Title: UK REACH Alternative Transitional Registration Model (ATRm) **IA No:** **RPC Reference No:** **Lead department or agency:** Department for Environment Food and Rural Affairs **Other departments or agencies:**	**Impact Assessment (IA)** **Date:** 16/05/2024 **Stage:** Consultation **Source of intervention:** Domestic **Type of measure:** Secondary Legislation **Contact for enquiries:** Rusty Odihiri(rusty.odihiri@defra.gov.uk)

Summary: Intervention and Options

RPC Opinion: Not Applicable

Cost of Preferred (or more likely) Option (2019 prices, 2020 present value)			
Total Net Present Social Value £1,031m (£1,417m in '24 prices, '25 PV)	**Business Net Present Value** £1,031m (£1,417m in '24 prices, '25 PV)	**Net cost to business per year** -£120m (-£165 in '24 prices, 25 PV)	**Business Impact Target Status** -£599m

What is the problem under consideration? Why is government action or intervention necessary?

The UK REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) Regulation[1] is one of the main pieces of legislation for the regulation of chemicals in Great Britain. UK REACH requires substances manufactured in, or imported into, GB to be registered with the Agency for UK REACH (the Health and Safety Executive ((HSE)). Registrations include information on the hazards, uses and exposure of the substance. Registration information is used by HSE for regulatory purposes and by the registrants to identify appropriate risk management measures for themselves and other users down the supply chain.

There are two problems under consideration in this IA:

1. **The significant cost of gaining access to hazard data to fulfil the current transitional registration requirements while ensuring the solution to that does not adversely affect protections to human health and the environment**

As outlined in the UK government's impact assessment[2], which accompanied the UK REACH Statutory Instrument for extending registration deadlines published last year, the estimated cost to industry associated with buying or accessing EU hazard information (which would have been needed to complete these registrations of transitional substances) is ~£2bn by 2030.

This cost arises from the need for companies operating in Great Britain to engage in negotiations with EU industry consortia to gain access or buy data previously provided to the European Chemicals Agency (ECHA) for EU REACH registration purposes. This significant cost had led to industry concerns that companies may choose not to register. This could potentially lead to fewer substances being available on the market, resulting in significant supply chain problems and the UK sector becoming less competitive.

In 2021, the government committed to addressing these concerns, particularly focusing on alleviating the financial burden associated with acquiring the data required to support their registrations. Defra, HSE, and the Environment Agency (EA) were tasked with developing an Alternative Transitional Registration model (ATRm) within the framework of REACH that could both deliver the high levels of protections for human health and the environment while reducing the costs to industry.

[1] Regulation (EC) No 1907/2006 (EUR 2006/1907).

[2] Impact assessment on extending the UK REACH Submission Deadlines; see also "Monetised costs and benefits", section (i) below

2. Improving UK REACH processes

The current restriction and reporting models, inherited from EU REACH, are appropriate for an agency purposed to regulate chemicals across the multiple EU member states with opinions on risk and socio-economics tested in separate committees. This is not reflective of the committee structure and reporting requirements within UK REACH and can lead to nugatory and duplicative work, as our agency challenges opinions through a single independent scientific advisory board and produces regular business plans to cover all its functions. Following the UK's exit from the EU, there is now an opportunity for the UK to review its restriction and reporting processes to make them smarter, more agile and functional for GB.

Currently, testing proposals (including those involving animals) are only evaluated by HSE for substances manufactured or imported in quantities of 100 tonnes or more - even though testing on vertebrate animals may be conducted by registrants to fulfil information needs in lower tonnages. This is a problem because it is difficult to ensure that appropriate alternatives have been explored before animal tests are conducted.

What are the policy objectives of the action or intervention and the intended effects?

The key policy objective relating to the ATRm is to maintain the UK REACH chemical framework, ensuring high levels of protection of human health and the environment, while significantly reducing the cost to businesses of acquiring data to support their registrations under the current transitional provisions.

The improvements that are being proposed to the UK REACH restriction and reporting processes are intended to streamline and simplify these processes while ensuring transparency in operation and stakeholders' ability to engage is maintained. Also, we now have the opportunity to increase protections against unnecessary animal testing by extending the requirement to submit testing proposals for vertebrate animal testing to all tonnage bands. This proposal would further ensure that vertebrate animal testing only occurs as a last resort and is clearly justified by the evidence needs.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

The cost-benefit assessment considers three options, including a 'do nothing' option.

<u>Option 0</u>: Do nothing:

The problems under consideration would be left unaddressed under this option. This option maintains the status quo and retains the existing regulatory framework. It does not meet the government's drive towards reducing the cost of acquiring data while ensuring high levels of protection of human health and the environment.

<u>Option 1:</u> (preferred option):

There are **four** sets of measures under this proposal. They are:

(a) Proposals on registration requirements: amending hazard data requirements, use and exposure data requirements, and Chemical Safety Reports
(b) Proposals on ATRm regulatory powers and duties: introducing Transitional Evaluations, changes to compliance checks on dossiers, and a revision of publication of substance data.
(c) Proposals on substance groups, data sharing and joint data submission: technical changes to remedy omissions not addressed by the Withdrawal Act.

(d) Proposals for a smarter UK REACH process: amendments to the restriction process to consolidate statutory consultation and reduce period to 3 months, facilitated by providing information earlier in the process that supports responses. Removing reporting requirements and reducing duplicative information in reports, where this information is known from other processes. Extending testing proposal requirements including vertebrate animal testing to all tonnage bands.

Option 2: Industry Proposal and the Chemical Safety Report (CSR) Variant

The Industry Proposal would permanently exempt transitional registrations from the full registration requirements under UK REACH. The CSR Variant requires registrants to submit a Chemical Safety Report. The scope of Option 2 is the same as that of Option 1 (a) and (b); it does not provide alternatives to Option 1 (c) and (d).

Option 1 is the government's preferred option. It aims to strike a balance between delivering the aims and principles of UK REACH while taking into account proportionality and feasibility of implementation the transitional provisions on data submission.

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:**				
Is this measure likely to impact on international trade and investment?		Yes		
Are any of these organisations in scope?	**Micro** **Yes**	**Small** **Yes**	**Medium** **Yes**	**Large** **Yes**
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)		**Traded:** N/A	**Non-traded:** N/A	

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible SELECT SIGNATORY: Date:

Summary: Analysis & Evidence Policy Option 1

Description: Alternative Transitional Registration model and a smarter UK REACH process

FULL ECONOMIC ASSESSMENT

Price Base Year 2024	PV Base Year 2025	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: 746	**High:** 2,137	**Best Estimate:** 1,417

COSTS (£m)	**Total Transition** (Constant Price) Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Cost** (Present Value)
Low	13	0	**11**
High	121	0	**103**
Best Estimate	23	1	**24**

Description and scale of key monetised costs by 'main affected groups'

The main affected group, in terms of monetised costs, is the UK chemical industry. The costs faced are the cost of complying with revised use & exposure data requirements (transitional cost of £22m, and an ongoing annual cost of £0.2m), familiarisation costs (a one-off, transitional £0.3m cost), and the cost of complying with Transitional Evaluations [1] (with an ongoing annual cost of £0.4m over the 10-year duration).

Other key non-monetised costs by 'main affected groups'

BENEFITS (£m)	**Total Transition** (Constant Price) Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Benefit** (Present Value)
Low	964	0	**849**
High	2,516	0	**2,148**
Best Estimate	1,567	10	**1,441**

Description and scale of key monetised benefits by 'main affected groups'

The group affected by monetised benefits is the UK chemical industry. The largest benefit is the reduced costs for registration of transitional substances, with a benefit of £1,660m (present value: £1,441m) over the 10-year duration, with the large majority of this a one off transitional – rather than annual – cost.

Other key non-monetised benefits by 'main affected groups'

We expect this option to lead to industry developing a stronger understanding of the risks associated with their chemicals by generating improved use and exposure information.
Also, the proposal to streamline the restriction process and the reporting process should bring about simplifications, which may bring about a small staff time saving associated with removing the fixed costs of running a second consultation. Extending the testing proposal requirement may further ensure unnecessary vertebrate tests are not conducted.

Key assumptions/sensitivities/risks	3.5%

Substance volume forecast, and extent of costs for UK REACH registration policy that would have arisen without this intervention.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m (2024 prices, 2025 base year):			**Score for Business Impact Target (qualifying provisions only) £m, 2019 prices, 2020 PV:**
Costs: 3	**Benefits:** 167	**Net:** -165	-599

[1] See page (7) for definition

Evidence Base

Problem under consideration and rationale for intervention

Background

1. Following the UK's exit from the EU, the UK established an independent framework for chemical safety known as UK REACH[1]. UK REACH is one of the main pieces of legislation for overseeing chemical regulation 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.

2. In accordance with the European Union (Withdrawal) Act 2018[4], UK REACH maintains 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.

3. The Registration process is key to UK REACH. It requires safety information (data) on substances that are manufactured in, or imported into Great Britain, to be compiled in a dossier and submitted to the Agency for UK REACH, the HSE. It also allows the regulator to know which chemicals are on the market and who is placing them on there. The data include information on the hazards, use and exposure, and risk assessments. It is needed for effective chemicals regulation for protection of human health and the environment. EU Exit transition measures, as set out in the UK REACH[5] regulation, specify that this data should be submitted to the regulator over a series of registration deadlines in the years 2026-30.

Problem under consideration

4. The main problem under consideration is the question of how to ensure that regulators, firms and the public get access to appropriate information on the hazards and risks associated with chemicals in a cost-effective way without compromising our overall commitment to high levels protection for human health and the environment. This problem definition applies to the policy discussed here with the largest potential impacts – registration data requirements for transitional substances.

5. The estimated cost of accessing data to complete transitional registrations is ~£2 billion (within the range £1.3bn - £3.5bn) by 2030. This cost arises from the need for companies operating in Great Britain to buy data from industry consortia (or firms upstream of them) which had previously provided it to ECHA for EU REACH registration purposes. If these costs are too high then some companies may decide not to register chemicals with UK REACH after all, or might raise their prices, generating potential supply chain disruption and costs. This estimate carries a high degree of uncertainty, as it depends on the actual behaviour of companies in practice.

6. In response to concerns around the cost of acquiring the data required to complete their registrations, the government first extended registration deadlines, and then developed an Alternative Transitional Registration model (ATRm). This model aims to reduce costs to businesses of transitioning from EU REACH to UK REACH whilst maintaining existing human health and environmental protections. The new approach aims to reduce costs to industry by removing the need for the purchase of expensive data from EU consortia.

[1] UK REACH

[2] Windsor Framework

[3] 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] https://www.legislation.gov.uk/ukpga/2018/16/contents/enacted

[5] The REACH (Amendment) Regulations 2023

7. Defra, HSE, and the EA were tasked with developing a transitional model within the framework of REACH that would, using the powers of the 2021 Environment Act[6], ensure an effective regulatory transfer of the REACH Regulation into the UK and deliver high levels of protection for human health and the environment while reducing the costs to industry of acquiring the data.

8. This impact assessment appraises the costs and benefits of the government's proposals to introduce an alternative registration model (ATRm) under UK REACH to address the issues arising from the current transitional provisions.

Rationale for Intervention

9. In general terms, government action or intervention is needed due to the substantial ~£2bn costs linked to the current policy, which requires GB businesses to acquire costly data to support their registrations. The rationale for intervention is examined within the framework of the four key policies proposed under the ATRm. They are:

    - Proposals on registration requirements
    - Proposals on ATRm regulator powers and duties
    - Proposal on substance groups, data sharing and joint data submission
    - Proposals for a smarter UK REACH process

Proposals on registration requirements

10. The proposals on these requirements relate to transitional provisions for registration that extend to 2030. There are two underlying market failures that chemical registration policy seeks to address. Firstly, the negative externality of chemical pollution, and secondly, the asymmetric information that arises when chemical substances are poorly understood (which can make the first market failure more likely to occur). Registration aims to improve the understanding of chemicals – across producers, consumers and society in general – and make that information widely available. This should reduce the extent of asymmetric information, and reduce the risk of adverse exposure to chemicals.

11. One of the biggest challenges for UK REACH is that it currently requires the same hazard information for full registrations as EU REACH. The estimated cost of accessing data to complete these transitional registrations is ~£2 billion. This had led to industry concerns that companies may choose not to register. This could potentially lead to substances dropping off the market, resulting in significant supply chain problems and the UK sector becoming less competitive.

12. We therefore announced in Dec 2021 our intention to explore an Alternative Transitional Registration model (ATRm) and made a policy announcement on the ATRm[7] of 9th November 2023 updating industry on our progress and policy direction on the ATRm. As stated in our policy announcement, it has become evident that our regulators do not need to hold a complete replica of all the registration data on all chemical substances held under EU REACH in order to support UK REACH prioritisation of regulatory work.

13. This changes the character of the asymmetric information market failure that chemical registration under UK REACH would seek to address, and therefore requires the changes in registration policy described in this Impact Assessment. This is because for existing chemicals, much information on the hazard associated with them is already in the public domain. Our solution has been to modify the information requirements that applies to existing chemicals on the market. Instead of requiring

[6] Environment Act 2021

[7] UK REACH: alternative transitional registration model (ATRm)

full data on 'hazard', our more proportionate proposal is to require businesses to provide only hazard classifications to fulfil the hazard information requirements when submitting their dossiers to register their substances. This is sufficient to drive appropriate risk assessment and management.

14. PBT[8] assessment conclusions and DNEL[9] and PNEC[10] 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. This reduction in hazard data has been proposed in light of a greater focus on use and exposure information. The proposed reduction in hazard information is augmented by increased use and exposure information and the use of Transitional Evaluations.

15. 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. However, Defra's analysis of existing EU REACH registrations shows that these sections are often incomplete within the Chemical Safety Reports, or that information is not provided in sufficient detail for regulatory purposes. To address this gap and improve the use and exposure information received under the ATRm, registrants would be expected to provide enhanced information relating specifically to the use and exposure of chemicals in a GB 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.

16. These provisions align with our policy objective and outcomes outlined on page 12, specifically in reducing cost burdens on industry and ensuring that the regulator has access to sufficient information Failing to implement these changes to the current registration policy is anticipated to result in significant industry costs, estimated at around £2 billion. This would likely translate into increased prices, diminished consumer choice, risks to security of supply and decreased profits for businesses. A survey of chemical sector firms found that, in response to EU REACH registration costs, 69-78% absorbed registration costs, 13% altered production, and 19-22% increased prices.[11]

Proposals on ATRm regulator powers and duties

17. This proposal comprises Transitional Evaluations, Compliance Checks and Publication of data.

    - **Transitional Evaluations:** Although reducing information requirements also reduces the burden on industry, there may be instances where a lack of information around potential hazards and risks associated with chemicals may result in market failure. Industry and government may act on imperfect information without considering the full environment and health impacts of the substance. Industry and government may decide not to act based on imperfect information and consequently leave concerns unaddressed. Transitional Evaluations are being introduced to remedy this situation. REACH currently contains two procedures whereby HSE places an obligation on duty-holders to provide information after registration:

[8] (PBT) Substances that are Persistent, Bioaccumulative and Toxic in accordance with the criteria in Annex 13 of UK REACH.

[9] Derived No Effect Level - exposure levels beneath which a substance does not harm human health

[10] Predicted no-effect concentration – concentration level at which a chemical will likely have no toxic effect to the ecosystem

[11] Monitoring the Impacts of REACH on Innovation Competitiveness and SMEs, 2015, European Commission Table 3.3.12; monitoring-the-impacts-of-reach.pdf (rpaltd.co.uk)

dossier evaluation (compliance checks and test plan evaluation) and substance evaluation. A new 'transitional evaluation' process would be provided in legislation and included in Title VI of UK REACH - Evaluation.

Transitional Evaluations refer to a regulatory decision directed at industry duty holders requiring them to supply the information specified. Under the ATRm, a Transitional Evaluation would occur where a registrant(s) has provided a compliant ATRm registration dossier, but the regulator considers that it requires information in addition to the contents of that dossier to fulfil its regulatory responsibilities, including further assessing the potential hazards and/or risks and assurance that registrants have correctly identified these. The parameters of a Transitional Evaluation would be limited to the information requirements which would have applied if the registration dossier had followed the current provisions under UK REACH. For instance, a Transitional Evaluation may be initiated by the regulator to obtain access to an original study report for a complex endpoint or borderline result. Government intervention is required to address potential information failures that might result from reduced hazard requirements by increasing the power available to the regulator to demand information on the potential hazards and risk associated with chemicals. This has the objective of ensuring high levels of protection of human health and the environment.

- **Compliance checks**: 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 use and exposure information requirements, the regulator may want to focus on certain uses, exposures or other parameters in these compliance checks. Government intervention is necessary to ensure that the refocus of the type of registration data now required by the regulator on use and exposure is mirrored by a refocus in regulatory compliance checks.

- **Publication of data**: As with compliance checks, the change in the type of data held by the regulator will necessitate a change in what is published.

Proposal on substance groups, data sharing and joint data submission.

18. These policy proposals are technical changes to remedy omissions not addressed by the Withdrawal Act[12], rather than substantive or novel policies. The rationale for introducing them is to allow the policy to function as intended.

19. 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. 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.

20. Defra considers that similar to SIEFs, "Substance Group" provisions should be added to UK REACH and should apply to all UK REACH registrants, regardless of their route into UK REACH. This includes grandfathered registrants, DUINs (post submission of an Article 26 inquiry), NRES (New Registrants of Existing Substances) and new substances. Government intervention is required to ensure the UK REACH maintains the legislative tools that facilitate data sharing and joint submission in order to increase the efficiency of the registration system, to reduce costs and

[12] European Union (Withdrawal) Act 2018

to reduce testing on vertebrate animals. This meets the policy objective of reducing the cost burden on businesses.

Proposals for a smarter UK REACH processes

21. 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. 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.

22. 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.

Restrictions Process

23. The restrictions process is a system to correct the market failure due to a negative externality from the use of hazardous substances. In general economic terms, intervention is justified where the private industry costs do not reflect the cost to society (however, in policy terms, the trigger for intervention is an "unacceptable risk" to health or the environment). The rationale for intervention is to reduce the duration and administrative burden of the restriction process, while maintaining its effectiveness. This should enable the market failures described above to be addressed, to some degree, in a more timely and efficient fashion.

Reporting Process

24. The reporting processes under UK REACH requires HSE to provide reports,[13] at different times, to the appropriate authorities on the operation of the regulation on evaluation and enforcement and a report on the status of implementation and use of non-animal test methods and testing strategies used to generate information. There are also a series of other reports which HSE is required to produce each year for the UK Government. The rationale for intervention is to reduce the administrative burden of producing these reports without reducing transparency of the activities carried out and being delivered under UK REACH or other useful information made available to stakeholders.

Further protections against unnecessary animal testing:

25. The ATRm 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. Under the proposal for smarter UK REACH processes we propose to further tighten the existing measures to protect against unnecessary animal testing where alternative methods and tools are available. The rationale for intervention is to avoid the use of vertebrate animals in unnecessary testing.

Rationale and evidence to justify the level of analysis used in the IA (proportionality approach)

26. The largest monetisable impacts from this set of policies will relate to changes to registration requirements, and in particular, the reduction of hazard data requirements from Transitional Registrations. The cost analysis of this issue has two key elements: volumes and unit costs.

[13] UK REACH Article 117

Volumes, as was the case in the REACH (Amendment) Regulations 2023 Impact Assessment[14], are a significant driver of uncertainty.

27. Data used here is primarily notification data from the initial UK REACH transition. This is the most suitable dataset to use, because it covers the step in commercial decision-making that precedes the one of interest, so it is the best predictor available. However, the link between notification and full registration is not a clear one – many notifications, including Downstream User Information Notifications (DUINs) are unlikely to lead to full registrations. This could occur because the registration requirements are fulfilled by other market participants, such as an upstream firm, or due to a commercial decision not to proceed with registration, among other reasons. To address this uncertainty, a sensitivity analysis is presented. The unit costs for hazard data are based on cost estimates for the existing REACH registration model, with cost elements scaled down according to expert policy judgement. Unit costs for use and exposure registration requirements are based on consultants' expert judgement of the employee time required to perform the relevant tasks. These figures will not be precisely accurate in all circumstances, but are likely to be close enough to the true values to support well-informed decision-making. We are seeking information through the consultation to strengthen these estimates of hazard and use and exposure costs.

28. The analysis uses an appraisal period of ten years, starting in 2025. These parameters were chosen to provide a standard appraisal period length that captures the time period of the key impacts (though smaller-scale annual impacts continue into perpetuity).

Description of options considered

Three options were considered, including a 'Do Nothing' option.

Option 0*: *Do Nothing

29. This option relates to maintaining the status quo. It would require GB registrants to buy or negotiate access to EU data needed to support their registrations and as required under the current registration model. This option would not have the desired effect of reducing the ~£2bn cost of accessing or buying data, with the associated impact of fewer substances being available on the market, reduced firm profits, increased consumer prices and reduced consumer choice. This option would also result in no changes being made to the restrictions process, the HSE reporting processes, or animal testing protections.

Option 1: The Alternative Transitional Registration Model (ATRm), Improving UK REACH processes, and Substance Groups

30. This option implements the proposals in the Alternative Transitional Registration Model, meeting the government's objective of significantly reducing the estimated ~£2bn costs to businesses while ensuring we maintain the high levels of protection of human health and the environment. It aims to achieve this by reducing the 'hazard' information required for transitional registrations as well as improving what information on 'use and exposure' GB registrants will need to provide.

Option 2: The Industry Proposal and the Chemical Safety Report (CSR) Variant

31. This option relates to the proposal put forward by industry to permanently exempt transitional registrations from full UK REACH registration requirements. The Chemical Safety Report (CSR) variant, which is a variant of the industry proposal, sought to require CSRs as the key information provisions.

32. The industry proposal would permanently exempt industry, including downstream users[15] from submitting any additional data beyond what they had provided through their initial notifications

[14] Impact assessment

[15] IP Completion downstream users and distributors under Article 127E of UK REACH

and would rely largely on data calls as a means of yielding the information necessary for the regulator to identify risk or take regulatory action. It would also shift the responsibility of ensuring the safety of the substances they place on the market onto the regulator - thereby altering the current balance of responsibilities for the safe management of chemicals between government and industry and undermining one of the fundamental principles of REACH.

33. The “CSR variant” would provide better protection than the original industry proposal but would be potentially weaker than the existing approach. It would replace the requirement to produce full data with a requirement to provide some information on use and exposure. A model involving a smaller, revised CSR would further reduce the amount of registration data which would need to be submitted by companies. The regulator could only fulfil its different regulatory needs by supplementing CSR information through searches on public databases or by data calls. The ability to assure the public that chemicals are being effectively managed would be at most risk.

34. Following extensive discussions with industry and within government, we decided not to take either the industry proposal or the Chemical Safety Report (CSR) variant any further forward. There were some areas where we agreed that these possible models could deliver similar outcomes to the preferred approach, however, these were outweighed by significant areas where we did not think they would. The industry proposal would, for example, result in permanently different rules for importers from the EU compared to GB manufacturers or importers from the rest of the world. It would also mean that importers from the EU could continue without necessarily identifying the substances concerned. While there were certain areas where the new models showed potential for similar outcomes to the current approach, the significant disparities in other aspects led us to this decision.

35. Nevertheless, there are some elements of the Industry Proposal and the CSR variant that have been adopted into the ATRm such as data calls (formalised as Transitional Evaluations) and a reduction in the hazard information in CSRs.

36. Most of the policy problems considered here derive from the UK REACH regulatory framework. This means that it will not be possible to address them by any means other than amending regulation. However, some proposals in Option 1d (smarter UK REACH processes) may be achieved through non regulatory means and are being tested at consultation.

Policy objective

37. The policy objective is to ensure high levels of protection of human health and the environment while significantly reducing the cost burden to GB businesses of accessing or acquiring data to support their registrations. Government intervention will have the desired effect of removing the need for GB businesses to access or acquire expensive data packages by safely reducing hazard requirement and only retaining hazard data that is necessary to achieve robust risk assessment and risk management. The desired outcomes of the ATRm policy proposal are outlined below.

Outcomes

- Registration under ATRm should ensure the regulator has access to sufficient information for the identification and prioritisation of chemicals for further action, encourages efficiency, avoids unnecessary cost to industry and avoids repeated testing on vertebrate animals.

- Registration requirements should encourage / not be a barrier to innovation towards the use of less harmful chemicals.

- Manufacturers and importers of chemicals should be able to demonstrate to regulators (and by extension wider society) that they understand risks of the chemicals they manufacture / import and how the risks can be managed appropriately, including updating information if/when new information is generated. This includes ensuring appropriate communication throughout supply chains, in respect of hazard and risk associated with different uses of these chemicals.

- Registration obligations should seek to minimise the risk that data owners can impose an onerous administrative or cost burden on GB based manufacturers and importers for obtaining access to data for registration purposes.

- Indicators for success: Progress will be measured through the UK REACH monitoring and evaluation strategy, which is described in the final section of this IA.

Summary and preferred option with description of implementation plan

38. The preferred option is Option 1. It will be given effect through secondary legislation using the UK REACH amending powers in the Environment Act 2021[16]. It will apply to England, Scotland and Wales with the measures coming into effect immediately. The measures, when implemented, will safely reduce the hazard information required for transitional registrations, as well as improving the information on 'use and exposure' in GB which registrants would need to provide.

Option 1

39. There are four key policies being proposed under the ATRm. They are:

(i) Proposals on registration related requirements:

- **Hazard requirements:** proposal to significantly reduce the hazard information for transitional substances. This would mean that largely, UK REACH registrants will not need to access and pay for data packages held by EU industry consortia – resulting in a significant reduction of the estimated ~£2bn costs to industry associated with buying or accessing EU hazard information.

- **Use & Exposure information:** proposal to enhance/refine what specific information registrants in Great Britain need to provide on use and exposure. This is the critical information that we would expect industry to have or be able to obtain from their supply chain to ensure they fully understand and manage potential risks, and that GB regulators need to prioritise regulatory action. This use and exposure information will be required for all UK REACH registrations including new substances and not only registrations of transitional substances made under the ATRm.

- **Chemical Safety Reports (CSRs):** proposal for reduced hazard requirements in CSRs carried out by all registrants of a substance over 10 tonnes.

(ii) Proposals on ATRm regulator powers and duties:

- **Transitional Evaluations:** Proposal to introduce new powers for regulators to enable them to require and receive data from registrants for regulatory or risk prioritisation purposes, ensuring we can respond to new or emerging risks.

[16] *The Environment Act 2021*

- **Compliance checks:** HSE will continue to undertake compliance checks on 20% of dossiers in line with the current regulatory requirements[17]. The regulator may want to focus on certain uses, exposures or other parameters in these compliance checks to encourage and ensure adherence to these new ATRm requirements..
- **Publication of data:** a proposal to revise/review the data to be included in the Public Register for substances subject to ATRm.

(iii) Proposals on substance groups, data sharing and joint data submission:

40. Proposals to organise UK REACH Registrants of the same substance into substance groups to enable data sharing agreement and joint submission of hazard classification and data on the intrinsic properties of substances. This will enable us to formalise practical arrangements already established within the registration process under EU REACH.

(iv) Proposals for a smarter UK REACH process:

Restriction and reporting process

41. Proposal on options to streamline the UK REACH restrictions process by making adaptions to the statutory restriction process. The preferred option will consolidate the two consultations - on the restriction dossier and on the draft socio-economic opinion - into one consultation and reduce the consultation duration from six to three months. Also, the proposal to streamline HSE's reporting processes will reduce administrative burdens. Specifically, the changes will: allow draft annual reports to be submitted on the same date each year; remove the statutory requirement for HSE to produce financial reports and; remove HSE's duty to publish certain elements of a stand-alone report on the operation of UK REACH every 5 years. The justification for removing certain elements of the 5-year report is that the annual reporting requirements make it unnecessary.

Animal testing proposal process

42. Proposals to further protect against unnecessary animal testing would extend the testing proposals requirement to all testing on vertebrate animals (regardless of tonnage band) for the purposes of UK REACH. For some hazard end-points, there are currently no suitably validated alternatives to animal tests. Therefore, if implemented this proposal will result in the regulator 'approving' greater numbers of vertebrate animal tests. However, this proposal would further ensure that registrants consider testing on vertebrate animals only as a last resort and tests that are conducted are clearly justified by the evidence needs, as assessed by our expert regulators. The proposal may also drive the development and effort to validate New Alternative Methods (NAMs), including non-animal tests.

43. Government intervention in relation to these proposed measures under Option 1 would translate in cost reduction to industry resulting from safely reducing the duty on industry to access or buy expensive data hazard data without undermining the 'no data no market' principle. The renewed emphasis on use and exposure information is crucial for sustaining robust safeguards for human health and the environment.

44. HSE is the Agency for UK REACH and has responsibility for most regulatory functions including operation and enforcement of the proposed measures.

[17] Article 41(5) UK REACH

Option 2

Industry Proposal and the Chemical Safety Report (CSR) variant

45. In 2021, trade associations and manufacturers within the chemicals sector wrote a joint letter to the UK Government to outline concerns around the transitional cost of accessing the data needed to support UK REACH registrations. A proposal was made to amend registration processes under UK REACH.

46. The proposal consisted of an upfront notification of basic information, which the UK Agency could then supplement through searches on public databases (in particular, but not limited to, ECHA's) or through targeted requests to companies for further data.

47. A Working Group was established to examine the proposal and a thorough evaluation of the proposal was conducted against an agreed list of principles and tests. It became clear that the model had significant drawbacks that would potentially shift responsibility and costs from the industry to the government - putting GB out of step with the way chemicals regulation is evolving globally. The Working Group therefore explored whether there was a variant of the industry proposal we might include in the discussions that would mitigate some of the problems the model presented.

48. While the CSR variant was an improvement over the original industry proposal on environmental and health protections, it retained many of the same risks and would have required the regulator to supplement CSR information through searches on public databases (such as ECHA's website).

49. Proposals iii (Proposals on substance groups, data sharing and joint data submission) and iv (a smarter UK REACH process) could theoretically be combined with Option 2. The effects of iii and iv would be similar under Options 1 and 2. While the outcomes of iii and iv would be slightly different under Option 2 due to the policies' interactions, the overall effect would be minor. Because Option 2 is not being taken forwards, it is not proportionate to provide a detail account of these interactions here.

Monetised and non-monetised costs and benefits of each option (including administrative burden)

<u>Monetised costs and benefits</u>

Option 1

i. Proposals on registration requirements
ii. Proposals on ATRm regulator powers and duties
iii. Proposal on substance groups, data sharing and joint data submission.
iv. Proposals for a smarter UK REACH process

(i) Proposals on registration related requirements

*<u>Transitional substances' Hazard requirements</u>***:**

50. The reduction in costs associated with the hazard data requirements for a single substance are estimated by considering the cost of registering a substance under the Standard Model[18], and excluding those cost elements which do not apply under ATRm. Most of the costs of preparing a

[18] UK REACH - Establishing and refining the information requirements for transitional registration proposals and assessing the feasibility and impacts, Table 5.4, WSP-Yordas, 2023 (Unpublished)

registration dossier are retained, while study costs are excluded**.** Most of the costs of preparing a Chemical Safety Assessment / Report are retained, and a significant portion of legal and all of training costs are retained. Using this method, the remaining cost is found to be 24-30% of the Standard Model cost. Weighting by tonnage band, for the expected distribution of substances across tonnages, the average substance cost for hazard data is estimated at 27% of the Standard Model full registration cost.

51. The assumptions and method to forecast substance registration volumes are almost identical to those used in the previously published Impact Assessment on extending REACH registration timelines. Each distinct substance is counted once, in the highest tonnage band in which it appeared in notification data. For substances with no tonnage, they are apportioned to other tonnage bands in line with the distribution of substances for which there is data. The cost associated with transitional registrations in the baseline is £2.17bn[19]. This figure is composed of an average of £103k per substance, across 21,000 substances.

52. The saving against this figure is composed of an average saving per substance of £75k, across the 21,000 substances (a one-off saving of £1.6bn). The £1.6bn saving figure is profiled to correspond to the three transitional registration deadlines, with the largest share of the savings expected to arise at the third transitional deadline, in 2030, as that is the year in which the highest number of registrations is forecast to occur. Separately, we forecast a further ~130 registrations per year of those substances by new market participants (an annual recurring saving that amounts to £100m over the evaluation period, against a baseline of £140m). Adding these two savings, the forecast cost reduction to industry of this change is estimated to be £1.7bn over the evaluation period (ten years).

Transitional substances' Use and Exposure requirements

53. The estimate of the unit costs associated with these increased requirements is based on consultants' expert judgement. The only cost associated with compiling the required use and exposure data is taken to be staff time. The cost per hour of staff time is £32[20]. The number of hours taken per substance is estimated to be in the range 33-133, varying by tonnage band. Accounting for tonnage distribution, the average number of hours is 91 per substance, giving an average cost per substance of £2,900, for the highest-priority ("Level 3") substances.

54. For substances at Level 2, the time and cost are estimated, based on expert judgement[21], to be 50% of the Level 3 quantities. The volume of substances affected by the Level 3 requirements is estimated to be 170, with this figure derived from an estimate of the number of CMR 1a/1b substances which would require new information to be reported. 15,900 substances are estimated to be affected by Level 2 requirements. This is based on the proportion of substances that were classified as hazardous / PBT / vPvB under EU REACH. The one-off cost of the additional requirements is estimated at £22m.The annual, recurring cost relating to the ~130 registrations by new market participants - using the same assumptions for the distribution of substances across Levels as above in this paragraph - amounts to £0.1m annually, or £1.4m over the period.

[19] The revision of this figure upwards from the £2.0bn figure in the 2023 IA is the net effect of the inclusion of data on late DUINs and a correction to exclude notifications below 1 tonne. Figures in this section are presented in time-undiscounted terms.

[20] Based on the average labour compensation per hour worked in the sector 'Professional, scientific and technical activities' according to ONS (ONS (2022): Labour costs and labour income, UK.
https://www.ons.gov.uk/economy/economicoutputandproductivity/productivitymeasures/datasets/labourcostsandlabourshare) which is uplifted by 50% to account for overheads (based on expert judgement)

[21] Cost estimates will be tested through consultation

Proposal for revised registration requirements for new substances

55. New substances are those which had not been registered under EU REACH prior to the date of EU Exit. They remain subject to full hazard data requirements[22], which is not a policy change, and therefore has no impact measurable here. They do become subject to the new use and exposure requirements. We estimate that 40 New / Novel substances will be registered per year. This figure is based on two years of New / Novel substance data[23], projected into the future. Assessing the costs of this requirement uses the same method as that used for transitional substances' use and exposure above, with the same distribution of substances across Levels 1, 2 and 3. This gives a recurring annual impact of £40,000, or £0.4m over the period.

Chemical Safety Reports (CSR)

56. The proposed changes to CSRs are accounted for within the calculations for changes to hazard requirements in the preceding paragraphs, so they are not presented separately.

(ii) Proposals on ATRm regulatory powers and duties

Transitional Evaluations**:**

57. We assume 0.1% of substances (21 substances) are subject to Transitional Evaluations each year over the 10-year appraisal period. The true number of substances is uncertain, and will depend on future priorities identified by HSE and EA. Indicatively, this number exceeds the number of substances subject to other REACH processes (such as additions to the Candidate List and Annex XIV) so it represents a reasonable upper bound for analytical purposes. It is not a target or policy commitment. We estimate that 10% of those Transitional Evaluations would request full substance data, with an average value of £100k[24], while 90%[25] would be for a targeted data request, at 11%[26] of the full cost. "Full" and "targeted" Transitional Evaluations would each have an estimated annual cost to business of £200k, leading to an annual cost to business of £400k for the duration of the appraisal. In undiscounted terms, the cost associated with Transitional Evaluations is estimated to be £4.3m over the 10-year period.

Compliance checks**:**

58. We have not monetised the impacts that arise as a result of compliance checks. The issue is discussed in the section on Non-monetised Costs and Benefits below.

Publication of data**:**

59. We have not monetised the impacts that arise as a result of revisions to the Public Register of substances. The issue is discussed in the section on Non-monetised Costs and Benefits below.

(iii) Proposals on substance groups, data sharing and joint data submission

60. We have not monetised the impacts of these policy proposals. The issue is discussed in the section on Non-monetised Costs and Benefits below.

[22] Because otherwise that data would not be available to regulators, industry or civil society

[23] 73 dossiers received, as at Oct 2023

[24] Equivalent to the cost of fully registering a substance under the Standard Model

[25] Based on the policy judgement that "untargeted" data calls would be significantly less likely than targeted ones, due to the superfluous data submissions they would generate.

[26] This share represents the share of the cost of a full registration constituted by ecotox data requirements, which represents a plausible subset of data to be subjected to a targeted request.

(iv) Proposals for a smarter UK REACH process

61. We have not monetised the impacts of these policy proposals. The issue is discussed in the section on Non-monetised Costs and Benefits below.

Familiarisation costs

62. To reflect the initial familiarisation costs for firms associated with this package of policies, a familiarisation cost is estimated. This is not intended to cover all regulatory compliance time; staff time spent understanding and complying with specific technical elements of policies is accounted for already within the hazard and use and exposure costs set out above. With 2.5 hours[27] of reading time across each of 3,500 companies, and an hourly labour cost of £32[28], the central estimate of familiarisation costs is a one-off amount of £280k.

Aggregate savings

63. The aggregate percentage savings across transitional registrations is 71%. This is calculated as a £1.54bn net saving as a share of the £2.17bn baseline cost, over the 10-year evaluation period. Expanding the scope of the calculation to take into account the impacts associated with new market participants and Use and Exposure requirements for New/Novel registrations, the percentage savings figure remains at 71%, based on a £1.64bn saving against a baseline of £2.30bn.

Option 2

64. We have not monetised the impacts of these policy proposals because they were ruled out at an earlier stage of the policy development process.

Non-monetised Costs and Benefits

Option 1

(i) Proposals on registration related requirements

Human Health and Environmental impacts

65. The ATRm aims to reduce industry costs while ensuring high levels of protections of human health and the environment. Hazard information, concerning the intrinsic properties of a substance, cannot be expected to lead to different hazard conclusions in UK REACH compared to EU REACH as in most cases it would ultimately be based on the same studies; consequently, there would also be no change in how this element of risk assessment contributes to the whole. It is on this basis that we propose to reduce the duty to supply supporting hazard data in the registration dossier.

66. As set out in more detail in the Rationale section, use and exposure information has been shown to often be incomplete or insufficiently detailed within Chemical Safety Reports. The requirement to provide enhanced GB-specific use and exposure information should address this gap and improve the quality of information received. This should improve industry's own understanding, assessment and management of the risks of their chemicals, leading to overall improved risk management, as well as improving the regulator's ability to prioritise regulatory actions. The environmental and health impacts here are inherently very difficult to accurately monetise. This is

[27] Based on an indicative 10,000 words (or 33-40 pages) and a words per minute reading rate of 150 (centre of range from Business Impact Test guidance)

[28] Same source as the staff time figure used for Use & Exposure costs above

because the nature of the policy intervention is to gather currently unavailable information on environmental and human health risks.

Costs to industry

67. Registration requirements should not be a barrier to innovation towards the use of less harmful chemicals. Costs for transitional substances have been monetised, so are not discussed here. For New substances, the provision of use and exposure data requirements relating to environmental endpoints should be straightforward, and therefore have low costs to business. However, in the case of human health endpoints, particularly for substances which have not previously been registered at over 10 tonnes per year in the EU, meeting this requirement is likely to be more challenging. In the case of high-hazard substances, the requirements will present further challenges. However, this scenario is likely to arise infrequently.

68. Given the stability of the chemicals market (where numbers of new chemicals registered per year are in the dozens, relative to the over 20,000 established chemicals) and the size of the GB market relative to the EU market, instances where the above scenario arises are likely to be rare. Costs generated here are likely to be orders of magnitude lower than the savings generated by the reduction in hazard data requirements.

Public sector impacts

69. Changes to registration requirements do not directly impact the public sector. The indirect impacts that are expected to arise are described in the following section.

(ii) Proposals on ATRm regulatory powers and duties

Transitional Evaluations

70. Transitional Evaluation will be used as a tool to augment the ATRm process and bolster the regulators' powers to request data. Transitional Evaluations are a regulatory decision directed at industry duty holders requiring them to supply the information specified if the regulator considers that it requires it in addition to the contents of the registration dossier to fulfil its regulatory responsibilities, including further assessing the potential hazards and/or risks and assurance that registrants have correctly identified these. The required data would be within the bounds of that already specified in REACH legislation, accounting for tonnage band.

71. The benefits would be driven by the increase in the ability for HSE and EA to ensure that risks and potential hazard have been correctly identified and managed. Further, we expect the policy to encourage data quality and compliance, which should increase the awareness of substances within industry. Because we do not know the nature or scale of the evidence gaps, or the resulting risky activity, we are unable to monetise these benefits. The powers are expected to be used in a targeted, limited fashion (as set out in the section on monetised impacts above), so the resulting public-sector impacts are expected to be limited in scale.

Compliance checks:

72. The changes to registration requirements mean that the work done by the Health and Safety Executive and the Environment Agency to check registration dossiers for compliance changes. Despite no change to the legal requirements needed to check dossiers, the quantity and nature of work required will change because the dossiers themselves will have changed substantially, under the revised registration requirements. Neither the scale nor the net direction of the change in workload has yet been established. Answering this question is a priority for the next stage of the ATRm project.

73. No further business impacts are expected as a result of compliance checks, as the monetised impacts on business already assume full compliance.

Publication of data:

74. The publication of chemical data would have occurred in the baseline, as well as under the policy intervention. This means that, while there will be staff and IT costs associated with the revised policy, to a large extent, these costs would also have arisen in the baseline, so they are not in scope for inclusion here.

75. The reduction in the amount of hazard data received would mean that the regulator could include less hazard data in the statutory Public Register. However, it is likely that more use and exposure information would be published unless the registrant submitted a confidentiality claim. There will be some regulator time required to administer these claims. A fee is payable, which should make the cost impact of the claims neutral for the regulator. This policy is complementary to revised registration requirements, so it can be expected to bring about non-monetised benefits of the type described in the section on non-monetised benefits for revised registration requirements above (paras 53 and 54).

(iii) Proposals on substance groups, data sharing and joint data submission

76. These policy proposals are technical changes to remedy omissions in the Withdrawal Act, rather than substantive or novel policies. Introducing them will allow the policy to function as intended. For this reason, the impacts of the policy are not analysed in detail. Indicatively, they will help support fair data sharing and reduce the risk of anti-competitive behaviour.

(iv) Proposals for a smarter UK REACH process

Restriction

77. The main benefit anticipated is a reduction in the time between a risk that is not adequately managed being identified and controls being implemented to address it. The minimum timeline that a decision can be made is expected to reduce from 27 months in duration to 24 months. The expected impacts of restriction proposals vary significantly in character and scale between cases, so it is not possible to quantify the average effect of a restriction, nor that of reducing the duration between risk identification and controls being implemented.

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78. There is no staff time saving due to reducing the duration of the consultation, as the consultation being open does not involve any workload. There may be a small staff time saving associated with removing the fixed costs of running a second consultation, but it has not been possible to quantify this. We also anticipate some benefit from removing the burden for regulators to draft, clear and publish the final risk assessment and (later) the SEA opinion at pace; the latter is currently required to be completed in the space of a month. Removing this burden should allow for the regulator to provide final opinions sooner to the appropriate authorities. The impacts of specific restriction proposals are analysed in detail as part of the development of each proposal.

Reporting

79. The main benefit anticipated is a reduction in HSE staff time required for these reporting tasks. This is expected to allow HSE staff to focus on higher-priority work, which can be anticipated to indirectly bring about improvements to human health and environmental protections. As the exact nature of the re-prioritisation cannot be known in advance, it is not possible to assess the impacts here in further detail.

Animal testing

80. The main benefit anticipated is assurance that registrants have fully considered all existing animal testing data and alternatives before conducting vertebrate animal testing and this testing only occurring after acceptance of the testing proposal from the UK REACH regulator. A material reduction in vertebrate animal tests conducted for the purposes of UK REACH may not be realised, since registrants are already expected to abide by the 'last resort' principle. However, this proposal should further ensure that principal is maintained and mitigate for unnecessary (or repeat) animal testing, where all other evidence/options have not been considered.

81. The number of test proposals is estimated to be 50-100 per year, dependent on the number of novel registrations. However, the actual number will be much lower than this due to tests being conducted for other regulations, such as EU REACH.

82. As registrants at the lower tonnage bands, at present, do not need to wait for approval for new animal tests before they conduct them, the proposal could introduce time burdens for industry bringing products to market. Given the likely low volume of test proposals affected, as set out above, this impact – if any – would be small.

Option 2

83. Both the industry proposal and the CSR options were ruled out as they would lead to weaker protections for human health and the environment in Great Britain. Neither proposal would provide sufficient data sets required by the regulators or demonstrate that GB companies were fulfilling their obligations. Both options would potentially shift responsibility and costs from the industry to the government.

Risks

84. As part of the ATRm proposals reduce the hazard data requirements, it is possible that the absence / lack of clarity of this data could impact on the ability of HSE to carry out some regulatory processes for some substances, where that requires additional certainty around hazard information. However, to mitigate this potential risk the government has introduced Transitional Evaluations which gives the regulators the power to require data from UK registrants. The parameters of a Transitional Evaluation under the new provision would be limited to the information requirements (relevant to the annexes of REACH which give the information requirements for certain tonnages) which would have applied if the registration dossier had followed the current provisions under UK REACH.

85. We expect that the UK REACH regime will still be able to ensure high levels of protection for human health and the environment. This is because:

- Although we do not hold a replicated EU repository of hazard information, and have reduced the hazard requirements for registrants, industry will still have access to the core exposure values[29] and the necessary classification information needed for characterising risk and undertaking an exposure assessment when a substance has an adverse classification[30]. Also, where there are data gaps, the regulator will be able to request data from industry in a targeted way as part of a Transitional Evaluation. To this end, the outcomes in terms of risk assessment and any subsequent risk management remain comparable to the EU in terms of ensuring high levels of protection of human health and the environment.

[29] Derived No Effect Level (DNELs) and Predicted No Effect Concentration (PNEC)

[30] If the substance is classified as hazardous or fulfils the criteria for a persistent, bioaccumulative or toxic (PBT) substance, as described in REACH Article 14(4).

- Information and knowledge on chemicals registered under EU REACH continues to be available to HSE, EA and GB registrants. They can also draw on their own considerable experience and expertise from their previous work under EU REACH, and external expertise as provided for under UK REACH. As well as the information publicly available on the EU REACH database, those previously involved in EU REACH registrations will be familiar with information relating to hazards, uses and exposure.

- Importers from the EU will continue to receive EU REACH-compliant Safety Data Sheets from their EU suppliers which will enable them to identify and apply appropriate risk management measures.

- HSE is able to seek risk management data from other sources, if necessary, as they did when acting as a Competent Authority under EU REACH. This could include calls for evidence and other relevant sources that can provide GB-specific hazard and exposure information (such as academic journals). They can also draw on their own considerable experience from elsewhere in HSE such as COSHH and inspectors/enforcement.

Assumptions and Sensitivity

86. The key assumptions are as follows:

- **The conversion of notification volumes to full registrations**. As was the case in the REACH (Amendment) 2023 Impact Assessment, it is assumed that the tonnage profile of substances for which no tonnage has been reported reflects the tonnage profile of those for which tonnage has been reported. Also as in that IA, a “high cost” and “low-cost” scenario are used to describe the impacts that would have arisen before the ATRm intervention (i.e., the baseline). In the “low-cost” scenario, grandfathered registrations and notifications for which no tonnage band was reported are left out of the costings. This also applies in the “high cost” scenario. In addition to this, the “high cost” scenario incorporates multiple registrations per substance, including all grandfathered registrations and downstream user impact notifications for which a tonnage is reported. The latter scenario applies per-registration costs, rather than per-substance costs. Using this baseline, the range of impacts of the change in registration data requirements for transitional substances is a saving to business of £960m – £2.5bn, around a central estimate of a saving of £1.6bn, with all figures presented in undiscounted terms.

- **The extent of reduced baseline registration data costs in the UK-specific context**. Otherwise unquantified factors are likely to have led to lower costs under the UK REACH Standard Model than those seen under EU REACH (data pre-existence, data ownership, trading relationships with data owners, and an industry statement called for consortia to refrain from charging data owners). The 2023 Impact Assessment used a value of 0.67 to proxy for these effects. An attempt to generate better data as part of the consultation preceding that did not provide clear data. A survey by consultants done as part of the development of ATRm provides an alternative datapoint that can be used as a proxy. That survey found that costs under UK REACH could be 22% of the costs seen under EU REACH. This can be interpreted as a “cost-reduction factor” of 0.22. This figure is based on a small sample size, so it is unlikely to be a reliable estimate of the true population value. Using this figure causes the central estimate of the saving for transitional substances to fall from £1.6bn to £520m. This would be against a backdrop of proportionally lower baseline costs; the percentage reduction in costs remains constant. It remains a significant source of uncertainty.

Impact on medium, small and micro businesses

87. There are 3,470 registered businesses in the chemical sector, of which 3,090 (89%) are small and micro businesses, and 295 (9%) are medium-sized. Of the 85,000 employed directly in the sector, small and micro businesses employ 20%, and medium-sized businesses employ 30%. Of the £36bn turnover in the sector, 10% is generated by small and micro businesses, and 24% by medium-sized businesses[31].

Option 1

(i) Proposals on registration related requirements

88. No disproportionate impacts on micro, small or medium sized businesses are foreseen. While the Use and Exposure requirements would likely be more challenging for a smaller firm to comply with than they would be for a larger firm, the overall policy impact is expected to be proportionately more favourable to smaller businesses than to larger ones. This is because ATRm removes the requirement to provide full hazard data packages. This requirement is likely to have been something that micro, small, and medium firms would have found more challenging than larger firms, due to larger firms being more likely to own hazard data and to have in-house staff with relevant skills to produce compliant dossiers. The data required to comply with the proposed Use and Exposure requirements should be more accessible within a smaller business than the full Hazard data would have been.

89. These factors are expected to apply both when firms hold the data internally, and when they need to seek it from other firms along the supply chain, with no further disproportionate impacts identified in the latter case. For new substances, given the low expected aggregate impact of that policy change, the impact on small, medium and micro businesses is expected to be negligible.

(ii) Proposals on ATRm regulatory powers and duties

90. It's likely that some medium, small and micro businesses will be required to comply with Transitional Evaluation requests. Given firms which place more substances on the market have a higher likelihood of being subject to Transitional Evaluations, and given that larger firms are likely to market more substances, there is unlikely to be a disproportionate cost impact of this policy on small, micro or medium businesses. These considerations also apply with respect to Compliance Checks. The effects of changes to Publication on small, medium and micro businesses are expected to be negligible.

(iii)Proposals on substance groups, data sharing and joint data submission

91. For the reason set out in the account of the non-monetised impacts of this policy above, the impacts of this policy for small, medium and micro businesses are not analysed in detail.

[31] https://www.gov.uk/government/statistics/business-population-estimates-2023 for stats except total employment, which is sourced from JOBS03: Employee jobs by industry - Office for National Statistics (ons.gov.uk), and total turnover, which is sourced from Monthly Business Survey turnover in production industries - Office for National Statistics (ons.gov.uk). JOBS03 and MBS are preferred sources for these statistics, but they do not include breakdowns by company size, so BPE is used for that purpose.

(iv) Proposals for a smarter UK REACH process

92. Changes to the Restriction and Reporting processes are not expected to impact small, medium or micro businesses. The Animal Testing proposal, as set out in the section on non-monetised costs above, is likely to cause a low volume of test proposals to be affected, and so, the impact on small, micro and medium businesses is expected to be negligible.

A summary of the potential trade, innovation and competition implications

93. The UK Government will be notifying the WTO on the implications of this policy on the Technical Barriers to Trade (TBT) in the second half of 2024. We consider there to be a low risk of WTO challenge as we have assessed there to be no potential breaches of our WTO Agreements.

94. It is likely that the proposed changes to registration requirements would facilitate international trade – specifically importation of chemicals into GB. This is because – as set out in the "Monetised costs and benefits" section on "Proposals on registration related requirements" section above – it significantly reduces the costs of bringing chemicals onto the GB market. It has not been possible to quantify the size of the impact. The changes do not favour firms from any particular nation or region.

95. Given the expected reduction in costs to business, which is expected to ensure a broad range of chemical substances remain available on the market, the overall policy package can be expected to positively impact innovation and competition. Further to this, the chemicals industry underpins UK manufacturing, supplying raw materials and inputs to a range of sectors, with more than 95% of all manufactured products in the UK contain inputs from the chemicals industry. This means that measures supporting innovation and competition in the chemicals sector can be expected to positively affect the wider UK economy. The proposals on substance groups, data sharing and joint data submission should remedy a situation which may have allowed anti-competitive behaviour to occur, where firms could have hindered their competitors' ability to comply with regulations by withholding consent to participate in data sharing and joint submission.

Monitoring and Evaluation

96. There is already a monitoring and evaluation strategy in place for the transition from EU REACH to UK REACH, which is a seven-year plan incorporating process, impact and value for money evaluations[32]. The evaluation methodology includes management information, trade data, interviews and surveys with industry, and interviews with authorities and NGOs. The proposals covered under this impact assessment can be readily incorporated into the evaluation strategy as evaluating REACH registration policy is a key part of the strategy.

97. The evaluation of UK REACH uses a theory of change -based approach due to the lack of ability to measure impacts on human health and the environment (at this current time). The evaluation strategy takes an agile approach so as to respond effectively to future requirements. Prior to any changes being implemented we will undertake a theory of change analysis to identify the inputs, activities, outputs, outcomes and impacts associated with the proposals and, as part of this, we will identify the key data requirements and sources of these, as well as processes for data collection.

98. Utilising a theory of change based approach enables the evaluation to assess whether the objectives and outcomes of the ATRm (as outlined in the Rationale section above) are being realised.

[32] https://sciencesearch.defra.gov.uk/ProjectDetails?ProjectId=21617

99. It is anticipated that the evaluation will include:

Impact evaluation (with the counterfactual being the existing process for UK REACH)

- Number of transitional registrations (Comply with UK REACH database)
- Costs to business to fully register transitional registrations (industry interviews/survey)
- Reasons for not fully registering transitional registrations (industry interviews)
- Quality of registration dossiers and ability to undertake appropriate risk management and regulatory measures (interviews: expert opinion, regulator and industry opinion)
    - Quality of the use and exposure data provided (interviews: expert opinion, regulator opinion)
    - Transitional Evaluation: Additional information requested from the Authority in how many cases (management information) and the quality of information provided (interviews: expert opinion, regulator opinion)
- Number of substance groups (management information/Comply with REACH database)
- Outcome of the review and revision of the “hazard data” to be included in the Public Register for substances subject to ATRm (interviews: exert, regulator, NGO and industry opinion).
- Efficiency and effectiveness of revised restriction processes (management information; regulator opinion, industry opinion)
- Changes to the quantity of vertebrate animal testing as a result of the proposed changes

Process Evaluation

- Seeking to understand how well the revised registration process is working from an industry and regulator perspective and identify what, if any, improvements could be made (Interviews: industry and regulator; industry survey).
- Compliance and enforcement: The proportion of registration dossiers checked for compliance by the Authority and the level of compliance in the dossiers. (Management information, Interviews: regulator).
- How well the proposed revised restriction process working and whether is it working as intended. Identifying what, if any, improvements could be made (Interviews: industry and regulator).