Department
for Environment
Food & Rural Affairs

Consultation on UK REACH

16 May 2024

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We work closely with our 33 agencies and arm's length bodies on our ambition to make our air purer, our water cleaner, our land greener and our food more sustainable. Our mission is to restore and enhance the environment for the next generation, and to leave the environment in a better state than we found it.

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Glossary

ATRm: Alternative Transitional Registration model

CSA: Chemical Safety Assessment

CSR: Chemical Safety Report

DNELs: Derived No Effect Level

DN(M)EL: Derived No (Minimal) Effect Level

DUIN substances: Downstream User Import Notification

EA: Environment Agency

ECHA: European Chemical Agency

Grandfathering: The process that allowed existing holders of EU REACH registrations to submit initial preliminary information on their substances, to allow continuity of supply until the full registration deadlines.

Hazard classifications: Use of criteria for defining and describing a range of physicochemical, health and environmental hazards of substances and mixtures.

HSE: Health and Safety Executive

IUCLID: International Uniform Chemical Information Database

New substances: An existing substance is one which was registered under EU REACH at the end of the EU Exit implementation period and a new substance is one that was registered under EU or UK REACH for the first time after that date. New substances are still subject to the standard REACH hazard data registration requirements and are not included in the transitional provisions.

NRES: New Registrants of Existing Substances. These registrants are new entrants to the GB market who were not part of a supply chain under EU REACH.

On-site isolated intermediate: In this consultation, this refers to a substance manufactured for and consumed in or used for chemical processing in order to be transformed into another substance, the synthesis of which takes places on the same site which is operated by one or more legal entities.

PBT: Substances that are Persistent, Bioaccumulative and Toxic in accordance with the criteria in Annex 13 of UK REACH.

PNEC: Predicted No Effect Concentration

REACH: Registration, Evaluation, Authorisation and restriction of Chemicals. UK REACH only operates in England, Scotland and Wales. EU REACH continues to operate in Northern Ireland.

RISEP: UK REACH Independent Scientific Expert Pool

SI: Statutory Instrument

Substance Groups: Substance Groups apply where there is more than one registrant of the same substance. The purposes of these groups are to facilitate sharing of information on the intrinsic properties of a substance (such as its hazards) and the agreement of classification and labelling. Substance Groups will apply to all UK REACH registrants, regardless of their route into UK REACH.

The Agency: The functions and powers of the Agency are stipulated under UK REACH to be functions and powers of the HSE. Accordingly, any reference to the Agency in the UK REACH legislation and this consultation must be read as meaning the HSE.

Transitional evaluations: Transitional evaluations are regulatory decisions directed at industry duty holders requiring them to supply the information specified. This information will stay in scope of the expected registration information of a normal dossier at the relevant tonnage.

Transitional provisions: Legal measures afforded to registrants of transitional substances to facilitate the transition from EU REACH to UK REACH.

Transitional registrants: UK REACH registrants of transitional substances. These include registrants of grandfathered, and NRES substances, and protected transitional imports (DUINs).

Transitional substances: These substances include substances that are capable of being subject to a grandfathered or NRES registration or included in a DUIN.

Use and exposure: Use relates to how and where chemicals are used. Exposure relates to the human and environmental contact to or with a chemical during all stages of the life cycle of the substance.

Foreword

1. The Government is consulting on changes to reducing costs to businesses moving from EU REACH regime to UK REACH, whilst upholding existing human health and environmental protections. This includes reducing duplication and speeding up decision-making. We are also consulting on proposals to introduce further protections against unnecessary animal testing.

2. This consultation is seeking stakeholders' views on the UK government's proposals to amend the current transitional provisions under UK REACH for submitting registration information to the Health and Safety Executive (HSE). Following an in-depth analysis of the current UK REACH requirements, Department for Environment, Food and Rural Affairs (Defra), working with the HSE and the Environment Agency (EA) have devised an Alternative Transitional Registration model (ATRm) for UK REACH. The aim of this model is to uphold existing human health and environmental protections (by gaining better information on the use and exposure of substances in Great Britain (England, Scotland and Wales)), while reducing costs to businesses transitioning from EU REACH to UK REACH. Following the standard consultation questions set out in **Part One**, the details and consultation questions on the ATRm can be found in **Part Two**.

3. As part of our ongoing project to improve UK REACH, we are also consulting on proposals for changes to the restriction and reporting process, as well as proposals to introduce further protections against unnecessary animal testing. These proposals can be found in **Part Three** and represent the immediate areas we have identified for improvement which form part of our ongoing review for improvement of UK REACH operations. **Part Four** covers and seeks stakeholders' views on impacts to trade**. Part Five** provides further detail on the UK REACH Article 1 consistency statement. Finally, **Part Six** will provide a list of all the consultation questions covered in this document.

4. This consultation will provide us with a useful opportunity to consider stakeholder views at this stage of our policy development before introducing legislative changes necessary to bring the proposed changes into effect. This will be followed by a second consultation, which we plan to support with a Statutory Instrument and a final impact assessment. As required under the Environment Act 2021, we will publish, before or alongside the second consultation, an explanation of why the Secretary of State considers that the provision to be made by the regulations is consistent with Article 1 of UK REACH (see Part Five for further detail).

Background

5. Following the UK's exit from the EU, the UK implemented its own independent chemicals management framework, including UK REACH.[1] UK REACH is one of the

[1] Registration, Evaluation, Authorisation and Restriction of Chemicals (https://www.legislation.gov.uk/eur/2006/1907/contents)

main pieces of legislation overseeing chemical manufacture, supply and use in Great Britain. Under the terms of the Windsor Framework,[2] Northern Ireland continues to apply EU REACH[3] in order to preserve its unique dual market access to both the EU market and the UK internal market.

6. In accordance with the EU (Withdrawal) Act of 2018[4], UK REACH retains the fundamental approach and key principles of the EU REACH regulation. It upholds the objectives of ensuring high levels of protection for both human health and the environment.

7. Both EU REACH and UK REACH operate on the basis of 'no data, no market'. UK REACH mandates that information (data) concerning substances manufactured in or imported into Great Britain at a level of at least 1 tonne per annum must be compiled into a dossier and submitted (registered) to the HSE, which acts as the regulatory agency for UK REACH. The data include the identity and physicochemical characteristics of each substance, together with information about their hazards, their uses and the exposures that can occur to people and the environment. Risk assessments are also included to help registrants identify appropriate risk management measures for themselves and other users down the supply chain. All of this information is available for use by the HSE and EA for regulatory purposes.

Context

8. To facilitate the shift to UK REACH, businesses were afforded a transitional period to submit their data.[5] However, as detailed in the UK government's impact assessment, which was published in 2023,[6] the estimated cost to industry associated with buying or accessing EU hazard data (which would have been needed to complete the registrations of transitional substances) was ~£2 billion[7] by 2030.

9. This cost has led to concerns that companies may choose not to register their chemical substances under UK REACH. This could in turn lead to fewer substances being available on the Great Britain market, resulting in supply chain problems in some sectors and UK industries becoming less competitive. The UK Government therefore announced in December 2021 its intention to explore an ATRm.

10. Defra, HSE, and the EA have developed a model within the framework of UK REACH that would use the powers of the Environment Act 2021, to ensure high levels of protections for human health and the environment, while reducing the costs of registration to industry.

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[2] https://www.gov.uk/government/collections/the-windsor-framework-further-detail-and-publications

[3] https://echa.europa.eu/regulations/reach/legislation (Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH))

[4] European Union (Withdrawal) Act 2018 (legislation.gov.uk)

[5] Article 127(B) of the REACH etc. (Amendment etc.) (EU Exit) Regulations 2019

[6] https://www.legislation.gov.uk/ukdsi/2023/9780348247329/impacts

[7] This estimate carries a high degree of uncertainty (within the range £1.3bn - £3.5bn), as it is driven by the actual behaviour of companies in practice.

11. In parallel to the work we have been undertaking on the ATRm, Defra, HSE and EA, in cooperation with the Devolved Administrations in Scotland and Wales, have reflected on the experience of operating UK REACH. In doing so, we have identified initial potential efficiencies which could improve the UK REACH restrictions and reporting processes and make these processes more appropriate for operation in Great Britain. In considering other ways we could improve UK REACH, we are also proposing options to further protections against unnecessary animal testing, through reinforcing the last resort principle, the details of which can be found in Part Three. We also intend to use Environment Act 2021 powers to enact these UK REACH Improvement policy proposals.

Purpose

12. The purpose of this consultation is to seek stakeholders' views on the government's proposals and policy options on the UK REACH ATRm, which will apply to UK REACH registrants of transitional substances.[8] We are also seeking stakeholder views on initial UK REACH Improvements, which include proposals on both the UK REACH restrictions and reporting processes and furthering protections against unnecessary animal testing.

13. The policy areas we are consulting on for ATRm and UK REACH Improvement are summarised below. Full descriptions of these proposed policy options are described from page 17 onwards.

ATRm policy proposals

Proposals on registration-related requirements:

- **Hazard requirements**
  Proposal to significantly reduce the hazard information provided in registrations for transitional substances. This has been proposed in light of a greater focus on use and exposure information. These revised hazard requirements will apply to all registrations of substances that were on the market before the end of the Exit Implementation Period. The full hazard information requirements will continue to apply to registrations of new substances that enter the market after that date (see paragraphs 34-45 for further detail).

- **Use and exposure information**
  Proposal to enhance what information on 'use and exposure' registrants in GB need to provide in registrations.

[8] Grandfathered, Downstream User notifications and New Registrations of Existing Substances.

- **Chemical Safety Reports (CSRs)**
  Proposal for reduced hazard requirements in CSRs carried out by all registrants of a transitional substance manufactured or imported in quantities of over 10 tonnes per annum.

Proposals on ATRm regulatory powers and duties:

- **Transitional evaluations**
  Proposal to support regulator needs by enabling the Agency to require and receive data from registrants for regulatory or risk prioritisation purposes, ensuring we can respond to new or emerging risks.

- **Compliance checks**
  The regulator will undertake compliance checks to select no less than 20% of registrations. The regulator may also want to focus on certain uses, exposures or other parameters in these compliance checks to encourage and ensure adherence to hazard and new use and exposure information requirements.

- **Publication of data**
  Proposal to review and revise the “hazard data” to be included in the Public Register for substances subject to ATRm.

Proposal on Substance Groups, data sharing and joint data submission:

Proposal to organise UK REACH registrants of the same substance into Substance Groups to enable data sharing and joint submission of data on the intrinsic properties of substances including hazard classifications. This will enable us to formalise practical arrangements already in place within the registration process under EU REACH.

Further detail on the ATRm policy proposals and the corresponding consultation questions can be found from page 17.

UK REACH Improvement policy proposals

Proposals to improve the restrictions process:

Proposal to amend the statutory consultation requirements in UK REACH to better support how opinions are developed according to UK REACH committee structures. These changes should make the process more functional for the Agency and potentially allow decisions which protect human health and the environment to be made faster.

Proposals to improve the reporting process:

Proposal to introduce further amendments to UK REACH legislation, to reduce the administrative burden on the Agency to provide duplicative reports to government.

Proposals to introduce further protections against animal testing:

Proposal to further ensure that testing on vertebrate animals is minimised for the purposes of UK REACH via reinforcing the last resort principle on animal testing by either a legislative (extending the testing proposal requirements in UK REACH) or non-legislative (support through guidance) approach.

Further detail on our initial UK REACH Improvement policy proposals and the corresponding consultation questions can be found from page 31.

Audience

14. This is a public consultation, and we welcome all views, particularly those from chemical businesses, downstream users of chemicals and NGOs. The questions are presented in a way to accommodate both a general audience and stakeholders with specialist knowledge on the regulation of chemicals.

Responding to this consultation

15. Please respond to this consultation in one of the following ways:

Online using the Citizen Space consultation hub at Defra.. For ease of analysis, responses via the Citizen Space platform would be preferred, if at all possible, but alternative options are provided below if required:

By email to: ATRmConsultation@defra.gov.uk

By post:

UK REACH Legislation and Policy team,

Defra Ground Floor, Seacole Building,

2 Marsham Street,

London, SW1P 4DF

Duration

16. This consultation will run for 10 weeks. The consultation opened on 16 May 2024 and closes on 25 July 2024. Please note, any responses sent by post must arrive at the above address by the closing date of the consultation 25 July 2024 to be counted. Unfortunately, any responses received after this date will not be analysed.

Confidentiality and data protection information

17. A summary of responses to this consultation will be published on the UK Government website at: www.gov.uk/defra. An annex to the consultation summary will list all organisations that responded and what part of the UK they represent but will not include personal names, addresses or other contact details.

18. Defra may publish the content of your response to this consultation to make it available to the public without your personal name and private contact details (such as home address, email address).

19. If you click on 'Yes' in response to the question asking if you would like anything in your response to be kept confidential, you are asked to state clearly what information you would like to be kept as confidential and explain your reasons for confidentiality. The reason for this is that information in response to this consultation may be subject to release to the public or other parties in accordance with the access to information law (these are primarily the Environmental Information Regulations 2004 (EIRs), the Freedom of Information Act 2000 (FOIA) and the Data Protection Act 2018 (DPA)).

20. We have obligations, mainly under the EIRs, FOIA and DPA, to disclose information to particular recipients or to the public in certain circumstances. In view of this, your explanation of your reasons for requesting confidentiality for all or part of your response would help us balance these obligations for disclosure against any obligation of confidentiality. If we receive a request for the information that you have provided in your response to this consultation, we will take full account of your reasons for requesting confidentiality of your response, but we cannot guarantee that confidentiality can be maintained in all circumstances.

21. If you click on 'No' in response to the question asking if you would like anything in your response to be kept confidential, we will be able to release the content of your response to the public, but we will not make your personal name and private contact details publicly available.

22. There may be occasions when Defra will share the information you provide in response to the consultation, including any personal data with external analysts. This is for the purposes of consultation response analysis and provision of a report of the summary of responses only.

Compliance with the consultation principles

23. This consultation is being conducted in line with the Cabinet Office “Consultation Principles” and can be found at: https://www.gov.uk/government/publications/consultation-principles-guidance.

    If you have any comments or complaints about the consultation process, please address them by e-mail to: consultation.coordinator@defra.gov.uk

Part one: standard consultation questions

Confidentiality and some details about you

1. Would you like your response to be confidential? (required)

   ○ Yes

   ○ No

   If you answered Yes to this question, please give your reason.

2. What is your name?

3. What is your email address?
   If you enter your email address, then you will automatically receive an acknowledgement email when you submit your response.

4. Are you responding as an individual or on behalf of an organisation?

- ○ Individual
- ○ Organisation

5. What type of organisation are you responding on behalf of?

- ○ A government body
- ○ Non-governmental organisation (NGO)
- ○ Local authority
- ○ Charity
- ○ Consultancy
- ○ Small or micro business (Less than 50 employees, including any global operations)
- ○ Medium business (50 to 249 employees, including global operations)
- ○ Large business (250 or more employees, including global operations)
- ○ Industry association
- ○ Other

If you answered Other, please state your organisation type.

6. If you are responding on behalf of an organisation, what is the name of the organisation?

7. For organisations that have legal responsibilities as a result of UK REACH, what is your role? (Select all that apply)
    - ○ Only Representative (OR)
    - ○ Manufacturer of substances
    - ○ Importer of substances and/ or mixtures from the EU or EEA
    - ○ Importer of substances and/ or mixtures from Northern Ireland
    - ○ Importer of substances and/or mixtures from RoW (Rest of the World)
    - ○ Exporter of substances from Great Britain to the EU or EA
    - ○ Exporter of substances from Great Britain to RoW
    - ○ Downstream user of chemical substances (companies who directly handle chemical substances in the course of their business activities and are not themselves the Great Britain -based manufacturer or importer of the substances)
    - ○ Not applicable
    - ○ Other, please specify:

Part two: ATRm policy proposals and consultation questions

24. This section of the consultation covers the ATRm policy proposals (Registration-related requirements; ATRm Regulatory Powers and Duties; and Substance Groups, Data sharing and Joint Submission), with the relevant consultation questions following each policy proposal.

The Alternative Transitional Registration model

25. The overall purpose of UK REACH is to ensure high levels 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. Article 1 of UK REACH also states that it is based on the principle that manufacturers, importers and downstream users should ensure that they manufacture, place on the market or use substances in such a way that does not affect human health or the environment adversely. As such, it is primarily industry's responsibility to ensure the safe use of

chemicals, which means the proper assessment, management and control of risk throughout the supply chain.

26. UK REACH registration serves to ensure that companies collect and assess information in order to fulfil their own duties including those relating to safe use. It can also serve to enable the HSE and EA to undertake its regulatory responsibilities. These include the prioritisation and delivery of regulatory activity, as well as being able to assure civil society that industry duty holders have complied with their obligations (for instance by compliance checks).

27. When pursuing the ultimate aim of risk management, it is important to avoid envisaging hazard information and use and exposure information as two unconnected elements, as opposed to a package. Instead, we want to ensure that we build a system which best serves the overall purpose of managing and controlling the risks while ensuring that the UK sector remains competitive.

28. In general, hazard information concerning the intrinsic properties of a substance would not lead to different hazard conclusions[9] in UK REACH compared to EU REACH. Consequently, there would be no change in how this element of risk assessment contributes to the overall risk management process. This means that we can reduce the duty to supply supporting hazard data (compared to the hazard data previously required by UK registrants under EU REACH) in the registration dossier for transitional registrations without undermining the 'no data no market' principle, given that there is no need[10] to completely replicate ECHA's database of hazard information. As a result, it is considered possible to reduce the costs associated with submitting a registration dossier under UK REACH by 70% against current UK REACH baselines.[11] This does not, of course, remove the duty on industry to update their hazard conclusions and risk assessments, where necessary.

29. Regulators in the UK and the EU have identified a range of deficiencies in the nature and scale of use and exposure information submitted in EU REACH registrations to date. If REACH is to operate effectively, it is important to ensure that companies fully meet these elements of registration data requirements. Therefore, against the largely stable background on hazard, where information previously gathered for EU REACH is relevant for UK REACH, the government wishes to use the ATRm to focus attention on the understanding and specificity of information provided on the use and exposure of substances in GB. The UK's exit from the EU has also provided a good opportunity to work on a 'one-country' basis to address and respond to some of the shortcomings identified within EU REACH,[12] (notably on the information on the use and exposure

[9] For classification under CLP, PBT assessment conclusions, and PNEC/DNE(M)Els, where relevant.

[10] Or legal requirement

[11] This is an estimated cost

[12] https://circabc.europa.eu/ui/group/a0b483a2-4c05-4058-addf-2a4de71b9a98/library/d61929be-bd43-4fe1-9e8e-0e17cdaef0bd/details

of chemicals, which impacts the risk management of hazards), as well as address problems associated with the costs of accessing hazard information for UK REACH.

30. The UK Government wants to learn from EU REACH and develop UK REACH risk management further by requesting more targeted and enhanced information on use and exposure for GB. The aim of adding enhanced information on use and exposure to the existing hazard conclusion is to increase the overall quality of assessment, management and control of risk. This should enable industry to fulfil its own responsibility to ensure the safe use of chemicals through the supply chain.

31. Additionally, the clarity of the information available about how the substance is used and who and what (in terms of humans and the environment) may be exposed in Great Britain will improve. Under EU REACH, this clarity is often hidden within more generalised information in EU REACH dossiers (which have to span multiple Member States). Thus, a greater focus on use and exposure under UK REACH should allow for a clearer identification of associated risks in a Great Britain context.

32. Against the backdrop of the reduced hazard data requirements under the ATRm, the UK Government will provide new powers to the regulator to require submission of supporting hazard information in certain circumstances (referred to as “transitional evaluations”). Registrants will still be responsible for ensuring their hazard conclusions appropriately reflect the data which is publicly available (including taking account of data from higher tonnages if available in the EU). Furthermore, the introduction of transitional evaluations will enable the regulator to receive more detail if the reasoning behind a submitted hazard conclusion is not clear.

Registration-related requirements

33. The registration-related requirements being consulted on comprise our proposals on:

- hazard information
- use and exposure information
- Chemical Safety Reports (CSRs)

Hazard information

34. Our policy intention for hazard information requirements is to ensure high levels of protection of human health and the environment, while reducing the hazard information requirements for registrants of transitional substances. The aim of this is to reduce the financial burdens industry face in having to either buy or transfer existing information on the hazards of their chemicals, given that the hazard information for the substances subject to the transitional arrangements has already been submitted to ECHA. As such, the following section assumes that registrants will not be importing a substance into the UK at a higher tonnage than is registered with ECHA.

35. UK REACH[13] currently provides for a two-stage data submission process for registrations of grandfathered substances. At the first stage, basic data specified in Article 10(a) (Technical Dossier)- including company details, the chemical registered, quantities produced and evidence of their existing ECHA registration – had to be submitted[14] by UK REACH grandfathered registrants to HSE[15]. UK REACH registrants of grandfathered substances should have already provided this information:

    - Article10(a) (i) identity of the registrant
    - Article 10(a) (ii) identity of the substance
    - Article10(a) (iii) information on manufacture and use[16]
    - Article10(a) (viii) an indication of which of this information has been reviewed by an assessor.

36. At the second stage, the full information appropriate to the registrant's tonnage band is required to be submitted to HSE by the end of the transitional period.[17] This currently includes the remaining elements of the technical dossier such as hazard and the use and exposure information. The outstanding hazard information requirements are:
    - Article 10(a) (iv) classification and labelling
    - Article 10(a) (vi) study summaries
    - Article 10(a) (vii) robust study summaries
    - Article 10(a) (ix) testing proposals.

37. The ATRm proposes that businesses will now only need to provide the hazard classifications of the substance in question to fulfil the hazard information requirements when submitting their chemical dossiers to register their substances under UK REACH. PBT assessment conclusions and DNEL (Derived No Effect Level) and PNEC (Predicted No Effect Concentration) will continue to be required at >10tpa and some physicochemical and fate hazard data will be needed if an exposure and risk assessment is triggered[18].

38. The reduced hazard requirements will also apply to pre-IP completion day downstream users and distributors (DUINs)[19] who wish to continue importing from the EU after the extended submission deadlines.

39. This reduction in hazard data has been proposed in light of a greater focus on use and exposure information. These revised hazard requirements will apply to all registrations of substances that were on the market before the end of the Exit Implementation Period. The full hazard information requirements will continue to apply to registrations of new substances that enter the market after that date. The following sets out the outstanding hazard requirements under the ATRm.

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[13] Article 127B(4) of UK REACH.
[14] With a deadline of 30 April 2021 for grandfathered registrants.
[15] NRES had a similar timeframe to that allowed for grandfathered registrants.
[16] Note that the data submitted here will not meet the new ATRm information requirements on use.
[17] Extended submission deadlines under the REACH Amendment Regulation 2023.
[18] Annex A sets out in further detail the hazard information requirements for these different tonnage bands and hazard criteria.
[19] Article 127E(1)(a) of UK REACH.

Classification and labelling (Article 10(a) (iv))

40. Knowledge of whether and/or how a substance is classified as hazardous is essential to industry's duty to understand the risks it may present and ensure safe use when it is placed on the market. It is the direct trigger for other duties under REACH, for example, the requirements to proceed to the exposure and risk sections of the Chemical Safety Assessment (CSA) for the Chemical Safety Report under Article 14(4) or the provision of Safety Data Sheets (SDS) under Article 31. Under the ATRm, Article 10 (a) (iv) is also now the trigger for additional use and exposure information requirements relating to human health. It can also be a starting point for prioritising regulatory actions such as the authorisation or restriction processes.

41. Classification information is necessary for the regulator or enforcing authorities to validate that registrants have properly carried out their duties with regard to CSA and CSRs or SDS. In addition, where possible, classification information should normally be submitted jointly by all the registrants for a substance which will support consistency in how they respond to these further duties.

42. Defra's conclusion, as informed by HSE and EA, is that classification and the associated information on labelling (item (iv)) should remain a requirement of the full registration under ATRm (including for registrations of intermediates).

Study summaries and robust study summaries (Article 10(a) (vi) and (vii))

43. The study and robust study summaries detail the scientific studies or analyses performed to fulfil UK REACH information requirements and generate hazard information conclusions. Given that under the ATRm registrants of transitional substances will no longer be required to submit any hazard information other than hazard conclusions [20], hazard classifications and labelling (Article 10(a) (iv) above), which is sufficient to drive appropriate risk assessment and management, we have concluded that study summaries and robust study summaries (items 10(a) (vi) and (vii)) should not be automatic requirements of full registrations under the UK REACH transitional arrangements (see paragraph 62 on Transitional Evaluations).

Testing proposals (Article 10(a) (ix))

44. Testing proposals as well as summary hazard reports for substances already on the EU market (and which are therefore subject to the UK transitional arrangements) would have been submitted to ECHA. Given ATRm removes the requirement to provide summaries of hazard study reports for registration of all but new substances, it is unlikely that testing proposals for these substances would be submitted to HSE. See the section on 'Furthering Protections against Animal Testing' (paragraphs 87 to 97 in Part Three of this consultation) for further detail on Defra's proposed changes to current testing proposals under UK REACH.

[20] DNELs, PNECs and PBT

45. We have been able to reduce hazard requirements while continuing to ensure high levels of protection for human health and the environment by adopting a targeted and proportional approach that requires registrants to submit only the hazard information necessary to drive appropriate risk assessment and risk management of the substance. We have augmented this by asking for more /enhanced use and exposure information (see paragraphs 46-53) and given the regulator the powers to request further information if needed (see paragraph 62).

Consultation questions on hazard information requirements

8. To what extent do you agree that the removal of the more detailed elements of the hazard information requirements from UK REACH registrations would not compromise high levels of protection of human health and the environment?

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree
- ○ I don't know
- ○ I'd prefer not to say

Please explain the reasons for your answer

9. What are your views on our assessment that the regulator does not need to hold a replica set of hazard data (the same used for EU registration dossiers) to inform prioritisation of regulatory actions?

10. Please comment on the extent to which you expect the revised hazard data requirements will reduce costs to business. Where possible, please provide supporting quantitative evidence.

Use and exposure information requirements

46. Use and exposure information is used to inform many regulatory activities under UK REACH, including restrictions and prioritisation of substances for inclusion on the authorisation list. It is also needed by industry to support safe use of the substances they place on the market. However, our view, supported by HSE and EA's analysis of existing EU REACH registrations is that these sections are often incomplete within IUCLID dossiers and Chemical Safety Reports, or that information is not provided in sufficient detail to be fit for purpose. The EU has also identified similar shortcomings[21].

47. To address these gaps and improve the use and exposure information received under the ATRm, registrants would be expected to provide enhanced information (at three different levels[22]) relating specifically to the use and exposure of chemicals in a Great Britain context. This will improve:

    - industry's own understanding, assessment, and management of the risks of the chemicals they manufacture, import and use within the UK. This should lead to overall improved risk management
    - the regulator's capability to prioritise regulatory actions

48. These new requirements will also apply to new substances and ensure a consistent approach to risk management for all substances in the future.

49. Under EU REACH, registrants are already required to provide information on use and exposure for all registrations. We are taking steps, working with industry, to improve compliance with the existing use and exposure requirements. Alongside this, the ATRm will further build on these requirements and differentiate the amount of use and exposure information required on human health across three levels. Under ATRm, the level of information a registrant would provide is determined by the hazard profile of the substance. Requirements for use and exposure related to environmental hazards are also expected to increase under this approach and information in line with the requirements of Level 2 would be the standard requirement for registrants at all tonnages and hazard criteria. Given the existing standards for strictly controlled conditions set out in article 17(3) and 18(4) of UK REACH, requirements for

[21] Circabc (europa.eu)

[22] See next page for description of levels

intermediate registrations are not changing. The triggers for each level are described below.

Level 1

50. Applies only to use and exposure information for human health as all registrants will now be expected to provide environmental protection information requirements at Level 2. It represents the existing use and exposure information requirements for substances between 1-10 tonnes (set out in Annex 6 of UK REACH). It is considered that, in comparison to how this information is provided and presented under EU REACH, many registrants will need to improve the information they provide to meet the regulatory expectations.

Level 2

51. This level reflects the new requirements under ATRm for human health and environmental protection. This level will be the new “baseline” level for environmental use and exposure data. For human health, it will apply to substances being imported above 10 tonnes. It will also apply to substances between 1-10 tonnes that meet the human health hazard criteria set out in Article 14(4) of UK REACH which trigger the exposure and risk elements of the Chemical Safety Assessment.

Level 3

52. This level covers substances which meet the toxicity criteria for human health classification as described in Annex 13 Section 1.1.3 points (b) and (c) of UK REACH. It also covers all categories of respiratory and skin sensitisers. Level 3 only applies below 10 tonnes as, above this, requirements to complete a Chemical Safety Assessment/Chemical Safety Report take effect and these would provide the necessary information.

53. The detailed information requirements for Levels 1, 2 and 3 are set out in **Annex B** to this consultation. Please note that each level “builds on” the lower level – so Level 2 includes everything required for Level 1 and Level 3 includes everything required for both Level 1 and Level 2. At all levels and tonnages, existing requirements regarding article 14(4) obligations and other use and exposure information will remain in place.

Consultation questions on use and exposure

11. To what extent do you agree that requesting more detailed, Great Britain-specific use and exposure information will meet the aims of improving industry’s risk management of chemicals and the regulatory capability for the regulators?

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree

- ○ Strongly disagree
- ○ I don’t know
- ○ I’d prefer not to say

12. To what extent do you agree with the proposed trigger points and corresponding information requirements for registrants? (see Annex B)

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree
- ○ I don’t know
- ○ I’d prefer not to say

Please explain the reasons for your answer

13. What is your estimate for the length of time it will take to complete the necessary tasks for the registration process under UK REACH? Particularly, considering the revised ATRm requirements for use and exposure information? Please first tick the level of use and exposure information you understand you will need to provide [if you envisage registering multiple chemicals at different levels, please try to provide separate answers for the relevant levels using the text box to specify].

- ○ Level 1
- ○ Level 2
- ○ Level 3

Please provide your estimate of time and explain the reasons for your answer

14. Please comment on the extent to which you expect the revised use and exposure data requirements will increase costs to business. Where possible, please provide supporting quantitative evidence.

Chemical Safety Reports

54. UK REACH retains the obligation for all registrants of a substance over 10 tonnes to undertake a Chemical Safety Assessment (CSA) and produce a Chemical Safety Report (CSR). There are no proposals to change this tonnage threshold.

55. Under the proposed ATRm, we have concluded that UK registrants of transitional substances do not need to provide detailed hazard information (including study summaries and robust study summaries) to fulfil their duties regarding safe use or support of UK REACH prioritisation of regulatory work. It follows, therefore, that a CSR submitted with a UK REACH ATRm registration does not need to include full details of the hazard assessment prescribed under UK REACH[23] (unless the details differ from that provided under EU REACH).

56. Under the ATRm, the CSR need only report the key hazard data (classification under CLP (classification, labelling and packaging) and a conclusion on PBT (substances that are persistent, bioaccumulative and toxic[24]) properties) that determine whether the registrant has to proceed to the exposure and risk parts of the CSA,[25] along with DNEL and PNEC values or other hazard assessment conclusions and the data needed to undertake exposure assessment and risk characterisation (if triggered).

57. Also, under the ATRm if the UK REACH registrant's DNEL or PNEC values or conclusions are the same as those in EU REACH dossiers it will not be necessary for registrants to explain, in the CSR, how these values are derived, although an explanation together with supporting data may be required under a transitional evaluation. Should a UK REACH registrant's DNEL or PNEC value deviate from the EU REACH value, the registrant would be expected to provide a justification for this.

58. Where a substance requiring a CSR meets the hazard criteria in Article 14(4) of UK REACH, registrants (often working in Substance Groups) will remain responsible for undertaking exposure assessments and risk characterisation, identification of risk

[23] Annex 1 of UK REACH - General provisions for assessing substances and preparing chemical safety reports (CSRs)
[24] In accordance with the criteria in Annex 13 of UK REACH.
[25] As required under Article 14(4)

management measures and communicating exposure scenarios and risk control measures in CSRs and Safety Data Sheets. UK REACH registrants (or Substance Groups) will also be responsible for keeping these up to date.

59. Defra, HSE and EA do not consider that these changes to the reporting of the hazard assessment for transitional and ATRm substances will negatively impact on the effectiveness of chemical safety assessments by registrants or their ability to generate exposure scenarios and communicate these and risk control measures downstream (as explained in paragraphs 33 to 44 on hazard information).

Consultation questions on Chemical Safety Reports

15. To what extent do you agree that the proposed reduction in hazard assessment data will not negatively impact a registrant's ability to undertake exposure assessment and risk characterisation in their CSA and communicate the exposure scenarios and risk control measures downstream (where Article 14 (4) of UK REACH applies[26])?

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree
- ○ I don't know
- ○ I'd prefer not to say

Please explain the reasons for your answer

16. To what extent do you agree with our assessment of which aspects of information should be required or should no longer be required for CSRs (see paragraphs 54-59)?

- ○ Strongly agree
- ○ Agree

[26] Classified as dangerous in accordance with GB CLP or assessed to be a PBT or vPvB

- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree
- ○ I don't know
- ○ I'd prefer not to say

ATRm regulator powers and duties

60. The regulator powers and duties under the ATRm include our policy on:
    - transitional evaluations
    - compliance checks
    - publication of data

Transitional evaluations

61. UK REACH currently contains two procedures whereby the Agency places an obligation on duty-holders to provide information after registration: dossier evaluation (compliance checks and testing proposal examination) and substance evaluation. Under the ATRm, a new 'transitional evaluation' process would be provided in legislation and linked to Title VI of UK REACH - Evaluation.

62. "Transitional evaluations" refers to a regulatory decision directed at industry duty holders requiring them to supply the information specified. Under the ATRm, the broad circumstance for a transitional evaluation would be where a registrant(s) has provided a compliant ATRm registration dossier, but the Agency considers that it requires information in addition to the contents of that dossier. This is to fulfil its regulatory responsibilities, including further assessing the potential hazards and/or risks and assurance that registrants have correctly identified these.

63. The suggested parameters of a transitional evaluation under the proposed provisions would be the information requirements which would have applied if the registration dossier had followed the standard approach for new substances under UK REACH rather than the ATRm (which would remain the default requirement under UK REACH). For instance, a transitional evaluation may be initiated by the Agency to obtain access to an original study report for a complex endpoint or borderline result. It would, in effect, sit between the two existing types of evaluation (dossier evaluation and substance evaluations).

64. Requests for information beyond the standard requirements set out in the REACH annexes would continue to be the subject of substance evaluation (substance evaluations can still apply to all types of registration dossiers for a given substance).

Similar evaluation processes would apply, for example with regard to draft decisions and setting deadlines for submitting the required information, in the same way transitional evaluations would be appealable and enforceable.

65. Regarding timelines, we envisage a response to a transitional evaluation would be required within a minimum of 3-months to a maximum of 12-months, depending on the nature and extent of the data concerned.

Compliance checks

66. At present, HSE undertake compliance checks on 20% of registrations, which is expected to remain the same under the ATRm. To ensure that the registration-related information submitted on a substance under the ATRm is compliant with the proposed hazard and new use and exposure information requirements, the regulator may want to focus on certain uses, exposures or other parameters in these compliance checks.[27]

Publication of data

67. UK REACH places a duty on HSE to make available a "Public Register" of information on all registered substances. Article 119 lists the information to be published including hazard information (such as study summaries and robust study summaries). Since these hazard requirements are now being amended (as discussed in Part Two of this consultation), changes are required to what hazard information will be included in the Public Register for transitional substances to reflect the amended hazard requirements and new use and exposure information.

68. Proposed changes to the use and exposure information requirements for both transitional and new substance registrations will result in more detailed information being submitted to HSE. Use and exposure information is already included in the public register operated by ECHA and we intend to continue with this approach for use and exposure information under UK REACH.

69. Defra, HSE and EA propose that the Public Register will continue to:
    - include the hazard information listed in Article 119(1)(d) and (e) and Article 119(2)(c) (subject to a confidentiality claim under Article 10 (a) (xi)) where that has been submitted to HSE either as part of a registration in response to a transitional evaluation or otherwise. This means that ultimately Article 119(1)(a)-(c) and (f)-(h) will always apply.
    - contain details of use and exposure information submitted with a registration (subject to a confidentiality claim under Article 10(a)(xi)).

[27] And cases where hazard conclusions or classification differ from that in the public domain

Consultation questions on ATRm regulator powers and duties

17. To what extent do you agree that the introduction of powers for transitional evaluations is an appropriate way for regulators to request supporting information on an “as and when needed” basis?

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree
- ○ I don’t know
- ○ I’d prefer not to say

Please explain the reasons for your answer

18. To what extent do you agree that the information contained in the Public Register should be adapted in the manner set out in the policy proposal in paragraph 69 of the consultation?

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree
- ○ I don’t know
- ○ I’d prefer not to say

Please explain the reasons for your answer

Substance Groups, data sharing and joint submission of data

70. The express provisions for “Substance Information Exchange Fora" (“SIEFs”) in EU REACH had expired when UK REACH took effect and consequently are not included in the UK REACH Regulation. EU REACH SIEFs operated where there was more than one registrant of the same substance. The purposes of SIEFs were to facilitate sharing of information on the intrinsic properties of a substance (such as its hazards) and the agreement of classification and labelling. This in turn supported the joint submission of these data, improving the efficiency of registration, reducing costs and avoiding unnecessary animal testing.

71. EU REACH experience shows that the activities undertaken by SIEFs remain relevant after registrations have been submitted, including when new registrants come to market and for co-ordinating responses to regulatory decisions requiring the submission of further information.

72. Defra, HSE and EA consider that:
    - similar to SIEFs, “Substance Group” provisions should be added to UK REACH;
    - Substance Groups will apply to all UK REACH registrants, regardless of their route into UK REACH. This includes grandfathered registrants, DUINs (Downstream User Import Notification) (post submission of an Article 26 inquiry), NRES (New Registrants of Existing Substances) and new substances.
    - the hazard information required for ATRm registrations should be agreed within Substance Groups and submitted by a lead registrant on behalf of all members of the substance group in a joint submission.
    - registrants should be entitled to opt out of the joint submission of information on registration where it would be disproportionately expensive, lead to the disclosure of commercially sensitive information or where they disagree with the selection of the information.
    - where a transitional evaluation or other regulatory decision requires the submission of further information on the intrinsic properties of a substance, the response should be a joint response from all members of the Substance Group. Members of the Substance Group will need to agree how the information requirement will be met, including a process for sharing data and the costs of data.

    - Substance Group provisions in UK REACH should require that:
        - all members of the substance group make every effort to reach an agreement that includes sharing of costs under ATRm, including the costs of meeting information requirements to respond to regulatory decisions, with a means of referring disagreements to the Agency
        - the costs of sharing data are determined in a fair, transparent and non-discriminatory way
        - costs sharing models shall apply to all registrants, including future registrants

Consultation questions on Substance Groups, data sharing and joint submission of data

19. Do you have any concerns with Substance Groups operating in the manner proposed in this consultation?

- ○ Yes
- ○ No
- ○ Don't know

Please explain the reasons for your answer

20. Whilst the actual operation of Substance Groups will be for members to work together and cooperate on independently of the Regulator (similar to SIEFs), are there any areas for improvement from the EU legislation on SIEFs which should be considered for UK REACH legislation?

21. If you would like to comment on the analysis of the ATRm policy proposals in the accompanying Impact Assessment or provide relevant data or evidence to support improving that analysis, please do so here.

Part Three: UK REACH improvement policy proposals and consultation questions

73. As UK REACH was largely carried over from EU REACH, the reporting and restrictions processes were designed for an agency which regulates multiple EU

member states and formulates risk assessment and socio-economic opinions through separate committees.

74. Following the UK's exit from the EU, there is now an opportunity for the UK to review these processes to make them smarter, more agile and functional for our Agency, which develops opinions through a single independent scientific advisory board, and which produces regular business plans to cover all their functions. There is also an opportunity for the UK to go further than EU REACH to further our protections against unnecessary animal testing. These are the immediate areas we have identified for improvement which form part of our ongoing review for improvement of UK REACH operations.

Improving the UK REACH restrictions process

75. The UK REACH restrictions process enables the regulator to produce high quality opinions, based on robust risk assessment and supported by independent scientific advice and stakeholder consultation. This process ensures that stakeholders, such as chemical businesses and NGOs, are able to maintain engagement with the regulator through the restrictions process. However, as the restrictions process was inherited from EU REACH, it is not reflective of the Great Britain committee structure, present to develop opinions.

76. We have therefore identified changes to the statutory consultation requirements, which could streamline the restrictions process. Currently, the restrictions process (inherited from the EU, Figure A) requires:

- A 6-month consultation on the restriction (Annex 15) dossier (which includes a risk assessment (RA) and socioeconomic analysis (SEA)) – 'the first consultation'; and
- A 60-day consultation on the draft SEA opinion – 'the second consultation'.

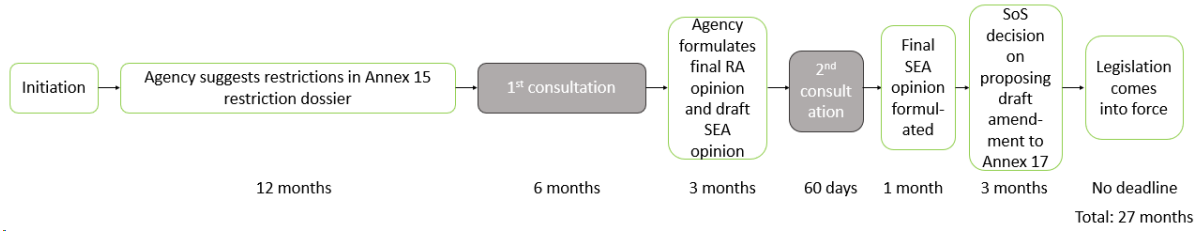

Figure A: Current UK REACH restrictions process:
[Alternative text: A flowchart representing the current UK REACH restrictions process. Within 12 months of initiation of a restrictions proposal, the Agency shall suggest restrictions within a dossier complying to Annex 15 of the UK REACH regulations. There is then a six-month public consultation on the suggested restrictions ('the first consultation'). Within nine months of the publication of the dossier, HSE formulates its opinion on the risk assessment (RA) and formulates an opinion the socio-economic analysis (SEA) within 12 months. As part of this process, the HSE will also publish a

draft opinion on SEA, which is subject to a further 60-day public consultation ('the second consultation'). In practice can be seen as a final RA opinion and draft SEA opinion formulated 3 months after the 1st consultation, the second consultation following for 60 days and the final SEA opinion formulated 1 month after the second consultation. The decision to propose draft amendments to Annex 17 of the UK REACH regulations, is subsequently made by the Defra Secretary of State, with the consent of Welsh and Scottish Ministers, 3 months post formulation of the final SEA opinion. The next stage is for the legislation to then come into force. The total time outlined in this process is 27 months.]

77. This separation in delivery of the RA and SEA opinions exists due to the separate committees to consider each opinion in the EU. In Great Britain we do not have the same committee structure and a single document containing the RA and SEA opinion elements is informed by engagement with the UK REACH Independent Scientific Expert Pool (RISEP) for independent advice. This split in opinion delivery in the inherited process also results in major 'crunch points' that occur before and after the second consultation. Before the second consultation there are pressures for the Agency to deliver the RA and SEA opinion to RISEP for formulation and publish it before the second consultation. After the second consultation there is a requirement on the Agency to formulate a final SEA opinion, within 12 months of the date of publication of the restriction (Annex 15) dossier (so effectively within one month of the end of the second consultation). Furthermore, the first consultation is significantly longer than standard UK Government consultations (usually 1-3 months).

78. This process would be accelerated, and unnecessary crunch points removed, if there was a reduction of the 6-month consultation (in line with standard consultation periods) and consolidation of the two consultations (Figure B). This would result in final RA and SEA opinions being formulated at the same time (9 months post the Agency suggesting restrictions in the Annex 15 dossier).

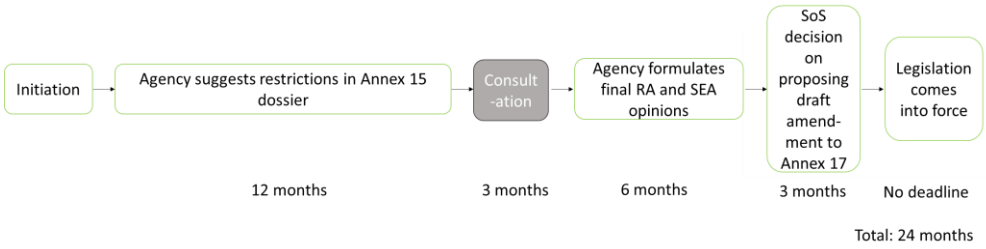

Figure B: Recommended approach consolidates the first and second consultations and reduces the period of consultation:
[Alternative text: A flowchart representing a proposed amendment to the UK REACH restrictions process. Within 12 months of initiation of a restrictions proposal, the Agency shall suggest restrictions within a dossier complying to Annex 15 of the UK REACH regulations. There is then a three-month public consultation on the suggested restrictions. Final RA opinion and final SEA opinions are then formulated 6 months after the consultation. The decision to propose draft amendments to Annex 17 of the UK REACH regulations, is subsequently made by the Defra Secretary of State, with the consent of Welsh and Scottish Ministers, 3 months post formulation of

the final SEA opinion. The next stage is for the legislation to then come into force. The total time outlined in this process is 24 months.]

79. We would like feedback on what additional information would be useful for the UK Government and/or the Agency to provide (in the restrictions (Annex 15) dossier or otherwise) before the consolidated consultation outlined in Figure B, which could facilitate robust responses delivered by stakeholders in a reduced period. Without a mandated second consultation, the Agency may also be able to hold informal, shorter and perhaps more targeted consultations on draft RA and/or SEA opinions within the 6 months following the consultation on the restriction (Annex 15) dossier; we would also like feedback on this.

Consultation questions on improving the UK REACH restrictions process

*These questions are in regard to the **current** restrictions process.*

22. In your view or experience (including experience of contributing to the EU REACH restrictions process), what actions must a manufacturer, importer or affected stakeholder of a chemical proposed for restriction take (for example, confirming supply chain actors) in order to draft a response to the first consultation? (please specify how long in days or months each action takes).

Please explain your answer.

23. In your view or experience (including experience of contributing to the EU REACH restrictions process), is there any SEA information you would usually provide in the second consultation that you would not/cannot provide in the first consultation? If so, why can this information not be provided in the first consultation?

Please explain the reasons for your answer.

*These questions are in regard to potential **amendments** to the current restrictions process.*

24. What information and/or engagement from the UK Government/the Agency would be helpful ahead of the publication of the restriction dossier (for example, information on

similar restrictions in other jurisdictions or engagement to confirm supply chain actors that hold information that downstream users might not have) that may allow for a shorter, consolidated consultation period?

Please explain the reasons for your answer.

25. If the consultations are consolidated as outlined in paragraphs 78 and 79, are there any potential consequences (not outlined in paragraph 78 and 79) you expect or concerns you have? If so, are there any ways in which these concerns could be overcome?

- ○ Yes
- ○ No
- ○ Don’t know

Please explain the reasons for your answer.

26. If greater information is provided by the UK Government/the Agency before the consolidated consultation and informal consultations are considered before final opinions are published, to what extent do you agree with the recommended approach (included in Figure B) is a reasonable amendment to the current UK REACH restrictions process?

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

Please explain the reasons for your answer.

Improving the UK REACH reporting process

80. We also propose further amendments to UK REACH, to reduce the administrative burden on the Agency to provide duplicative reports to UK Government.

Table 1: Dates for the Agency to return reports produced each year to the government.

Reports the Agency produce each year	Deadline
1. Report of activities in the previous year (Article 83)	Each year (no specific deadline)
2. Work programme for the coming year (Article 83)	Each year (no specific deadline)
3. Multi-annual work programme (Article 83)	Each year (no specific deadline)
4. Annual accounts (Article 83)	Each year (no specific deadline)
5. Forecast budget (Article 83)	Each year (no specific deadline)
6. Rolling action plan (for substance evaluation) (Article 44)	Submit draft Rolling action plan by 31 May each year

81. Aligning the dates the Agency provide the required reports to government can remove overlap, remove time for additional clearance processes and support business planning. Therefore, we propose providing a fixed date for the Agency to provide these reports to government.

82. We believe that consolidating reports 2 and 3 (reports on the work plan) is the best way to describe the Agency's future plans, whilst minimising repetition between different documents. Therefore, we propose consolidating reports 2 and 3 so that the Agency can produce a "Work programme for the coming years".

83. As the Agency agrees its budget with Defra through business-planning discussions, the annual accounts and forecast budget information (in reports 4 and 5) is already

known to Defra. Therefore, we propose removing the Article 83 obligation for the Agency to produce these financial reports.

84. Every 5 years, the Agency must produce a report on the experience acquired operating UK REACH (Article 117(2)). One year after this, the Secretary of State must produce a general report on the experience acquired with the operation of UK REACH and the amount and distribution of funding made available by the Appropriate Authorities for the development and evaluation of alternative test methods (Article 117(4)).

85. As the Agency provide an annual report on evaluation (Article 54), we propose removing the 5-yearly Agency report (Article 117(2)) but retaining the Secretary of State report (Article 117(4)). We expect the Agency could expand their annual report on evaluation in every fifth year to provide the information currently required in 117(2). We are not recommending removing the requirement on the Agency to submit a report to government every 3 years on the status of implementation and use of non-animal test methods, used to generate information requirements for UK REACH (117(3)).

86. The requirements under Article 117(2) also include a report on the outcomes of enforcement action (in collaboration with other enforcement bodies). We value the importance of this information. Therefore, we propose maintaining the requirement in legislation for the Agency to present this information every 5 years.

Consultation questions on improving the UK REACH reporting process

27. Do you agree with the proposed reporting changes outlined in paragraphs 81 to 86?

- ○ Agree with all of the proposed changes.
- ○ Agree with some of the proposed changes.
- ○ Do not agree with any of the proposed changes.
- ○ No view on the proposed reporting changes.

Please explain the reasons for your answer and specify if there are any potential consequences not outlined in paragraphs 81-86 that influenced this answer.

Further protections against unnecessary animal testing

87. The UK Government actively supports the development and dissemination of the 3Rs principle: the replacement, reduction and refinement of animal testing used for experimental and other scientific purposes. This principle is embedded in UK REACH in accordance with Article 25 and Annex 6 to UK REACH, testing on vertebrate animals shall be undertaken only as a last resort.

88. The ATRm approach which we have outlined above will reduce the need to repeat animal tests that were conducted to meet the information requirements of EU REACH, given the requirement to provide summaries of hazard study reports is removed from registration for all but new substances. Therefore, the possibility of new animal tests being undertaken applies in large part to the registration of new substances. However, we want to go further to protect against unnecessary animal testing where alternative methods and tools are available.

89. Annexes 7, 8, 9 and 10 of UK REACH set out the standard information requirements for substances manufactured or imported in quantities of 1 tonne or more per year, per registrant (manufacturer or importer); 10 tonnes or more per year, per registrant; 100 tonnes or more per year, per registrant; and 1000 tonnes or more per year, per registrant, respectively. Testing on vertebrate animals may be required to fulfil some of the standard information requirements for each tonnage band, however more extensive information is required for higher tonnages.

90. Currently, a registrant intending to generate new information (through animal or non-animal tests, or by predictive modelling) to meet the requirements set out in Annexes 9 or 10 of UK REACH must submit a proposal to the Agency for approval. In line with UK REACH Article 40, the Agency examines these proposals to ensure that they adequately address the information needs and avoid unnecessary testing that would involve the use of vertebrate animals.

91. If a proposed test involves vertebrate animals, the evaluation includes a 45-day consultation. This is to confirm that there is no existing information (valid data or studies which address the relevant substance hazard endpoint) available. The registrant may only proceed with testing when the Agency has issued a formal decision in line with the options set out in Article 40 of UK REACH (that is to permit the proposed test, a modification of the proposed test, or a different test). The proposal to conduct tests can also be rejected entirely by the Agency.

92. At present, there is no explicit requirement for testing proposals to be made for new tests conducted to meet the requirements set out in UK REACH Annexes 7 or 8 (substances manufactured or imported in quantities of 1 tonne or more per year per registrant and 10 tonnes or more per year per registrant respectively) - even though testing on vertebrate animals may be conducted by registrants to fulfil some of the

information needs at these tonnage levels. However, approaches that do not involve new tests on vertebrates should always be explored first, in line with the last resort principle (Article 25) of UK REACH. These might include adaptations of the standard information requirements based on a scientific argument (e.g. *in vitro* data, weight of evidence approaches, chemical grouping, or the use of computer models, as detailed in UK REACH Annex 11). The use of existing data is also possible. Importantly, the responsibility for considering, using and justifying such approaches rests with the registrant, not the Agency.

93. For some hazard endpoints listed in Annexes 7 and 8 (for example, acute dermal and inhalation toxicity, short-term repeated-dose toxicity, reproductive toxicity and fish toxicity), there are either no currently validated alternative tests or models or, if a model does exist it may not be applicable for all substances (e.g. acute oral toxicity). Consequently, new tests on vertebrates might be used to fulfil some of the information needs in these cases. Therefore, it is not possible at present to prevent all testing in vertebrates without compromising the UK REACH data requirements on human health and environmental hazards. However, we would like feedback on potential legislative and non-legislative measures in relation to substances falling under Annexes 7 and 8 of UK REACH, which would reinforce the last resort principle, while ensuring sufficient flexibility to move with the science and incorporate the development and validation of new methods.

94. A potential legislative measure that could be introduced to further ensure that testing on vertebrate animals is minimised for the purposes of UK REACH is to extend the current testing proposal requirement where appropriate to Annex 7 and/or Annex 8 – whilst also reinforcing the last resort principle. In contrast to the requirement for Annexes 9 and 10, whereby registrants submit testing proposals for any new study (animal test or other), this proposal would only apply to studies conducted for the purposes of Annex 7 and/or 8, which involve vertebrate animals[28]. We wish to understand the extent to which this proposal could help drive the use and development of alternative methods.

95. We would reinforce that before deciding to submit a testing proposal, registrants should (in line with current registrant duties and the last resort principle (Article 25) of UK REACH) explore other opportunities to meet the information requirements which do not require the use of animals. Where there is an appropriate alternative approach to vertebrate testing available, the registrant should always use this approach. If the registrant chooses not to use an appropriate alternative to a vertebrate test or is unable to apply this (for example, this may be the situation for the acute oral toxicity of most substances of unknown or variable composition, complex reaction product or biological origin) we propose they provide a justification and a testing proposal to the Agency. This information should confirm the alternative approaches that have been

[28] We intend for this proposal to be in line with current UK REACH regulations that mandate that testing must be in line with the last resort principle and provisions in the Animals (Scientific Procedures) Act 1986 where applicable. This Act provides protections for protected animals: defined as any living vertebrate other than man and any living cephalopod.

considered and justify why these are not suitable and vertebrate testing is being proposed.

96. As noted above, there are circumstances where currently there are no appropriate alternatives to using vertebrate animals. In these cases, it may be appropriate to consider a different process/arrangement to the proposed legislative approach. We would like feedback on if there are any further options which could be considered to try to reduce the use of vertebrate animal testing, whilst ensuring that registrants maintain their responsibility for the provision of adequate information on the hazards of substance they manufacture and/or import.

97. Alternatively, rather than mandating the submission of testing proposals for compliance with Annexes 7 and/or 8 of UK REACH, a non-legislative approach could be to place greater focus on supporting registrants towards their responsibilities for minimising vertebrate tests via further guidance on alternative methods/approaches and their reasonable applications. This approach would help to ensure that the last resort principle is still addressed adequately in line with the intent of Article 25 of UK REACH. It would also ensure that the duty holders (with the responsibility for testing and the consideration of alternative approaches to the use of vertebrate tests) are the registrants themselves.

Consultation questions on protecting against unnecessary animal testing

28. To what extent do you agree that the legislative approach (paragraph 94) will reduce unnecessary testing on vertebrate animals?

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree
- ○ I don’t know
- ○ I’d prefer not to say

Please explain the reasons for your answer.

29. To what extent do you agree that the non-legislative approach (paragraph 97) will reduce unnecessary testing on vertebrate animals?

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree
- ○ I don’t know
- ○ I’d prefer not to say

Please explain the reasons for your answer

30. Do you think either of the above approaches would promote the development of non-animal alternatives to testing, and if so, how might it direct this development?

- ○ Yes
- ○ No
- ○ Don’t know

Please explain the reasons for your answer. If you agree one of the approaches would promote development of non-animal alternatives to testing, please specify which.

31. Are there alternative or supplementary measures (in particular for substances currently without appropriate alternatives to vertebrate testing) that could support and further ensure that unnecessary vertebrate animal testing does not occur to fulfil the requirements of UK REACH?

- ○ Yes
- ○ No
- ○ Don’t know

Please explain the reasons for your answer

32. If you would like to comment on the analysis of protecting against unnecessary animal testing in the accompanying Impact Assessment or provide relevant data or evidence to support improving that analysis, please do so here.

Part four: UK REACH and Trade

98. Defra has endeavoured to develop the policy proposals detailed above on the ATRm and REACH Improvement in line with and in adherence to our international trade obligations and we will continue to consider potential impacts on trade as policy develops. We welcome stakeholder views on any potential changes to trade and trade implications following the implementation of these policy proposals.

Consultation questions on UK REACH and trade

33. Do you anticipate any impact on trade from the ATRm policy proposals, and if so, what do you think this impact will be?

Please explain the reasons for your answer

34. Do you anticipate any impact on trade from the REACH Improvement policy proposals, and if so, what do you think this impact will be?

Please explain the reasons for your answer

35. If you would like to comment on the analysis of UK REACH and Trade in the accompanying Impact Assessment or provide relevant data or evidence to support improving that analysis, please do so here.

Part five: Article 1 consistency statement

99. Schedule 21 to the Environment Act 2021 gives the Secretary of State the power to amend the UK REACH Regulation. However, the Secretary of State can only do so if the amendments are consistent with Article 1 of the UK REACH, and to this end, the Secretary of State is required to publish a statement to explain how this condition is met. This consistency statement will be published later in 2024 alongside the second consultation (as mentioned in paragraph 4 of the Foreword).

100. Nonetheless, our initial consideration at this stage is that our proposed changes to the current UK REACH Regulation through the introduction of the ATRm and UK REACH improvements are consistent with Article 1 of UK REACH. This is because in recognising that the hazard information for substances subject to ATRm requirements is already known to industry users and has been submitted to ECHA, our focus on increased use and exposure information will help to ensure that the risk management of these already-known hazards is improved. This improved risk management by industry through the greater focus on use and exposure information will also allow for better understanding and regulation on the use of chemical substances by the regulator, therefore ensuring high levels of protection of human health and the environment, as required by Article 1 of UK REACH. A more detailed explanation of this will be covered in our second consultation.

101. Regarding the initial UK REACH improvement proposals, improving the efficiency of the restrictions process and potentially accelerating the period until a decision on restricting substances that present an unacceptable risk can be made, should further ensure high levels of protection of human health and the environment. Maximising the resource of the regulator by removing obligations to provide

duplicative reports to government should also support this. Additionally, if the legislative means proposed to further ensure protections against unnecessary vertebrate tests are implemented, this may support efforts to promote alternative methods for assessment of hazards and innovation via developing and validating further non-animal test methods.

Part six: all consultation questions

Standard consultation questions

1. Would you like your response to be confidential? (required)
2. What is your name?
3. What is your email address?
4. Are you responding as an individual or on behalf of an organisation?
5. What type of organisation are you responding on behalf of?
6. If you are responding on behalf of an organisation, what is the name of the organisation?
7. For organisations that have legal responsibilities as a result of UK REACH, what is your role? (Select all that apply)

Hazard information requirements

8. To what extent do you agree that the removal of the more detailed elements of the hazard information requirements from UK REACH registrations would not compromise high levels of protection of human health and the environment?
9. What are your views on our assessment that the regulator does not need to hold a replica set of hazard data (the same used for EU registration dossiers) to inform prioritisation of regulatory actions?
10. Please comment on the extent to which you expect the revised hazard data requirements will reduce costs to business. Where possible, please provide supporting quantitative evidence.

Use and exposure information requirements

11. To what extent do you agree that requesting more detailed, Great Britain-specific use and exposure information will meet the aims of improving industry's risk management of chemicals and the regulatory capability for the regulators?
12. To what extent do you agree with the proposed trigger points and corresponding information requirements for registrants? (see Annex B)
13. What is your estimate for the length of time it will take to complete the necessary tasks for the registration process under UK REACH? Particularly, considering the revised ATRm requirements for use and exposure information?

14. Please comment on the extent to which you expect the revised use and exposure data requirements will increase costs to business. Where possible, please provide supporting quantitative evidence.

Chemical Safety Reports (CSRs)

15. To what extent do you agree that the proposed reduction in hazard assessment data will not negatively impact a registrant's ability to undertake exposure assessment and risk characterisation in their CSA and communicate the exposure scenarios and risk control measures downstream (where Article 14 (4)) of UK REACH applies[29]?
16. To what extent do you agree with our assessment of which aspects of information should be required or should no longer be required for CSRs (see paragraphs 54 to 59)?

ATRm regulator powers and duties

17. To what extent do you agree that the introduction of powers for transitional evaluations is an appropriate way for regulators to request supporting information on an "as and when needed" basis?
18. To what extent do you agree that the information contained in the Public Register should be adapted in the manner set out in the policy proposal in paragraph 69 of the consultation?

Substance groups, data sharing and joint data submission

19. Do you have any concerns with Substance Groups operating in the manner proposed in this consultation?
20. Whilst the actual operation of Substance Groups will be for members to work together and cooperate on independently of the Regulator (similar to SIEFs), are there any areas for improvement from the EU legislation on SIEFs which should be considered for UK REACH legislation?
21. **If you would like to comment on the analysis of the ATRm policy proposals in the accompanying Impact Assessment or provide relevant data or evidence to support improving that analysis, please do so here.**

Improving the UK REACH restrictions process

22. In your view or experience (including experience of contributing to the EU REACH restrictions process), what actions must a manufacturer, importer or affected stakeholder of a chemical proposed for restriction take (for example, confirming supply chain actors) in order to draft a response to the first consultation? (please specify how long in days/months each action takes)

[29] Classified as dangerous in accordance with GB CLP or assessed to be a PBT or vPvB

23. In your view or experience (including experience of contributing to the EU REACH restrictions process), is there any SEA information you would usually provide in the second consultation that you would not/cannot provide in the first consultation? If so, why can this information not be provided in the first consultation?
24. What information and/or engagement from UK government/the Agency would be helpful ahead of the publication of the restriction dossier (for example, information on similar restrictions in other jurisdictions or engagement to confirm supply chain actors that hold information that downstream users might not have) that may allow for a shorter, consolidated consultation period?
25. If the consultations are consolidated as outlined in paragraphs 78 and 79, are there any potential consequences (not outlined in paragraph 78 and 79) you expect or concerns you have? If so, are there any ways in which these concerns could be overcome?
26. If greater information is provided by the UK Government/the Agency before the consolidated consultation and informal consultations are considered before final opinions are published, to what extent do you agree with the recommended approach (included in Figure B) is a reasonable amendment to the current UK REACH restrictions process?

Improving the UK REACH reporting process

27. Do you agree with the proposed reporting changes outlined in paragraphs 81 to 86?

Further protections against unnecessary animal testing

28. To what extent do you agree that the legislative approach (paragraph 94) will reduce unnecessary testing on vertebrate animals?
29. To what extent do you agree that the non-legislative approach (paragraph 97) will reduce unnecessary testing on vertebrate animals?
30. Do you think either of the above approaches would promote the development of non-animal alternatives to testing, and if so, how might it direct this development?
31. Are there alternative or supplementary measures (in particular for substances currently without appropriate alternatives to vertebrate testing) that could support and further ensure that unnecessary vertebrate animal testing does not occur to fulfil the requirements of UK REACH?
32. **If you would like to comment on the analysis of protecting against unnecessary animal testing in the accompanying Impact Assessment or provide relevant data or evidence to support improving that analysis, please do so here.**

UK REACH and Trade

33. Do you anticipate any impact on trade from the ATRm policy proposals, and if so, what do you think this impact will be?
34. Do you anticipate any impact on trade from the REACH Improvement policy proposals, and if so, what do you think this impact will be?
35. If you would like to comment on the analysis of UK REACH and Trade in the accompanying Impact Assessment or provide relevant data or evidence to support improving that analysis, please do so here.

Annex A: ATRm hazard data requirements

Registration tonnage / hazard profile	Annex A – ATRm hazard data requirements																		
	Hazard classification and associated labelling	PBT /vPvB assessment	PNEC (or other Ecotoxicological Hazard Assessment Conclusion)				DNEL (or other Toxicological Hazard Assessment Conclusion - including DMEL).							Physical and chemical properties[30]						
			Aquat organism	Air	Terr'tl organisms	Predators	Workers			General Population				Phys. state	Melt freeze point	Boiling point	Vap pressure	Part. Coeff (Kow)	Water Solubility	Biodegradability in water
							Inhalation	Dermal	Eye	Inhalation	Dermal	Oral	Eye							
Full (non-intermediate) registrations																				
Below 10 tonnes	P																			

[30] This is the physical and chemical end point data that is required for all exposure assessments under Annex 1. If other physical and chemical data is available or relevant to a particular exposure scenario (for example, BCF values or Granulometry) this will need to be included in an ATRm IUCLID / registration dossiers.

Registration tonnage / hazard profile	Annex A – ATRm hazard data requirements																		
	Hazard classification and associated labelling	PBT /vPvB assessment	PNEC (or other Ecotoxicological Hazard Assessment Conclusion)				DNEL (or other Toxicological Hazard Assessment Conclusion - including DMEL).							Physical and chemical properties[30]						
			Aquat organism	Air	Terr'tl organisms	Predators	Workers			General Population				Phys. state	Melt freeze point	Boiling point	Vap pressure	Part. Coeff (Kow)	Water Solubility	Biodegradability in water
							Inhalation	Dermal	Eye	Inhalation	Dermal	Oral	Eye							
Above 10 tonnes – Article 14(4) does not apply[31]	P	P	P	P	P	P	P	P	P	P	P	P	P							

[31] For all registrations over 10 tonnes Annex 1 of REACH applies and a registrant is required to complete a Chemical Safety Assessment and prepare a Chemical Safety Report

Registration tonnage / hazard profile	Annex A – ATRm hazard data requirements																		
	Hazard classification and associated labelling	PBT /vPvB assessment	PNEC (or other Ecotoxicological Hazard Assessment Conclusion)				DNEL (or other Toxicological Hazard Assessment Conclusion - including DMEL).							Physical and chemical properties[30]						
			Aquat organism	Air	Terr'tl organisms	Predators	Workers			General Population				Phys. state	Melt freeze point	Boiling point	Vap pressure	Part. Coeff (Kow)	Water Solubility	Biodegradability in water
							Inhalation	Dermal	Eye	Inhalation	Dermal	Oral	Eye							
Above 10 tonnes – Article 14(4) applies[32]	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P

[32] Where a substance fulfils the criteria for the hazard classes listed in Article 14(4) of the REACH Regulation or is assessed to be PBT or vPvB then the chemical safety assessment requires additional steps of exposure assessment and risk characterisation. Physical and chemical data is required to undertake effective exposure assessment.

Registration tonnage / hazard profile	Annex A – ATRm hazard data requirements																		
	Hazard classification and associated labelling	**PBT /vPvB assessment**	**PNEC (or other Ecotoxicological Hazard Assessment Conclusion)**				**DNEL (or other Toxicological Hazard Assessment Conclusion - including DMEL).**							**Physical and chemical properties[30]**					
			Aquat organism	Air	Terr'tl organisms	Predators	Workers			General Population				Phys. state	Melt freeze point	Boiling point	Vap pressure	Part. Coeff (Kow)	Water Solubility	Biodegradability in water
							Inhalation	Dermal	Eye	Inhalation	Dermal	Oral	Eye							
Intermediate registrations																			
All tonnage bands	P																		

Annex B: Use and exposure information requirements (revised on 07/06/2024)

	Level 1	Level 2	Level 3
	Existing Requirements (Annex 6)	**Additional information under UK ATR (inclusive of level 1 requirements)**	**Enhanced Requirements (Inclusive of level 1 and 2 Requirements)**
General information			
Relevant to both human and environmental exposure	• Overall manufacture quantities used for production of an article that is subject to registration, and/or imports in tonnes per registrant per year in: the calendar year of the registration (estimated quantity). • In the case of manufacturer or producer of articles: brief description of the technological process used in manufacture or production of articles. • An indication of the tonnage used for his own use(s).	• Description of identified uses(s) including lifecycle stage, description of use and detail of contributing scenarios using Use Descriptors (for example, list of uses and their CS).	• Identify linked downstream uses.

	• Form (substance, mixture or article) and/or physical state under which the substance is made available to downstream users. Concentration or concentration range of the substance in mixtures and quantities of the substance in articles made available to downstream users. • Uses advised against. • Likely routes of exposure. • Site(s) of Manufacture and/or Use (Registrant). • Dispersive use or not. • Pattern of exposure. • Product category (Industrial, professional and consumer uses).		
Manufacture, formulation and industrial uses			
Environment	• No requirements	• Maximum daily use amount at site for each use (stated as a range) • Number of days with any use (days per year) for each use (Use default value of 260 unless registrant states otherwise) • Annual use amount at a site for each use (stated as a range) • Total amount used for each use across all sites (as a fraction of registered quantity)	

		• Release fraction to air, water and soil (Registrants would use default values unless stating otherwise and including a justification)	
Waste	• Is substance mainly consumed, used in subsequent use or disposed of as waste?	• No additional requirements.	• Specific information on waste collection and disposal (quantity, method, regulatory obligations).
Worker		• Percentage (w/w) of substance in mixture/article. • Physical form of the used product. • Number of sites involved in each use (as a range). • How many workers will use the substance at a single site (as a range) • Provide any information on organisational, technical. Consider including: Maximum exposure period in a day per worker; Indoor or outdoor; details on segregation of substance from workers (all uses); details on ventilation used (including local exhaust ventilation/fume cupboards) for the use; Details on organisational measures (for example training**,** health monitoring**,** standard operating procedure, housekeeping, personal protective equipment**).** • Can any route of exposure be regarded as negligible and why?	• Duration of activity per contributing scenario • Operation temperature (elevated/room temperature) • Details on persona protective equipment used (glove type, respirator type, CS specific) and details of full risk management measures not covered by Annex VI section 5. • Details on ventilation used (inc. local exhaust ventilation/fume cupboards) and other technical measures for each contributing scenario. Details of full Risk management

			measures not covered by Annex 6 section 5.
Professional, consumer uses and service life uses			
Environment	• No requirements	• Professional Use only: average daily use amount at a single site (stated as a range) • Professional Use only: Average annual use at a site (stated as a range) • Each Use: Total amount used for each use across all sites/users (stated as a fraction of registered tonnage) • Release fraction to air, water and soil (default values recommended, if they are not used then justification required) • Description of identified uses(s) including lifecycle stage, description of use and detail of contributing scenarios using Use Descriptors.	
Waste	• Is substance mainly consumed, used in subsequent use or disposed of as waste?	• No additional requirements.	• Guidance given to consumer on labelling for disposal of waste (consumer and service life).

Professional worker/consumer		• Percentage (w/w) of substance in mixture/article. • Physical form of the used product. • Estimation of total number of professional users (selected from a pre-defined range) • Provide any information on exposure reduction methods usually used or recommended for the professional and consumer uses. This could include information from SWEDS, SCEDs or from the SDS if no data is available from DSUs. Consider including : Maximum exposure period in a day per worker; Indoor or outdoor; details on segregation of substance from workers (all uses); details on ventilation used (including local exhaust ventilation/fume cupboards) for the use; Details on organisational measures (for example training**,** health monitoring**,** standard operating procedure, housekeeping, personal protective equipment**)** • Can any route of exposure be regarded as negligible and why?	• Consumer Uses: Estimation of proportion of population that will use the substance on a weekly basis (stated as a range) • Consumer and service life uses only: State if the use is expected to be performed by a member of a vulnerable population.

Triggers table

1-10 tonnes		
Trigger	*Level of information (human health)*	*Level of information (environment)*
“Non-hazardous substances” meaning those that have no classification and do not meet Art. 14(4)	Level 1 baseline	Level 2
Substances meeting Art. 14(4) criteria	Level 2	Level 2
Most hazardous substances – those which meet the “T” criteria of PBT for HH classification (Annex 13 Section 1.1.3 points (b) and (C)) – covering Carc Cat 1, Muta Cat 1 and Repro Cat 1 and 2, as well as STOT RE Cat 1 and 2) and, additionally, respiratory and skin sensitisers (all categories)	Level 3	Level 2
10+ tonnes		
	Level 2	Level 2