Resources and organisational structure*

This Workplan will be delivered by specialists in our Chemicals Regulation Division (CRD), with support from the Environment Agency's Chemical Assessment Unit and independent scientists. There will be input from chemists, toxicologists, occupational hygienists, environmental scientists and socio-economists. In addition to the provision of advice and guidance, the work includes assessment of chemical hazards, exposure scenarios and risk assessment. It also includes the assessment of regulatory management options and opinions.

Delivery of UK REACH is managed in HSE alongside comparable regulatory programmes for biocides, Plant Protection Products and classification and labelling. This provides a substantial body of general regulatory expertise and enables a flexible approach to the deployment of scientific staff.

Enforcement of UK REACH is co-ordinated across numerous Government departments and agencies, given that the legislation includes duties relevant to occupational health and safety, environmental protection, consumer protection and public health (Annex I). Resourcing of this activity is not covered in this Workplan.

The Delivery teams in CRD will maintain close links with both internal and external stakeholders to ensure their activities are appropriate and effective.

Defra provides funding to HSE to undertake the functions of the UK REACH Agency. The work is underpinned by a formal Memorandum of Understanding between Defra and HSE. There is also a Partnership Agreement between HSE and the Environment Agency to ensure mutual expectations regarding work delivery are clearly set out. Working relationships between the EA, Scottish Environment Protection Agency and Natural Resources Body for Wales are also set out in a Memorandum of Understanding.

### *7.1 Resources*

The planned distribution of staff time across the various delivery activities described in this Workplan in 2021/22 is summarised in the following tables for HSE's CRD and the Environment Agency's Chemicals Assessment Unit, respectively. A particular feature this year is the significant training element included for new staff who have been recruited specifically for this work.

*Table 3: HSE's CRD resources for 2021/22*

| Activity in 2021/22 | % | Staff hours | FTE |
|---|---|---|---|
| Helpdesk and engagement. | 15 | 5800 | 3.56 |
| Registration, notification, product and process orientated research and development (PPORDs). | 14 | 5400 | 3.31 |
| Dossier Evaluation, including compliance checks and testing proposals. | 10 | 3880 | 2.38 |
| Priority setting and the analysis of regulatory options, including consideration of EU REACH regulatory dossiers (e.g. restriction and SVHC proposals) and preparatory work for substance evaluation. | 5 | 2000 | 1.23 |
| Substance evaluation | 0 | 0 | 0 |
| Authorisation: identification of SVHCs for the Candidate List, the prioritisation of substances for Annex 14, and processing applications. | 12 | 4650 | 2.85 |
| Restriction, specifically generation of Annex 15 dossiers for tattoo inks and lead ammunition. | 5 | 2100 | 1.29 |
| Technical support to policy departments, including international activity. | 5 | 2000 | 1.23 |
| Management: planning, reviewing, reporting, information sharing, general governance. | 7 | 2750 | 1.68 |
| ***Total on delivery*** | ***74*** | ***28580*** | ***17.73*** |
| Training: understanding the legislation and associated guidance; learning processes and procedures; developing knowledge of regulatory science, especially in the area of toxicology. | 26 | 10135 | 6.22 |
| **Total** | **100** | **38715** | **23.95** |

*Table 4: Environment Agency – Chemicals Assessment Unit (CAU) resources for 2021/22*

| Activity | % | Staff hours | FTE |
|---|---|---|---|
| Helpdesk and engagement. | 0.5 | 80 | 0.05 |
| Registration, notification, PPORDs. | 0.5 | 80 | 0.05 |
| Dossier Evaluation, including compliance checks and testing proposals. | 2 | 330 | 0.2 |
| Priority setting and the analysis of regulatory options, including consideration of EU REACH regulatory dossiers (e.g. restriction and SVHC proposals) and preparatory work for substance evaluation. | 37 | 6510 | 4 |
| Substance evaluation. | 0 | 0 | 0 |
| Authorisation: identification of SVHCs for the Candidate List, the prioritisation of substances for Annex 14, and processing applications. | 5 | 810 | 0.5 |
| Restriction, specifically generation of Annex 15 reports for tattoo inks and lead ammunition. | 60 | 1060 | 0.65 |
| Technical support to policy departments, including international activity. | 17 | 3090 | 1.9 |
| Training | 33 | 5860 | 3.6 |
| **Total** | **100** | **17820** | **10.95** |

## *7.2 Organisational structure*

### HSE's Chemicals Regulation Division

The technical work described in this plan will be delivered by HSE's Chemicals Regulatory Division (CRD). Many of those scientists involved will also contribute to HSE's regulatory programmes on CLP (the Classification Labelling and Packaging of Substances and Mixtures) and PIC (Prior Informed Consent), or to the assessment of dossiers relating to the regulatory control of Biocides and Plant Protection Products.

*Table 5: HSE delivery teams*

| REACH Delivery Team A | |
|---|---|
| Key areas of responsibility | Helpdesk and guidance,<br>Registration, Notification, PPORDs<br>Dossier Evaluation<br>Management of authorisation application processes<br>Technical support to policy departments (legislative aspects)<br>Chemistry<br>Socio-economic analysis<br>Stakeholder engagement<br>*Prior Informed Consent (PIC)* |
| Total number of posts at 5th April 2021 | 19 |
| Number of posts vacant at 5th April 2021 | 2<br>Plan to recruit 1 additional socio-economist and 1 additional chemist in 2021/22 |
| **REACH Delivery Team B** | |

| | |
|---|---|
| Key areas of responsibility | Priority setting<br>SVHCs<br>Authorisation applications<br>Restriction dossiers<br>Toxicology<br>Occupational hygiene and exposure modelling<br>Classification and labelling of hazardous substances (CLP) |
| Total number of posts at 5th April 2021 | 22 |
| Number of posts vacant at 5th April 2021 | *7*<br>Plan to recruit additionally 1 general regulatory scientist, 5 toxicologists and 1 occupational hygienist in 2021/22 |
| **Toxicology team** | |
| Key areas of responsibility | Human health hazard and risk assessment of plant protection products, biocides and other chemicals |
| Total number of posts at 5th April 2021 | 18 |
| Number of posts vacant at 5th April 2021 | 5 (not working on UK REACH) |

**Environment Agency's Chemical Assessment Unit**

The Environment Agency's delivery commitment to UK REACH under Article 2B is managed by the Chemical Assessment Unit (CAU), reporting to the Deputy Director of Research in the Chief Scientist's Group. There are 5 sub-teams: 3 focus on priority setting, research and evaluation activities; 2 focus on restriction, authorisation and regulatory management options analyses.

CAU also provides technical input to HSE's regulatory programme on CLP and to Defra on the UN Stockholm Convention on Persistent Organic Pollutants. The total number of posts at 5 April 2021 is 20, of which 8 are vacancies that are in the process of being filled.

The Environment Agency's Economist team will provide additional support.

## *8. Engagement*

### *8.1 Supporting dutyholders*

We provide information and advice to dutyholders and other interested parties to help them understand UK REACH and their obligations under this regulation. This service is a vital tool to help dutyholders comply with UK REACH. This work is particularly important this year to support dutyholders with the transition from EU REACH to UK REACH.

In accordance with Article 124 of UK REACH, we will operate a helpdesk that provides advice predominantly via email to manufacturers, importers, downstream users and any other interested parties on their respective responsibilities and obligations under UK REACH.

This high priority activity is a continuation of the service provided previously by HSE when acting as the UK Competent Authority for EU REACH.

Given the significant number of businesses in the UK who are likely to have obligations under UK REACH, the helpdesk is expected to receive significantly more enquiries than in recent years. This has already been observed with an approximately three-fold increase in the average number of enquiries received per month in the first two months of 2021 compared to last year.

In previous years, acting as the UK Competent Authority for EU REACH, we processed the great majority of queries within 3 working days. However, with the increased activity for businesses and our need to build capacity to cope with the likely high demand for advice, we have set a service standard in 2021/22 to respond to 90% of enquiries within 10 working days of receipt. This is compatible with similar services provided by HSE. Genuinely urgent queries will be prioritised, including any specifically related to immediate business continuity issues or concerns about the risks a substance may be posing to human health or the environment.

To ensure we provide an efficient service for dutyholders, a telephone-based helpline has been set up through the Environment Agency's National Customer Contact Centre (NCCC). This helpline acts as a first point of contact for routine queries, for example helping dutyholders use the new IT system for UK REACH ("Comply with UK REACH"). This allows dutyholders to get quick answers to simple queries and relieves pressure on the helpdesk, which will focus on more complex queries. The helpdesk has an important role providing expert technical advice to the NCCC helpline.

In addition to the provision of a helpdesk and supporting the NCCC helpline, we will also maintain and further develop the new UK REACH website. Working with Defra and the Environment Agency, the existing suite of guidance documents will be built on. We will also undertake public consultations and publish reports as required by UK REACH.

We will continue to issue regular e-bulletins, providing updates on upcoming deadlines, regulatory developments and other news about UK REACH to help duty holders. We aim to provide information to over 60,000 subscribers in this manner.

We will speak at awareness raising or other events set up by HSE, others in government, and by third parties. Priority will be given to those which target dutyholder groups we consider the most difficult to reach or most affected by the new UK REACH framework (including small to medium-sized enterprises).

*Objectives*

We will provide clear, helpful and timely advice to dutyholders and other stakeholders to aid their understanding and facilitate compliance with UK REACH. This includes:

- Provision of high-quality advice to helpdesk enquiries; answering 90% within 10 working days of receipt;
- Provision of timely, expert technical advice to the NCCC helpline to ensure this reduces pressure on our helpdesk
- Maintenance and continued development of HSE's UK REACH website.

### *8.2 Stakeholder engagement to support the formation of regulatory opinions and decisions; including provision of independent scientific advice*

*Stakeholder engagement*

Stakeholder engagement and participation in UK REACH processes has a key role in:

- Information dissemination and gathering to support our activities. Stakeholders can provide valuable information, as well as contribute technical and scientific expertise and knowledge in support of our assessments and opinion making. This can help service delivery.

- Ensuring transparency, trust and confidence in the UK REACH processes. Engagement will provide reassurance to stakeholders that they can have confidence in our scientific assessments and regulatory processes, that they are being applied openly and impartially, and ensure all available information is taken into account. This includes enabling the contribution of scientific advice that is independent of scientists in government.

We intend to create a focus for those with the closest interest and most significant need for regular dialogue with us.

Our stakeholders include businesses from multiple sectors, not just the chemical industry. They also include environmental and other non-governmental organisations (NGOs) and civil society groups. Policy makers, politicians, the media, and the general public may also have an interest in the development and performance of UK REACH. By involving stakeholders in our work in this way, we aim to ensure that our activities and the associated outcomes of importance to society take account of relevant views and are evidence-based.

A detailed appraisal of our approach and the opportunities available for stakeholder engagement is set out in our *Statement on Independent Scientific Advice and Transparency (Annex III)*. This includes an explanation of how Accredited Stakeholder Organisations will be identified and the opportunities open to them. We will also liaise and communicate through the UK Chemicals Stakeholder Forum and other relevant stakeholder groups.

We will be supported by relevant stakeholder engagement and wider communications teams in HSE, Defra and other government bodies. For example, Defra lead and co-ordinate the UK Chemical Stakeholder Forum.

*Independent Scientific Advice*

In accordance with Article 77 of UK REACH, we must take relevant independent scientific knowledge and advice into account when forming opinions for restriction and applications for authorisation. This relates to the reduction of risks to human health and the environment and to socio-economic matters. We may also seek advice on any other aspect concerning the safety of chemical substances that is within the remit of UK REACH.

We have developed a new approach to the provision of independent scientific advice through the establishment of RISEP.

It is not intended for RISEP to function as a scientific advisory committee. Rather, it will provide a source of individual experts who will support us in the preparation of scientific opinions by providing independent challenge and supplementary experience, knowledge and skills. Together with our own scientific and regulatory experts, and those from the Environment Agency and other government agencies, experts from RISEP will help us routinely to prepare and review our scientific opinions.

The provision of this advice through a panel rather than an advisory committee will support the provision of independent challenge and supplementary experience, knowledge and skills that is targeted to a wide range of applications and cases in a proportionate and flexible way.

This approach is described in our *Statement on Independent Scientific Advice and Transparency*. Appointment to RISEP will be gained through a selective application and interview process. The roles, responsibilities and conduct of members will be governed by the terms of reference and a code of practice.

RISEP experts will be supported by HSE. We will organise the work of these experts, support them in matters of administration and protocol, and ensure the efficient and effective running of RISEP experts' activities.

In addition to the UK REACH-specific and newly established RISEP, HSE and the Environment Agency also have access to long-standing government scientific advisory committees such as the Committee on Toxicity, the Committee on Mutagenicity, the Committee on Carcinogenicity and the Hazardous Substances Advisory Committee. These committees provide advice to the government and government agencies upon request and comprise independent chairs, scientific experts and public interest representatives. Additionally, the Workplace Health Expert Committee provides independent expert advice to HSE by assessing new and emerging issues in workplace health.

We will engage with these committees on issues of shared interest, taking account of any confidential information as necessary. When appropriate, we may also seek independent advice directly from these committees, or from individual scientists on an *ad hoc* basis. For example, when notably contentious or novel scientific issues arise, or where expertise in RISEP is insufficient.

*Objectives*

We will:

- Undertake stakeholder engagement, consultation and participatory activities in line with all relevant legal requirements and to a high level of stakeholder satisfaction and effectiveness of engagement;

- Publish statutory reports as required by UK REACH;

- Establish and manage the list of stakeholders with accredited status, ensuring their effective engagement, consultation and participation in applicable meetings and UK REACH activity; and

- Maintain close links with the UK Chemicals Stakeholder Forum and other relevant stakeholder groups, ensuring our activities are appropriate and effective in engaging with stakeholders.

- Recruit and establish RISEP as a multidisciplinary resource of individual experts who are capable, motivated and ready to provide a high level of expertise to help HSE and the Environment Agency ensure that the regulation of chemicals under UK REACH is informed by the best possible independent scientific advice;

- Induct and manage appointments to RISEP, with specific focus on ensuring adequate capacity and expertise;

- Support and facilitate the work of RISEP to ensure timely delivery of outputs in opinion formation; and

- As appropriate, undertake cooperation activities with Scientific Advisory Committees on issues of shared interest, taking account of any confidential information.

| Resources for Engagement | Estimate 2021/22 |
|---|---|
| Human resources (FTE): HSE | 3.56 |
| Human resources (FTE): Environment Agency (specifically support to HSE) | 0.05 |

## *9. Registration, Notification, PPORDs*

Under UK REACH, businesses should collect information on the properties and uses of the substances they manufacture or import above one tonne a year. They should also assess the hazards of the substance and any potential risks presented by its uses.

We will provide submission-specific advice and assistance to these businesses, including non-GB entities, to support them or their GB-based importers in fulfilling their legal obligations under UK REACH. This will be a continuous activity, with new businesses and new substances entering the GB market and the legislative framework evolving.

For businesses new to UK REACH, we will facilitate data sharing and joint registration through the substance inquiry process, as described in Article 26, that allows potential registrants to get in contact with any existing registrants or other potential registrants (that have submitted an Article 26 inquiry). We will also decide on data-sharing disputes and give dutyholders access to data when appropriate as described in A27.

We will process incoming dossiers covering registrations, exemptions of registration obligations (PPORD) under Article 9 and Downstream User Import Notifications (Article 127E).

Dutyholders may, if necessary, defer submission of the full data requirements for registration under UK REACH up to 27 October 2027 (depending on if certain criteria is met under UK REACH).

Any GB-based businesses that were registrants under EU REACH between 29 March 2017 and the end of the EU Exit transition period (31 December 2020), are eligible to 'grandfather in' their registration. A similar notification provision applies to those that were downstream users or distributors of substances registered by EU/EEA businesses or were regarded as such due to the appointment of an Only Representative[2].

The UK REACH IT service ('comply with UK REACH') went live at 12:01am 1 January 2021. At 24 February 2020, there had been 2,607 registrations submitted and 15,720 substances notified via a Downstream User Import Notification.

We anticipate increased submission activity as the following deadlines approach:

- 30 April 2021: *Grandfathering*. GB-based registrants with a pre-existing EU REACH registration must provide some initial information on their registration (Article 127B);

- 27 October 2021: *Downstream User Import Notification*. Certain information must be provided from GB-based legal entities that were importing substances and mixtures into GB from the EU and intend to continue after the end of the transition period.

Ahead of the deadline(s) for full data requirements to be met, we expect most of the registrations with any significant amount of registration data to be submitted from GB businesses that are manufacturing or importing a novel substance for the first time (in quantities of 1 tonne or more per calendar year). In this context, novel means the substance has not previously been registered in EU or UK REACH.

In addition, we estimate there will be 200-300 new registrations for substances that have already been registered in the EU and/or GB. For these registrations special arrangements will be needed to align the deadlines for submission of information to those for pre-existing EU registrants and former downstream users or distributors.

We will conduct a number of checks on all new registration dossiers upon arrival (i.e. excluding grandfathered registrations), including checking the completeness of the information and the payment of fee when applicable. A substantial part of the completeness check work is related to a manual verification of the information in the case of registration dossiers.

Once registrations have been accepted, we will verify whether confidentiality requests introduced by the registrants in their dossiers are justified. We also check the correctness of fee reductions granted to small to medium sized enterprises (SMEs) and of the level of fees paid. We will check that the principle of 'one substance, one registration' is respected, including whether the lead registrant is supported by the other co-registrants or is non-responsive. If it is later found that the legal requirements for submitting a registration were not met and the registrant fails to update the dossier with the requested information, we may revoke the corresponding registration decision.

[2] Under EU REACH, companies based outside EU/EEA can appoint an EU/EEA-based Only Representative (OR) to take over the tasks and responsibilities of importers for complying with EU REACH. The same applies under UK REACH, but this applies to GB and the OR must be based in GB.

We will also process notifications by producers and importers of substances that are named on the GB REACH Candidate List contained in articles and reports submitted by downstream users ((i.e. Substances of Very High Concern: SVHCs).

We will continue to support Defra in the further development of appropriate IT tools to effectively fulfil the requirements of UK REACH. This will include any support required in the construction of an electronic public access site which will provide information on registered substances, in accordance with UK REACH (Article 119).

*Objectives*

We will enable dutyholders, especially SMEs, to have access to data, tools and guidance for preparing and submitting complete and compliant dossiers. We will process the submissions in an efficient manner to ensure that companies meet their legal obligations while ensuring a good starting point for other regulatory processes.

We will:

- Bring potential registrants together with existing ones efficiently to allow them swift access to joint submission and the market. This will be through focusing the inquiry process and substance identity verification mostly on new substances versus already registered substances; and

- Process the continuous flow of registration dossiers (currently estimated at 50 novel substances per year and 200-300 new registrations of substances that have already been registered). Technical completeness checks will be completed within 3 weeks of their submission.

- Assess the PPORD notifications. We may ask notifiers for additional information or set conditions where it matters for safe use. It is anticipated there will be about 20 PPORDs to assess this year

| Resources for Registration, Notification and PPORDs | Estimate 2021/22 |
|---|---|
| Human resources (FTE): HSE | 3.31 |
| Human resources: Environment Agency | 0.05 |

## *10. Dossier Evaluation*

### *10.1 Compliance checks*

We will conduct compliance checks on a proportion of registration dossiers to examine whether they comply with the information requirements of UK REACH. This may lead to requests for further information from registrants. We aim to make checks on at least 20% of the new dossiers in each tonnage band.

This year, we are likely to focus on the registration dossiers of 'novel' substances, i.e. those that were not registered previously under EU REACH prior to the end of the EU exit transition period (31 December 2020). We will identify registration dossiers for compliance check on a case-by-case basis.

Our approach for compliance checks in this and future years will be affected by the transitional provisions in UK REACH which set out the data submission requirements for grandfathered registrations and “downstream user import notifications”. It is possible that many UK registrations will have little data in them before the submission deadlines in November 2023, November 2025 or November 2027.

### *10.2 Testing proposals*

All testing proposals included in the registration dossiers will be examined to ensure that unnecessary animal testing is avoided. We will produce decisions in a timely manner in accordance with the legal framework, assess the adequacy of the information that is submitted and potentially flag substances for further action, including any relevant regulatory risk management measures.

*Objectives*

We will:

- Conduct compliance checks on at least 20% of the dossiers for each tonnage band and, where appropriate, produce draft decisions and request additional information from registrants to bring incomplete dossiers into compliance; our focus will be on non-compliant registrations for 'novel' substances in the first instance, with the aim of expanding the scope to other substances using a risk-based approach. Based on our estimated number of registrations (see Section 9), we anticipate making 50-70 compliance checks in 2021/22.

- Examine testing proposals and prepare draft decisions within the set legal deadlines. We anticipate there being up to about 10 testing proposals in 2021/22.

- In accordance with Article 54 of UK REACH, provide useful regulatory advice to registrants and other interested parties on information requirements and on dossier evaluation processes.

| Resources for Dossier Evaluation | Estimate 2021/2022 |
|---|---|
| Human resources (FTE): HSE | 2.38 |
| Human resources (FTE): Environment Agency | 0.2 |

## *11. Substance Evaluation*

### *11.1 Preparatory work for substance evaluation*

We will work closely with the Environment Agency on substance evaluation activities.

In accordance with Article 44 of UK REACH, we will develop, in cooperation with the Appropriate Authorities, risk-based criteria for prioritising substances for substance evaluation. We will develop the criteria during 2021/22.

We will use these risk-based criteria to develop a rolling action plan (RAP) of UK REACH - registered substances for evaluation. Consistent with the developed criteria, selection for inclusion on the RAP will be based upon the hazard profile of substances, their

exposure potential and the quantities that are supplied. We will prepare the first draft RAP by 31 December 2021 and publish the final RAP by 31 March 2022.

We will update the RAP on an annual basis. In the first and each subsequent update of the RAP, we will give the year of evaluation of each substance, which will inform future work programmes.

In our approach to substance selection, we will seek to complement rather than replicate evaluation work performed by other regulatory regimes (such as via EU REACH). This will increase overall understanding of the hazard and risk profile of priority substances and their relevance to the UK.

### *11.2 Evaluation of substances*

We will conduct substance evaluation where a potential concern has been identified. This evaluation will determine if a conclusion on the concern can be drawn from the available data. If a conclusion cannot be drawn, we can require that registrants provide additional information to clarify the concern and will set a deadline by which the information shall be provided.

We will assess all registrations covering the same substance or group of substances. Evaluations will either cover all aspects of the substance / group of substances or will be targeted to specific hazards or uses. Ultimately, the evaluation will determine whether there are risks that require control. These will then be assessed via a Regulatory Management Options Analysis (RMOA).

As the first iteration of the RAP will not be published until 2022, no substances will be evaluated in 2021/22; the focus of substance evaluation-related activity during this work programme will be on the preparatory work: development of the criteria and selection of substances for inclusion on the first RAP.

*Objectives*

We will work with the Appropriate Authorities to develop risk-based prioritisation criteria that we will use to select substances for evaluation in the following years and will:

- Develop the criteria that will be used to prioritise substances for substance evaluation and work with stakeholders, the Environment Agency and other government agencies to identify substances that meet these criteria for inclusion on the first RAP; and

- Submit the draft RAP to the Appropriate Authorities for comment by 31 December 2021, then publish the first RAP by 31 March 2022.

| Resource estimates in 2021/22 | Staff hours | FTE |
|---|---|---|
| Human resources for preparatory work for substance evaluation: HSE | <2000* | <1.23* |
| Human resources for preparatory work for substance evaluation: Environment Agency | <6512* | <4* |
| Human resources for evaluation of substances: HSE | 0 | 0 |

| | | |
|---|---|---|
| Human resources for evaluation of substances: Environment Agency | 0 | 0 |

*These values represent the total resource allocated for both priority setting and the preparatory work for substance evaluation (2000 hours for HSE, 6512 hours for the Environment Agency).

Preparatory work for substance evaluation will involve input from toxicologists, occupational hygienists, and environmental scientists.

## *12. Risk Management*

### *12.1 Restrictions*

Restriction in the UK REACH framework is a measure for protecting human health and/or the environment from risks posed by chemicals on their own, in mixtures or in articles. Restrictions limit, ban or set conditions on the manufacture, placing on the market or use of a substance or group of substances.

We will prepare an Annex 15 restriction dossier if requested to do so by an Appropriate Authority or if we identify a risk that is not adequately controlled and needs to be addressed. During 2020/21, we worked closely with the Environment Agency and the Appropriate Authorities to identify priority restrictions for the first year of UK REACH (see below).

In preparing a dossier, working with the Environment Agency, we will refer to information available to us under UK REACH or submitted for other regulatory purposes. When a restriction proposal involves consideration of relevant environmental issues, we will also seek and incorporate advice from the Environment Agency and, through them, from the Scottish Environment Protection Agency and Natural Resources Wales.

*Objectives*

We will initiate projects to develop restriction proposals for the use and/or sale of lead ammunition and for substances in tattoo inks and permanent make up.

*Table 6: Restriction proposals to be initiated in 2021/22*

| Restriction | Scope of the proposed restriction |
|---|---|
| Use and/or sale of lead ammunition | Environment: wild birds; condition of terrestrial and freshwater aquatic environments<br>Human health: indirect exposure through eating game shot with lead gunshot |
| Substances in tattoo inks and permanent make up | Human health: consumers (substances classified for carcinogenicity, mutagenicity, reproductive toxicity, skin or eye irritation or corrosion; prohibited for use in cosmetic products; certain specified substances) |

Specific steps will include:

- Notification on HSE's website of an intention to prepare the two restriction dossiers listed above;

- Additional stakeholder communication through the website, the HSE REACH e-bulletin, UK Chemicals Stakeholder Forum, direct engagement with affected sectors, and potentially a call for evidence to support information gathering;

- For each proposal, case teams, comprising specialists from HSE and the Environment Agency, will prepare a restriction dossier that conforms to the requirements and format of Annex 15 of UK REACH, to demonstrate if action is required;

- Commissioning of appropriate expertise from RISEP; through Challenge Panels to be convened in 2022/23, draft opinions will incorporate ISA and be subject to scrutiny and challenge

- Further internal (HSE and the Environment Agency) consultation;

- Within twelve months of the request from the Appropriate Authorities, initiation of the formal restriction process by publication of the restriction reports on HSE's website, where the reports demonstrate that action is required; and

- Public consultations.

| Resource estimates in 2021/2022 | Staff hours | FTE |
|---|---|---|
| Human resources: HSE | 2100 | 1.29 |
| Human resources: Environment Agency | 1060 | 0.65 |

The generation of the Annex 15 restriction dossiers will involve input from toxicologists, occupational hygienists, environmental scientists and socio-economists. Enforcement input will also be needed in relation to the monitorability and enforceability of the measures under consideration.

### *12.2 Authorisation*

The aim of the authorisation process under UK REACH is to ensure the good functioning of the UK market whilst making sure that the risks from SVHCs are properly controlled, and that these substances are progressively replaced by less hazardous alternatives, where this is economically and technically feasible.

We will recommend priority SVHCs from the UK Candidate List to be included in Annex 14 of UK REACH. In making this recommendation, in accordance with the legislation, we shall consider our capacity to handle applications in the time provided for. We will send the first recommendation to the Appropriate Authorities by 31 December 2021, after which the Secretary of State, with the consent of the Scottish and Welsh ministers, will make a decision on additions to Annex 14.

To use or place on the market a substance listed in Annex 14, GB-based manufacturers, importers or downstream users will need to seek approval for specific uses through the submission to HSE of an application for authorisation.

On receipt of an application, we will, with the Environment Agency, assess the information in the application and give a draft opinion on this information within ten

months of the date of receiving the application. We may commission appropriate experts from RISEP to serve on a Challenge Panel, as necessary. Through the Challenge Panel, the draft opinion will incorporate independent scientific advice and be subject to scrutiny and challenge. In giving the draft opinion, we will also consider any information received from third parties via a public consultation for information on alternative substances or technologies.

We will manage data and share it with RISEP experts in accordance with our established data-management protocols.

The draft opinion will include the following:

a. An assessment of the risk to human health and/or the environment arising from the use(s) of the substance, including the appropriateness and effectiveness of the risk management measures as described in the application and, if relevant, an assessment of the risks arising from possible alternatives.

b. An assessment of the socio-economic factors and the availability, suitability and technical feasibility of alternatives associated with the use(s) of the substance as described in the application.

We will send the draft opinion to the applicant for comment; we will then consider the comments received before a final opinion is sent to the Appropriate Authorities and the applicant. The Defra Secretary of State, with the consent of the Scottish and Welsh ministers, will then make a decision on the application for authorisation, and a summary of this decision will be made publicly available.

Within UK REACH, there are transitional provisions for certain authorisation applications submitted previously by GB-based entities to ECHA under EU REACH. If an opinion was adopted by ECHA before the end of the Transition Period, then the applicant may submit the application directly to the Defra Secretary of State for a decision (with the consent of the Scottish and Welsh Ministers). There are approximately 10 applications that could benefit from this transitional provision and the applicants will need to submit the relevant information to the Defra Secretary of State under Article 127G. Together with the Environment Agency, we will answer technical questions from Defra about these in-flight authorisations.

*Objectives*

We will produce recommendations for inclusion of substances onto Annex 14 as required by UK REACH and process any applications or reviews in accordance with the legislation, producing a draft opinion within the legal deadline.

We will:

- Produce the first recommendation of priority substances to be included in Annex 14. This activity will comprise:
    - the use of agreed criteria to prioritise substances on the candidate list
    - publication of the draft recommendation with a public consultation
    - finalisation of the recommendation, considering comments received during the public consultation

- presentation of the recommendation to the Appropriate Authorities.

- Form case teams from HSE and the Environment Agency, including specialists and support staff, to process the 2 applications for authorisation received so far in 2021/22 (see Table 7).

  *Table 7: Authorisation applications received for processing by the end of 2021/22.*

| Substance | Reference | Type of application |
|---|---|---|
| Bis(2-ethylhexyl) phthalate (DEHP) | AFA001-01 | Review report |
| 4-(1,1,3,3-Tetramethylbutyl)phenol, ethoxylated (OPEO) | AFA002-01 | Initial (new use) |

- Undertake public consultations and commission appropriate experts from RISEP in relation to the above applications.

- Produce draft opinions on these applications, incorporating information submitted during the public consultation and independent scientific advice, and send them to the applicant for comment.

- We will progress the assessment of any applications submitted in 2021/22. As there are no Latest Application Dates due in the financial year 2021/22, applications are likely to be limited to new uses of Annex 14 substances. From information received, we expect to receive 0-3 applications to use octylphenol ethoxylate (OPEO) or nonylphenol ethoxylate (NPEO); and a review report for trichloroethylene.

- We anticipate requests for pre-submission meetings as companies prepare applications for submission by 30 June 2022. This is the extended latest application date in the transitional provisions set out in Article 127GA for eligible applicants and downstream users needing to make a new application in UK REACH; it includes eleven Annex 14 substances.

- Together with specialists from the Environment Agency, we will address technical questions regarding *in-flight* authorisations, as required by Defra to facilitate decision making.

| Resource estimates in 2021/22 | Staff hours | FTE |
|---|---|---|
| Human resources: HSE | 4650 | 2.85 |
| Human resources: Environment Agency | 810 | 0.5 |

Authorisation activities will involve input from chemists, toxicologists, occupational hygienists, environmental scientists and socio-economists.

### *12.3 Regulatory management options analysis in priority setting*

UK REACH places duties on HSE to identify and prioritise substances for regulatory action. In deciding which substances warrant further assessment, we will work closely with the Environment Agency to take account of all available information, including issues

identified for further action elsewhere, such as in EU REACH. This priority-setting will inform activities for future work programmes.

The legal basis for priority-setting activities as established in UK REACH is outlined below.

- Article 59 provides a framework for HSE, either on its own initiative or on behalf of the Appropriate Authorities, to propose substances meeting the criteria of Article 57 as substances of very high concern (SVHCs) to be placed on the candidate list;

- Article 58 requires HSE to recommend SVHC from the Candidate List to be included in Annex 14 (substances subject to authorisation). Priority will normally be given to substances that are persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB), have wide dispersive use or are supplied at high tonnage; and

- Article 69 provides a framework for HSE to propose restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles.

We will monitor the progress of other chemicals regulations around the world, including EU REACH. This will provide us with valuable insight to support the development of policy and new regulatory activity in the UK, enabling us to scan for future risks not yet present in the UK. However, we will not be providing bulletins about EU REACH on behalf of ECHA.

Before initiating any proactive risk management activity, there should be a good level of confidence that the right course of action is being taken in a GB-specific context. RMOA is a key tool to support this. A key factor that we will consider will be the likely regulatory effectiveness of the proposed actions.

The purpose of the RMOA is to describe the reasons why regulatory action is being considered, document the existing regulatory landscape around the concern, identify which regulatory action or actions might be needed to resolve the concern and highlight any key areas of uncertainty in the available information. In some cases, this process could also conclude that no new regulatory actions are needed, for example if industry-led activities are able to manage the concern or new information is identified that lessens the severity of or removes the concern.

When we undertake RMOAs, stakeholders will be invited to contribute to the process. Information on the mechanism of stakeholder participation in each case will be provided when the RMOA process is initiated.

We will conduct RMOAs alongside other assessments that aim to identify priorities for new regulatory actions. Working with the Appropriate Authorities, we will use all relevant sources of information when identifying and prioritising activity.

### *12.4 Priority setting - SVHC Identification*

Substances of very high concern (SVHCs) are identified on the basis of specific hazard criteria, as defined in Article 57 of UK REACH. Identified SVHCs are added to the Candidate List and may be prioritised for inclusion on the Annex 14 Authorisation List.

We will work with the Appropriate Authorities to identify and agree our priorities for SVHC identification in UK REACH. Our priorities will be based on our assessment of whether the available information on the substance is likely to fulfil the necessary hazard criteria for SVHC identification, but also on whether analysis has demonstrated that SVHC identification is appropriate. The analysis used for these assessments will often be an RMOA, but in some cases a lighter-touch approach might be used.

We will assess all the substances that have been submitted for SVHC identification in EU REACH to date (if they are not already on the UK REACH Candidate List) and consider if they are appropriate for SVHC identification in UK REACH. In the future, we will select candidate substances for SVHC identification from a wider range of sources, reflecting the identified issues in GB.

Once we have defined our priorities for SVHC identification, we will start to prepare dossiers that establish how substances meet the SVHC criteria, in accordance with Annex 15 of UK REACH.

*Table 8: Substances that HSE, the Environment Agency, and the Appropriate Authorities will consider for SVHC identification in 2021/22*

| | For consideration as SVHCs | EC No. | CAS No. |
|---|---|---|---|
| 1 | Dioctyltin dilaurate, stannane, dioctyl-, bis(coco acyloxy) derivatives, and any other stannane, dioctyl-, bis(fatty acyloxy) derivatives. wherein C12 is the predominant carbon number of the fatty acyloxy moiety | - | - |
| 2 | Bis(2-(2-methoxyethoxy)ethyl) ether; tetraglyme | 205-594-7 | 143-24-8 |
| 3 | Resorcinol; 1,3-benzenediol | 203-585-2 | 108-46-3 |
| 4 | 2,2-Bis(bromomethyl)propane1,3-diol (BMP); 2,2-dimethylpropan-1-ol, tribromo derivative, 3-bromo-2,2-bis(bromomethyl)-1-propanol (TBNPA); 2,3-dibromo-1-propanol (2,3-DBPA) | | |
| 5 | Glutaral | 203-856-5 | 111-30-8 |
| 6 | 2-(4-Tert-butylbenzyl)propionaldehyde and its individual stereoisomers | | |
| 7 | 1,4-Dioxane | 204-661-8 | 123-91-1 |
| 8 | Orthoboric acid, sodium salt | 237-560-2 | 13840-56-7 |
| 9 | Phenol, alkylation products (mainly in para position) with C12-rich branched or linear alkylchains from propene oligomerisation, covering any individual isomers and/ or combinations thereof (PDDP) | | |
| 10 | 4,4'-(1-Methylpropylidene)bisphenol; bisphenol B | 201-025-1 | 77-40-7 |

### *12.5 Priority setting – restrictions*

We will work closely with the Appropriate Authorities and other relevant government departments to identify and agree priorities for initiating restrictions in UK REACH in 2022/23.

We will inform this priority-setting activity by producing analyses on a range of proposals. As with SVHC identification, we will assess all EU REACH restriction proposals where the Annex 15 dossier has been published – but we may identify priorities from other sources and workstreams, possibly as an output from an RMOA (for example, the RMOA on PFAS that we will work on in 2021/22 with the Environment Agency, see below).

Assessment of an EU REACH restriction proposal may lead to the initiation of a UK REACH restriction proposal with a different scope that we believe is more appropriate to addressing a risk in UK REACH (c.f. the restriction initiated this year on lead ammunition).

As UK REACH matures, over the time following our exit from the EU, we will increasingly identify UK restriction priorities through wider analysis, based on the UK's needs.

Additional prioritisation activity will involve us working with stakeholders and other government agencies to identify and assess further substances for potential regulatory action under UK REACH or alternative legislation. One such example is the group of per- and polyfluorinated alkyl substances (PFAS). Some substances within this group are PBT and have adverse effects in humans. In 2021/22, we will produce an RMOA to characterise and understand the risk posed by PFAS and to assess the likely effectiveness and efficiency of various potential regulatory measures.

A further priority-setting activity that links to the above relates to Article 69 (2), whereby we shall consider if substances that are subject to authorisation (listed within Annex 14) pose a risk to human health or the environment that is not adequately controlled when they are used in articles. This activity is to be undertaken at an appropriate time after the sunset date has passed. Where we consider that the use of such a substance in articles is not adequately controlled, we shall prepare an Annex 15 restriction report.

We will use various sources available to us to compile information on the uses of Annex 14 substances in articles. These will include ECHA restriction proposals prepared under Article 69 (2); information gathered to support the identification of SVHCs and recommendations for inclusion in Annex 14, where this has been undertaken by us; applications for authorisation; uses identified in registration dossiers submitted to HSE; and substances-in-articles notifications made to HSE. To supplement these sources of information, we may also hold a call for evidence via our website.

If sufficient information is available, we shall prepare a screening Annex 15 report with our draft conclusion. This will be published on our website with a call for evidence to gather further information and comments on the assumptions presented.

We will use various information sources to identify other potential substances (or groups of substances) for investigation and analysis (such as via RMOA), on an ongoing basis. These substances will be identified from:

- Horizon scanning activities such as the Environment Agency's Prioritisation and Early Warning System for chemicals (PEWS).
- Surveys and analysis of scientific literature including evidence for key gaps in knowledge.
- Calls for evidence and information obtained from industry about how they are used, including future trends.

*Objectives*

In accordance with the principles described in UK REACH, we (with the Environment Agency) and the Appropriate Authorities will develop approaches to identify and prioritise

substances that might require further regulatory actions; and will initiate work to inform decisions about which action(s) are required for specific priority substances.

We will:

- Assess substances and issues to consider if SVHC identification or restriction is appropriate in UK REACH;
- Monitor regulatory activity elsewhere, including EU REACH, to help identify priorities for UK REACH;
- Undertake an RMOA on the group of per- and polyfluorinated alkyl substances (PFAS); and
- Undertake stakeholder communication through HSE's website, HSE's REACH e-bulletin, UK Chemicals Stakeholder Forum, and, where relevant, through direct engagement with affected registrants.

| Resource estimates in 2021/2022 | Staff hours | FTE |
|---|---|---|
| Human resources: HSE | <2000* | <1.23* |
| Human resources: Environment Agency | <6510* | <4* |

*These values represent the total resource allocated for both priority setting and the preparatory work for substance evaluation (2000 hours for HSE, 6512 hours for the Environment Agency).

Priority-setting activities will involve input from chemists, toxicologists, occupational hygienists, environmental scientists and socio-economists.

## *13. Support to other legislation and international activity*

UK REACH draws from – and influences – other activities that are carried out domestically and at an international level. Examples include, the development and refinement of test guidelines, particularly to minimise the use of animals; improved exposure and risk assessment approaches; updates of IUCLID (the software used for registration dossiers); and co-operation to investigate emerging concerns. Other links include the United Nations Globally Harmonised System for the hazard classification of substances and mixtures, and in particular proposals for substances to be considered under the United Nations (UN) Stockholm Convention on Persistent Organic Pollutants (POPs) (since derogations might affect existing UK REACH restrictions).

The Organisation for Economic Co-operation and Development (OECD) is a key partner. Bilateral discussions with other countries are also important. Regulatory co-operation provisions in the UK's new trade agreements will in future provide a framework for some of these, especially where there is a Chemicals Annex, as in the case with the EU Trade and Co-operation Agreement[3]. Public consultations carried out by ECHA might also be of interest.

Together with Defra, the Devolved Administrations, and the Environment Agency, we will give due consideration to any global restrictions being developed, and any exemptions

[3]https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/948119/EU-UK_Trade_and_Cooperation_Agreement_24.12.2020.pdf

associated with them. This intelligence will help in the prioritisation and timetabling for future development or amendment of restrictions in UK REACH.

Collaboration can enable the UK to demonstrate global leadership, influence international (including EU) agendas, promote information sharing, facilitate trade (through reducing the risks of new technical barriers to trade), contribute to consistency in approaches, and provide opportunities for efficiency savings.

*Objectives*

Staff from HSE and the Environment Agency will support the UK's international commitments by working with Defra, the Devolved Administrations, and other government stakeholders to provide appropriate expertise and technical support for such activities. Some specific examples during 2021/2 include:

- Provision of technical briefing for the UK position at the UN POP Review Committee meeting in September 2021 (including associated commenting rounds);

- Engagement with an ECHA study to develop alternatives to systemic toxicity testing in mammals as part of the international "Advancing the Pace of Chemical Risk Assessment" (APCRA) programme;

- Tracking progress of an EU-funded project on Precision Toxicology which aims to promote the adoption of New and Alternative Methodologies (NAMs) in regulatory risk assessment;

- Engagement with various OECD activities such as the Working Party on Hazard Assessment, Working Party on Manufactured Nanomaterials, Working Party on Risk Management and OECD/UNEP Global Perfluorinated Chemicals Group; and

- Development of IUCLID

Up to about 1 FTE of specialist resource is available both in HSE and the Environment Agency for this work.

## Annex I: Enforcement of UK REACH

UK REACH is very broad in scope, and contains duties relevant to occupational health and safety, environmental protection, consumer protection and public health. As such, its provisions are relevant to a number of GB enforcing authorities who have to cooperate to ensure its effective regulation. GB's approach to REACH enforcement does not change as a result of UK REACH coming into force. Enforcement is carried out on a risk-based, intelligence-led basis.

Further details on UK REACH enforcement can be found on the HSE website: https://www.hse.gov.uk/reach/enforcement.htm

***Allocation of enforcement responsibility in GB***

The authorities given enforcement responsibility in GB by the REACH Enforcement Regulations 2008 are those with existing remits to protect human health, consumer safety, and the environment:

- The Health and Safety Executive (HSE);The Environment Agency (EA);
- The Scottish Environment Protection Agency (SEPA);
- Natural Resources Wales/ Cyfoeth Naturiol Cymru (NRW);
- Office for Nuclear Regulation (ONR);
- Office of Road and Rail (ORR);
- The Department for Business, Energy and Industrial Strategy (BEIS); and
- Local Authorities (LAs), as regards health and safety and consumer protection (trading standards). Local authorities do not have a formal role under UK REACH in terms of environmental protection.

Broadly speaking:

- HSE, will enforce those duties in UK REACH concerning registration and evaluation;
- HSE will enforce supply-related duties up to the point of retail sale in GB, with local authority trading standards departments then responsible for consumer protection issues;
- A wide range of enforcing authorities will enforce use-related duties, as per existing arrangements for enforcing health, safety and environmental legislation (see Table 1 below) and https://www.hse.gov.uk/reach/authorities.htm
- HSE, ORR, ONR and LAs enforce use-related duties relating to occupational safety and health in GB.

***Table 9: Designated enforcers for use related duties.***

| **Enforcement of *use* related duties** | Environmental protection | Health and safety |
|---|---|---|
| England | Environment Agency | HSE & Local Authorities |
| Wales | Cyfoeth Naturiol Cymru Natural Resources Wales | HSE & Local Authorities |
| Scotland | SEPA | HSE & Local Authorities |
| Offshore | Department for Business, Energy & Industrial Strategy | HSE |
| Nuclear | ONR Office for Nuclear Regulation | ONR Office for Nuclear Regulation |
| Rail | ORR Office of Rail and Road | ORR Office of Rail and Road |

***Enforcement liaison in the UK***

The REACH Enforcement Regulations 2008 (as amended) require enforcing authorities to co-operate and share information with each other to assist in securing compliance with, and the effective enforcement of, UK REACH. The UK REACH Enforcement Liaison Group (ELG) was established to fulfil that requirement.

Under its terms of reference, members of the ELG undertake to use all reasonable endeavours to effectively co-operate and assist each other to carry out their responsibilities and functions in relation to UK REACH enforcement and to maintain effective working arrangements for that purpose.

Such co-operation is intended to facilitate compliance and improve the effectiveness of UK REACH enforcement and allow them to ensure effective co-ordination between the enforcing authorities where there are joint enforcement responsibilities, including discussion and agreement, where practicable, about the most appropriate enforcement activity. This includes proposing and co-ordinating joint enforcement activity where possible, discussing emerging enforcement issues, identifying best practice and reporting on enforcement outcomes.

***HSE enforcement***

HSE enforcement action is proportionate, targeted, consistent, transparent and accountable. It is in line with our Enforcement Policy Statement and Enforcement Management Model.

Details can be found at https://www.hse.gov.uk/enforce/enforcement.htm.

## Annex II: Statutory Reviews

### Statutory Reviews - summary of reviews and reports that are required in the UK REACH regulations:

| Review | Relevant Article | Required by | Responsible body |
|---|---|---|---|
| Report on the progress made over the previous calendar year on evaluation. This report shall include, in particular, recommendations to potential registrants in order to improve the quality of future registrations. | Article 54 | Annually, by 28 February each year | HSE |
| Report covering the activities of the Agency for UK REACH in the previous year | Article 83 | Annually | HSE, approved by Appropriate Authorities |
| Report on the operation of UK REACH. The report shall include sections on evaluation and enforcement, information on the joint submission of information in accordance with Article 11 and an overview of the explanations given for submitting information separately.<br><br>In relation to enforcement, the report shall include the results of the official inspections, the monitoring carried out, the penalties provided for and the other measures taken during the previous reporting period. | Article 117(2)<br><br>Article 127 | 1 April 2022 | HSE |
| Report on the status of implementation and use of non-animal test methods and testing strategies used to generate information on intrinsic properties and for risk assessment to meet the requirements of UK REACH. | Article 117(3) | 1 April 2022 | HSE |
| General report on the experience acquired with the operation of UK REACH and the amount & distribution of funding made available by the Appropriate Authorities for the development and evaluation of alternative test methods. | Article 117(4) | 1 April 2023 | Defra Secretary of State |
| Review to assess whether or not to extend the application of the obligation to perform a chemical safety assessment to substances produced in quantities of less than 10 tonnes per year | Article 138(1) | 18 months post-end of transition period | Defra Secretary of State |
| Formulate proposals for selecting polymers for registration on the basis of sound technical & valid scientific criteria | Article 138(2) | As soon as a practicable and cost-efficient way is devised | Defra Secretary of State |
| Review to assess whether or not to extend the scope of Article 33 (the duty to communicate information on substances in articles) to other dangerous substances | Article 138(8) | 18 months post-end of transition period | Defra Secretary of State |
| Review the testing requirements for reproductive toxicity (Section 8.7 of Annex 8) | Article 138(9) | 18 months post-end of transition period | Defra Secretary of State |

**Full text from relevant UK REACH Articles**

***Article 54 Publication of information on evaluation***

By 28 February of each year, the Agency shall publish on its website a report on the progress made over the previous calendar year towards discharging the obligations incumbent upon it in relation to evaluation. This report shall include, in particular, recommendations to potential registrants in order to improve the quality of future registrations.

***Article 83 Annual report by the Agency to the Appropriate Authorities.***

Each year, the Agency shall submit the following to the Secretary for approval:

(a) a draft report covering the activities of the Agency in the previous year, including information about the number of registration dossiers received, the number of substances evaluated, the number of applications for authorisation received, the number of proposals for restriction prepared by the Agency, the time taken for completion of the associated procedures, and the substances authorised, dossiers rejected, substances restricted; the Agency's compliance with Article 77(A1) by taking into account scientific knowledge and advice (including knowledge and advice relating to socio-economic matters); complaints received and the action taken;

(b) a draft work-programme for the coming year;

(c) the draft annual accounts;

(d) the draft forecast budget for the coming year;

(e) a draft multi-annual work programme.

The Agency must provide any draft submitted to the Secretary of State under points (a) to (e) to the other Appropriate Authorities at the same time it is submitted to the Secretary of State. The Secretary of State must consult the other Appropriate Authorities before giving approval to any draft submitted under points (a) to (e).

***Article 117 Reporting***

*[Art 117.2]* Every five years, the Agency shall submit to the Appropriate Authorities a report on the operation of this Regulation. The Agency shall include in its report sections on evaluation and enforcement information on the joint submission of information in accordance with Article 11 and an overview of the explanations given for submitting information separately. The first report shall be submitted by 1 April 2022.

*[Art 117.3]* Every three years the Agency, in accordance with the objective of promoting non-animal testing methods, shall submit to the Appropriate Authorities a report on the status of implementation and use of non-animal test methods and testing strategies used to generate information on intrinsic properties and for risk assessment to meet the requirements of this Regulation. The first report shall be submitted by 1 April 2022.

*[Art 117.4]* Every five years, the Secretary of State, in cooperation with the other

Appropriate Authorities, must publish a general report on (a) the experience acquired with the operation of this Regulation, including the information referred to in paragraphs 1, 2 and 3 and (b) the amount and distribution of funding made available by the Appropriate Authorities for the development and evaluation of alternative test methods. The first report shall be published by 1 April 2022.

### *Article 127 Report on enforcement activity*

The report referred to in Article 117(2) shall, in relation to enforcement, include the results of the official inspections, the monitoring carried out, the penalties provided for and the other measures taken during the previous reporting period.

## Annex III: Statement on transparency and Independent Scientific Advice

UK REACH: REACH Independent Scientific Expert Pool (RISEP) (hse.gov.uk)