Title: UK REACH: Extending data submission

deadlines IA No:

RPC Reference No:

Lead department or agency: Department for Environment

Food and Rural Affairs

Other departments or agencies:

Impact Assessment (IA)

Date: 5/07/2022

Stage: Consultation

Source of intervention: Domestic

Type of measure: Secondary

Legislation

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RPC Opinion: RPC Opinion Status

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Summary: Intervention and Options

Cost of Preferred (or more likely) Option (in 2022 prices)							
Total Net Present Social Value	Business Net Present Value	Net cost to business per year	Business Impact Target Status Qualifying provision				
£90m	£90m	-£10m	Quamying provision				

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

The UK REACH¹ (the Registration, Evaluation, Authorisation and Restriction of Chemicals) Regulation is one of the main pieces of legislation relating to the regulation of chemicals in Great Britain. It sets out requirements relating to the registration, evaluation, authorisation and restriction of chemicals. UK REACH regulates the use of chemicals in Great Britain as EU REACH continues to apply in Northern Ireland under the Northern Ireland Protocol. UK REACH currently requires information on substances that are manufactured in, or imported into, GB to be registered with the UK Agency - the Health and Safety Executive (HSE). The current deadlines for completing this transitional registration process are 27 October 2023, 27 October 2025, and 27 October 2027 depending on the tonnage and hazard profile of the substance.

In response to concerns raised by stakeholders around the cost of acquiring the data required to complete their registrations, the government is working with stakeholders to explore an alternative transitional registration model. The aim of this model would be to reduce costs to businesses of transitioning from EU REACH to UK REACH whilst maintaining or improving existing environmental and health protections, in line with our international commitments. Developing a new model is highly technical and complex and time is needed to develop a firm proposal. If a suitable model is found, operational (e.g., IT development) and legislative changes would need to be made to implement it.

The first of the current registration submission deadlines is in October 2023. Government intervention is therefore necessary to extend the current transitional deadlines for data submission to ensure there is sufficient time to allow for substantive development of the policy, and to make operational and legislation changes for the model. Industry would also need time to prepare for compliance with it. Extending the deadlines would reduce the likelihood of companies making nugatory spend in complying with current deadlines and data requirements and would allow them to plan their business decisions in relation to the extended deadlines.

The current legislative timelines for the UK regulator to carry out the 20% compliance checks requirement under Article 41 of UK REACH² also need to be amended to match the new deadlines to ensure that HSE are able to make the relevant checks after the data has been submitted. This would not be possible if it continued to apply to the current deadlines, as no data would have been submitted to the HSE to check for compliance.

¹ Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (EUR 2006/1907).

² Article 41(5) - to check compliance of registration dossiers the Agency shall select, until 31 December 2023, a percentage of those dossiers no lower than 20 % of the total received by the Agency for registrations in tonnage bands of 100 tonnes or more per year. The Agency shall, until 31 December 2027, also select a percentage no lower than 20 % of the total received by the Agency for registrations in tonnage bands of less than 100 tonnes per year.

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

The key policy objective is to maintain the principles and objectives of the UK REACH chemical framework. The intended effect of the action under consideration is to ensure that there is sufficient time for substantive development of the alternative transitional registration model - to operationalise and legislate for it, and to allow time for industry to prepare and comply. This will involve extending the current UK REACH transitional submission deadlines by up to 3 years. The current submission deadlines³ are phased between 27 October 2023, 27 October 2025 and 27 October 2027, depending on tonnage and hazard profile. See Table 1 (below).

The government's intention is to achieve this outcome by extending the current submission deadlines by up to 3 years. It will also help industry avoid making nugatory investments towards acquiring EU data from EU consortia to satisfy the requirements of the current submission deadlines.

Although a reduction in industry costs is one of the primary aims in developing an alternative registration approach, it is not one of the aims in extending the transitional deadlines, so any cost reductions set out in this Impact Assessment are incidental to the need to extend the deadlines.

Table 1: Current and proposed UK registration submission deadlines

Current Deadline	Option 1	Option 2	Tonnage	Hazardous Properties
27 Oct 2023	27 Oct 2026 (+3 years)	27 Oct 2026 (+3 years)	1,000 tonnes or more per year	Carcinogenic, mutagenic or toxic for reproduction (CMRs) - 1 tonne or more per year Very toxic to aquatic organisms (acute or chronic) - 100 tonnes or more per year Candidate list SVHC substances (as at 31 December 2020)*
27 Oct 2025	27 Oct 2028 (+3 years)	27 Oct 2027 (+2 years)	100 tonnes or more per year	Candidate list SVHC substances as at (27 October 2023)*
27 Oct 2027	27 Oct 2030 (+3 years)	27 Oct 2028 (+1 year)	1 tonne or more per year	

³ The REACH etc. (Amendment etc.) (EU Exit) Regulations 2020

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^{*}Current deadline

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

The changes envisaged require legislative intervention as the current deadlines are enshrined in law. The options being considered are:

- Baseline Do Nothing do not change the current submission deadlines. (27 October 2023, 27 October 2025, and 27 October 2027).
- Option 1 Extend all the current submission deadlines for each tonnage band by three years.
 To October 2026, October 2028, and October 2030).
- Option 2 (preferred option) Extend the first submission deadline by 3 years to October 2026, the second by 2 years to 2027 and the third by 1 year to 2028. Option 2 is government's preferred option because it means that the transitional registration data is still received as early as possible, while allowing industry sufficient time to comply.
- Alternatives to regulation As the current transitional deadlines are a legislative requirement
 it is not possible to achieve the objectives without amending the existing regulations.

Will the policy be reviewed? It will not be reviewed. If applicable, set review date: Month/Year							
Is this measure likely to impact on international trade and investment? No							
Are any of these organisations in scope?	Micro Yes	Small Yes	Mediu Yes	m	Large Yes		
What is the CO ₂ equivalent change in greenhouse gas emissions? (Million tonnes CO ₂ equivalent)		Traded: N/A	No		raded: 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

Description:

FULL ECONOMIC ASSESSMENT

Price Base	PV Base	Time Period	Net Benefit (Present Value (PV)) (£m)				
Year 2022	Year 2022	Years 10	Low: 110	High: 290	Best Estimate: 170		

COSTS (£m)	Total Tra (Constant Price)	nsition Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	0		0	0
High	0		0	0
Best Estimate	0		0	0

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

None

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

Regulatory actions such as authorisations and restrictions can still be carried out effectively; however, a delay in UK specific data may affect how the regulator targets or prioritises its actions. Under EU REACH, evidence beyond registration dossiers is also sought to help determine regulatory priorities and it is considered unlikely that changing the deadlines will lead to real-life consequences in Great Britain.

BENEFITS (£m)	Total Tra (Constant Price)	nsition Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	0		0	110
High	0		0	290
Best Estimate	0		0	170

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

The key monetised benefit is the reduced net present cost to business of UK REACH transitional registration. This benefit only arises when measured in present-value terms, as only the timings of the policy change.

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

The key non-monetised benefit is that the requirement for firms to submit information based on criteria that are likely to subsequently change is avoided. This benefit is not quantifiable because it depends on the impacts of an alternative registration model, which is currently under development.

Key assumptions/sensitivities/risks

Discount rate (%)

3.5

It is assumed that all substances that have been grandfathered or notified by a downstream user to UK REACH will be registered. It is assumed that costs per substance will be similar to those seen in EU REACH, once a cost reduction factor is taken into account.

BUSINESS ASSESSMENT (Option 1)

Direct im	pact on bu	ısiness (Equiv	alent A	nnual) £	lm:	Score for Business Impact Target (qualifying
Costs:	0	Benefits:	20	Net:	-20	provisions only) £m:
						-20

Summary: Analysis & Evidence

Policy Option 2 (Preferred Option)

Description:

FULL ECONOMIC ASSESSMENT

Price Base	PV Base	Time Period	Net Benefit (Present Value (PV)) (£m)				
Year 2022	Year 2022	Years 10	Low: 60	High: 120	Best Estimate: 90		

COSTS (£m)	Total Tra (Constant Price)	nsition Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	0		0	0
High	0		0	0
Best Estimate	0		0	0

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

None

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

Any human health, environmental or public sector impacts would be similar to those described under Option 1, but moderated due to the smaller amendments to submission dates under this option.

BENEFITS (£m)	Total Tra (Constant Price)	nsition Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	0		0	60
High	0		0	120
Best Estimate	0		0	90

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

The monetised benefits are similar to those described under Option 1, but moderated due to the smaller amendments to submission dates under this option.

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

The key non-monetised benefit is that the requirement for firms to submit information based on criteria that are likely to subsequently change is avoided. This benefit is not quantifiable because it depends on the impacts of an alternative registration model, which is currently under development.

Key assumptions/sensitivities/risks Discount rate (%)	3.5
As Option 1.	

BUSINESS ASSESSMENT (Option 2)

Direct imp	oact on bus	siness (Equiv	alent A	nnual) £m:	Score for Business Impact Target (qualifying
Costs:	0	Benefits:	10	Net : -10	provisions only) £m:
					-10

Evidence Base

Problem under consideration and rationale for intervention Background

- 1. UK REACH (the Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation). is one of the main pieces of legislation for the regulation of chemicals in Great Britain. UK REACH applies to Great Britain as EU REACH continues to apply in Northern Ireland. The Registration process is key to UK REACH. It requires safety information on substances (data) that are manufactured in, or imported into Great Britain, to be compiled in a dossier and submitted (registered) to the Agency for UK REACH, the Health and Safety Executive (HSE). The data include information on the hazards, use and exposure, and risk assessments and is needed for effective chemicals regulation for protection of human health and the environment.
- Registration is designed to provide public assurance that industry has met its obligations to understand the properties of the substances they manufacture or import and then to use this information to assess and manage the risks related to these substances. UK REACH also provides a regulatory framework to control or restrict the use of hazardous substances.
- 3. The government introduced transitional provisions in UK REACH pursuant to the European Union (Withdrawal) Act 2018 to reduce the disruption to industry as the UK moved to the new system (UK REACH). These provisions allow companies to submit initial 'notification' data in order to continue trading and then provide the full registration data after a further 2, 4 or 6 years from 28 October 2021 depending on the tonnage and hazard profile. This is to satisfy the no data, no market access principle of REACH.
 - The UK chemicals industry and environmental and health NGOs broadly support a REACH-type approach in the UK and have argued for staying as close as possible to EU REACH. However, there are potentially significant cost implications associated with acquiring or gaining access to the data necessary for the transition to UK REACH.
- 4. Defra, HSE, and the Environment Agency (EA) are working closely with industry and NGOs to devise, develop and deliver an alternative transitional registration model within the framework of REACH that can both deliver the high levels of protections for human health and the environment while reducing the costs to industry of acquiring the data.

Problem under consideration

- 5. The main problem is one of timing and the sequencing of the data submission timelines with the timeline for introducing the new transitional provisions. There are a range of legally defined deadlines currently in place for the transition to UK REACH. The first deadlines for submitting transitional registrations were in 2021, with relevant companies providing initial information to the UK Agency, assuring continuity of access to the GB market. The next stage is for companies to form substance groups to begin the process of sharing data and providing the full registration data. This is the point at which negotiating access to the data packages held by the EU consortia begins and industry are currently working towards the 27 October 2023 deadline. The government needs sufficient time to develop, consult and then legislate for the alternative transitional registration model. Therefore, it is necessary to extend the current submission deadlines.
- 6. Although the risk that companies will start to make investments in securing data packages over the next few months is considered low⁴, government action is necessary to minimise any risk of companies making nugatory investment towards acquiring information while the current alternative transitional registration model is under development. Moving the current dates for data submission will mitigate this risk.

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⁴ HMG published its plans to consult on its proposal to extend the deadlines on 6 December 2021

7. It is also necessary to make related amendments to Article 41(5) of the UK REACH Regulation, which places deadlines on HSE of 31 December 2023 and 2027 to carry out compliance checks on no less than 20% of the registration dossiers received, according to tonnage. These deadlines should be amended to reflect the proposed data submission deadlines to ensure that this regulatory process is applied in the most effective manner. This would not be possible if the Agency continued to be subject to the current deadlines in Article 41, as they would fall before the relevant submission deadlines.

Rationale for intervention

- 8. The government are currently developing an alternative transitional registration model with the aim of maintaining a high levels of protection of human health and environment while also alleviating costs to industry by removing the need for industry to engage in the expensive data negotiations with EU consortia. This should ultimately result in a refocus in the information industry will be required to submit to the regulator (HSE). There are legal provisions under UK REACH which require industry to submit full registration data by 27 October 2023, 27 October 2025 and 27 October 2027 (depending on the registrant's tonnage band or the hazard profile of the substance).
- 9. The government needs to defer the current deadlines to provide sufficient time to develop and consult on new legislation, and make operational changes (e.g., IT development) to introduce the alternative transitional registration model. Extending the deadlines will reduce the likelihood of companies making nugatory investments in complying with current deadlines and data requirements. It will allow them time to plan their business decisions in relation to the extended deadlines.
- 10. Government intervention is also necessary to move the dates currently mandated in UK REACH for HSE to complete the 20% compliance checks to ensure the checks are made after the data is submitted.

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

- 11. The issue under consideration in this IA is simply to assess any costs, benefits or risks associated with moving the current UK REACH submission dates. This IA does not consider the alternative transitional registration model itself, which is still at an early stage of development. That model will involve a much wider range of issues which will be examined in its own IA in due course. The evidence used here reflects the best possible evidence available given the proportionality of the analysis at this stage as a consultation Impact Assessment of limited scope.
- 12. The cost analysis in this impact assessment uses two main data sources. Forecast registration numbers are based on UK REACH Service data on grandfathered registrations and Downstream User Import Notifications. Unit costs are derived from three EU REACH evaluations⁵, one covering each of the three EU REACH registration deadlines. The rationale for using UK REACH data is that it is clearly the best available predictor of firms' UK REACH registration intentions, as registering with the UK REACH Service is a legally obligatory step in the transitional registration process. A weakness of this dataset is that actual registration behaviour, with respect to full registration data requirements, may differ considerably from the preliminary registration behaviour recorded so far, as companies keep their market strategies under review. It is not possible to resolve this uncertainty before registration activity completes. The use of this data is therefore appropriate.
- 13. The rationale for the use of EU REACH cost assessments is that they are the best available data source. The data requirements under EU REACH are identical to the current UK REACH data

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⁵Study on the impacts of the 2018 REACH registration deadline - Publications Office of the EU (europa.eu); Table 4.5, p46 (and two earlier studies referred to in that document)

requirements, so EU REACH costs are a suitable guide to UK REACH costs. However, the EU costs were linked to the generation of new data sets, including new tests. The UK REACH costs would be related to UK companies buying access to that data, rather than repeating tests to generate the same data.

- 14.A weakness of this dataset is that there are several reasons to believe that unit costs under UK REACH could be lower: the required data already exists, and some firms operating in GB will either own data already or have trading relationships with data owners, so they are likely to be able to access data on relatively favourable terms. For example, some trade bodies in the EU and UK have published advice that companies should not be charged a second time for data they have already accessed for the purposes of EU REACH.
- 15. So far, the evidence base for this IA was drawn from an informal consultation with a small number of industry bodies and NGOs which took place in February/March 2022. The purpose of the discussions was to seek views on the practical implications of the options for amending the deadlines rather than the costs of registration.
- 16.In March the government also informally sought the views on extending the data submission deadlines from a group comprising industry, NGOs and academia. Most of stakeholders indicated support for Defra's preferred option (Option 2), although some NGOs were concerned about the impact that further delays to submitting registration data might have on human health and environment protections.
- 17. Both the industry and NGOs representatives emphasised the uncertainty surrounding the timing and eventual shape of the new registration approach. There was a common view that the appropriate spacing between submission deadlines is likely to depend on the requirements finally placed on companies by the alternative registration approach.
- 18.A formal consultation, as required under the Environment Act 2021⁶, is scheduled for July 2022. The information we gather from this consultation will help strengthen the quality of our initial analysis and fill in any evidence gaps that have not been addressed through the informal consultation.

Description of options considered

<u>Baseline (Do Nothing)</u> – do not change the current submission deadlines (27 October 2023, 27 October 2025, and 27 October 2027).

- 19. Defra is currently working with industry, NGOs and key stakeholders to develop an alternative registration model which looks to reduce the burdens associated with the submission of information under the current model information, while improving the understanding by industry and regulators of the risks connected with use and exposure to chemicals in Great Britain. There are impending deadlines for the submission of information under the current legislation to which industry are legally bound. Moving to a new alternative transitional registration model is likely to change the information industry would have to provide under the current legislation.
- 20. With a 'do nothing option' the first deadline of 27 October 2023 will fall before the government has had time to develop and legislate for an alternative model. This will cause considerable uncertainty about what companies' duties are and what steps they should be taking to meet them. There is also a risk that industry could start making nugatory investment towards acquiring data that may not be necessary under the criteria set out in the alternative transitional registration model being devised.

Option 1 - Extend all the current submission deadlines for each tonnage band by 3 years. (October 2026, October 2028, and October 2030).

⁶ Schedule 21 of the Environment Act 2021

21. Option 1 would have the effect of amending the current legislative provisions by moving the current submission deadlines for each tonnage band In UK REACH by 3 years to 27 October 2026, 27 October 2028, and 27 October 2030 - as illustrated in *Table 2* below.

Table 2: UK registration submission deadlines under Option 1

Current Deadline	Option 1	Tonnage	Hazardous Properties
27 Oct 2023	27 Oct 2026 (+3 years)	1,000 tonnes or more per year	 Carcinogenic, mutagenic or toxic for reproduction (CMRs) - 1 tonne or more per year Very toxic to aquatic organisms (acute or chronic) - 100 tonnes or more per year Candidate list SVHC⁷ substances (as at 27 October 2024).
27 Oct 2025	27 Oct 2028 (+3 years)	100 tonnes or more per year	Candidate list SVHC substances as at (27 October 2026)
27 Oct 2027	27 Oct 2030 (+3 years)	1 tonne or more per year	

- 22. Option 1 would mean that industry would only have to submit registration information once conclusions have been reached on an alternative model and legislated for. The projected timeline for legislating for any new transitional registration model is 2024 at the earliest. Extending the first submission deadline by 3 years to 27 October 2026 would give the government time to introduce the alternative model.
- 23. Extending the remaining deadlines by 3 years for each tonnage band would have the desired effect of deferring the impending obligations on industry to provide information to HSE, giving them sufficient time to adopt and adhere to any new requirement under the new alternative model.
- 24. Option 2 Move the first submission deadline by 3 years to October 2026, the second by 2 years to October 2027, and the third by 1 year to October 2028.

Option 2 is the **government's preferred option**. Option 2 would move the first submission deadline back by 3 years, the second by two years and the final deadline by just one year as illustrated in Table 3 below.

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⁷ Substances of Very High Concern

Table 3: UK registration submission deadlines under Option 2

Current Deadline	Option 2	Tonnage	Hazardous Properties
27 Oct 2023	27 Oct 2026 (+3 years)	1,000 tonnes or more per year	 Carcinogenic, mutagenic or toxic for reproduction (CMRs) - 1 tonne or more per year Very toxic to aquatic organisms (acute or chronic) - 100 tonnes or more per year Candidate list SVHC substances as at 27 October 2024
27 Oct 2025	27 Oct 2027 (+2 years)	100 tonnes or more per year	Candidate list SVHC substances as at 27 October 2025
27 Oct 2027	27 Oct 2028 (+1 year)	1 tonne or more per year	

- 25. Moving the first submission deadline back by 3 years should give the government time to introduce the alternative transitional registration model and those subject to that deadline time to comply with it. Option 2 has the advantage of the transitional registration data being received by HSE earlier than under Option 1. Under this option, those subject to the second two submission deadlines would have less time to take account of what those subject to earlier submission deadlines did. We do not consider that there would be any significant impacts to industry as a result of the reduced gaps between submission deadlines, and believe any disadvantages are outweighed by the benefits of HSE receiving the transitional registration data sooner.
- 26. As set out in the Article 1 Consistency Statement⁸, the government considers that this option would be consistent with Article 1 of the UK REACH Regulation. In particular, with the purpose of ensuring a high level of protection for human health and the environment and the free circulation of substances.

Alternative options considered - Information and guidance

27. Information to industry, in the form of a government publication, was considered early on in the option development stages. However, the existing submission deadlines are legal requirements and information or guidance about progress on an alternative registration model could not override the duty on companies to comply with the existing law.

Policy objective

28. The primary aim of the government's intervention is to defer the current submission deadlines in UK REACH. The intended outcomes are twofold:

• Outcome 1, to provide sufficient time for the government to develop and introduce the new transitional registration model and any legislative changes to the current registration model

⁸ Paragraph 1(1) of Schedule 21 to the Environment Act 2021 gives the Secretary of State the power to amend the UK REACH Regulation. The Secretary of State can only do so if the amendments are consistent with Article 1 of the UK REACH Regulation, which sets out its aim and scope. The Secretary of State must publish a statement to explain how this condition is met. A statement has been published alongside the consultation on the govern proposals to extend the submission deadlines.

before industry would otherwise have had to comply with the existing requirement. This would have the effect of allowing the new transitional measures for submission of data come into force in 2024, before the revised submission dates.

• Outcome 2 - to defer the current submission deadlines to provide industry with sufficient time to prepare for and adhere to any new information requirements in the alternative transitional registration model that is being devised. Extending the deadlines would reduce the likelihood of companies making nugatory spend in complying with current deadlines and data requirements and allow them to plan their business decisions in relation to the extended deadlines.

Summary and preferred option with description of implementation plan

- 29. The preferred option (option 2) will be given effect through secondary legislation using the UK REACH amending powers in the Environment Act 20219. It will apply to England, Scotland and Wales with the measures coming into effect immediately. The measures, when implemented, will extend the current submission deadlines and provide government sufficient time to develop and implement an alternative registration model and industry with sufficient time to comply with revised obligations.
- 30. Government intervention will ensure industry is no longer under a legal obligation to provide information in 2023, 2025 and 2027 (depending on tonnage and hazard profile). Instead, they would be required to provide it at a later date when the data requirements under the alternative transitional registration model would have been determined. Government intervention will also obviate the potential for industry to engage in negotiations with EU consortia for expensive data that might not be required under the alternative registration model currently being developed.
- 31. HSE is the Agency for UK REACH and has responsibility for most regulatory functions including operation and enforcement of the proposed measures.

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

- 32. The only impact of these policy options that has been monetised is the change to the net present value of registration costs to firms. This arises as a result of changing the submission deadlines. Changing registration timelines only affects the point in time at which costs occur, rather than the actual scale of the costs. However, because of the potential scale of the costs involved, and the extent of the proposed changes to the timelines, the impact of changing timelines is still significant. Further information on the possible impacts of these options is being sought through the associated consultation.
- 33. The basis for the analysis of changing timelines is an assessment of the total cost of UK REACH transitional registrations as would be required under UK REACH¹⁰ as it stands.
- 34. The total cost of transitional registration under UK REACH as it stands has been calculated by multiplying the forecast number of substances to be registered by the cost of a registering a substance. The forecast number of substances registered is 22,400, which is an estimate of the number of distinct substances by EC number that have been grandfathered or notified to UK REACH. The cost per substance is derived from an EU evaluation of costs per substance, broken down by tonnage band¹¹. The cost is made of up the costs of preparing a dossier, study costs (physico-chemical, toxicological, ecotoxicological), training/familiarisation and legal costs, as reported in the preceding footnote. Substances that have been reported in multiple tonnage bands are counted only once, in the highest reported tonnage band. Substances for which no tonnage

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⁹ The Environment Act 2021

¹⁰ Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (EUR 2006/1907)

¹¹ Study on the impacts of the 2018 REACH registration deadline - Publications Office of the EU (europa.eu), Table 4.5, p46 for totals and Table 4.8, p53 for composition (see "Final Report" file, not "Executive Summary"); https://op.europa.eu/en/publication-detail/-/publication/bbf2a250-c996-11eb-84ce-01aa75ed71a1/language-en; Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs, Table 3.3.6; https://ec.europa.eu/docsroom/documents/14581/attachments/1/translations/en/renditions/pdf;

band has been reported are allocated to tonnage bands in proportion to substances for which tonnage is reported. The EU cost evaluations broadly reported that costs tend to be higher for higher-tonnage substances, however, this was not the case for all tonnage bands¹². Using those costs per substances directly would fail to take into account several factors which suggest that unit costs under UK REACH would be lower: the required data already exists, and some firms operating in GB will either own data already or have trading relationships with data owners, so they are likely to be able to access data on relatively favourable terms. In addition to this, some trade bodies in the EU and UK have published advice that companies should not be charged a second time for data they have already accessed for the purposes of EU REACH. It has not been possible to quantify these factors in disaggregated terms. For this reason, a cost reduction factor of 0.67, based on analytical judgement¹³, is applied across unit costs to reflect this combination of factors. Registration fees have been set to zero for grandfathered registrations, in line with UK REACH fee policy.

35. Taking into account all of the factors described above generates a total undiscounted cost of transitional registrations under UK REACH as it stands of £2.0bn (this figure is highly uncertain, but it might be expected to fall within the range £1.3bn- £3.5bn, although this depends heavily on how industry behaves in practice). In the central estimate, with 22,400 distinct substances, this implies an average cost per substance of £91,000. In net present value terms, a central cost estimate of £1.7bn for transitional registration under UK REACH as it stands is found (range: £1.1bn to £3.0bn). The undiscounted costs apply under all three of the options: Do Nothing, Option 1, and Option 2. It is only when discounting is applied that the quantified impacts of the options vary. The impact of Option 1 corresponds to the difference, in discounted terms, between the costs of UK REACH transitional registration under Option 1 and under the Do Nothing option. The equivalent applies for Option 2. The sensitivity analysis used to generate the range around the central estimate is described in the Assumptions section below.

Baseline (Do Nothing) – do not change the current submission deadlines. (27 October 2023, 27 October 2025, and 27 October 2027).

36. This means maintaining the status quo by keeping the existing submission dates. In line with the IA guidance, the 'do nothing' is the baseline against which all other policy options are appraised and as such, the costs and benefits are zero. The baseline assumes that not changing the deadlines would cause industry to make nugatory investments towards acquiring data for a registration approach which is likely to change.

Option 1 - Move all the current submission deadlines for each tonnage band by 3 years. (October 2026, October 2028, and October 2030).

37. This option will have the benefit of providing sufficient time for the government to devise an alternative registration model. There are also benefits to industry as they will not now need to make nugatory investment towards acquiring EU data. The extension of the current deadlines will provide some economic benefits to businesses as a result of delaying their obligations.

Human Health and Environmental impacts

38. The scientific data yielded from the registration process contributes to ensuring high levels of human health and environmental protection through underpinning REACH regulatory processes such as compliance checks and the prioritisation of substances for evaluation. Extending the current transitional deadlines means gaps in information held by the Agency would remain on the highest tonnage and most hazardous substances for a further three years beyond the current deadline of October 2023. The gaps in information held on other substances would either also be extended by three years (option 1) or by two years and one year (option 2).

¹² Costs for the 10-100 tonnes per year tonnage band were found to be higher than costs in higher tonnage categories.

¹³ The cost reduction is a significant evidence gap. Addressing this will be a priority, so the associated consultation document has several questions focused on this issue.

- 39. The absence of this data means that there could be impacts on the ability of HSE to carry out some regulatory processes such as compliance checks and prioritisation of substances for evaluation. This could lead to reduced regulatory oversight and regulatory delays, because of the additional time needed to acquire the requisite data from other external sources.
- 40. However, we are confident that these impacts will not be significant, even under Option 1, and that the UK REACH regime will still be able to ensure a high level of protection for human health and the environment because of:
 - The information and knowledge on chemicals registered under EU REACH that is available to both HSE and GB registrants. As well as the information publicly available on the EU REACH database, those involved in EU REACH registrations will be familiar with information relating to hazards, uses and exposure. It is expected that the value of some of this information may diminish over time, but that it will still be useful over the period of the extended submission deadlines.
 - 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's ability 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 using data from EU REACH and other relevant sources that can provide GBspecific hazard and exposure information (such as academic journals). 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.
 - Amending Article 41 of the UK REACH Regulation does not prevent HSE from carrying out compliance checks on dossiers that they receive before the submission deadlines and does not on its own have a significant impact on the protection of human health and the environment.
 - Other requirements that will continue to apply to manufacturers and users of chemicals such as the Control of Substances Hazardous to Health Regulations 2002 and the CLP Regulation¹⁴

Public sector impacts

41. As described in the above section on environmental impacts, changes to timings of data availability due to amended submission dates may change the timings or approach used by HSE to perform its activities, but the real-life implications of this for the public sector are expected to be negligible.

Business and consumer impacts

42. The concerns raised by NGOs in paragraph 16 on the impacts of the delays in submitting registration data are addressed in paragraph 40. The monetisable business impact of this policy is the change to the net present value of registration costs that arises as a result of changing the timelines. Changing registration timelines only affects the point in time at which costs occur, rather than the actual scale of the costs. Because this policy would shift the costs back in time, when

¹⁴ Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures (EUR 2008/1272).

considered in net present value terms, it generates a saving to business. The estimated net present cost of registration declines from £1.73bn to £1.56bn. The difference between these two figures is £170m, which is the saving, in present-value terms, associated with Option 1 compared to the baseline. The range around this central estimate is £110m-£290m. Familiarisation costs for this policy have not been quantified as the familiarisation time required to understand a submission deadline change is likely to be negligible.

Option 2 – Move the submission deadline by 3 years for the highest registration tonnages band (1000 tonnes and more), to 2028, two years for 100 tonnes or more, 2027 and 1 year for the 1 tonne or more, 2028 more by 2 years and 1 tonne or more by 1 year.

43. The impacts of this option are similar to Option 1. However, Option 2 has the advantage that the transitional registration data will still be received as early as possible, while allowing industry sufficient time to comply. Regulatory actions such as authorisations and restrictions can still be carried out effectively, although a delay in UK specific data may affect how the regulator targets or prioritises its actions. Option 2 will reduce the length of time that this effect might apply.

Human Health and Environmental impacts

44. Any human health or environmental impacts would be similar to those described under Option 1, but moderated due to the smaller amendments to submission dates under this option.

Public sector impacts

45. Any public sector impacts would be similar to those described under Option 1, but moderated due to the smaller amendments to submission dates under this option.

Business and consumer impacts

46. No consumer impacts have been identified. As described under the business impacts section of Option 1, the monetisable business impact of this policy is the change to the net present value of registration costs that arises as a result of changing the timelines. Changing registration timelines only affects the point in time at which costs occur, rather than the actual scale of the costs. Because this policy would shift the costs back in time less than under Option 1, when considered in net present value terms, it generates a saving to business that is smaller than that under Option 1. The costs of registration under Option 2, in present value terms, is found to be £1.64bn. Relative to the baseline of £1.73bn, this would lead to a saving, in PV terms, of £90m, with a range of £60m-£120m.

Risks and assumptions

47. Risks

- The absence of the transitional registration data could impact HSE's ability to carry out some regulatory processes - such as compliance checks and prioritisation of substances for evaluation.
- There is a risk of reduced regulatory oversight and regulatory delays, because of the additional time needed to acquire the requisite data from other external sources

48. **Assumptions**

- It is assumed that all substances that have been grandfathered or notified by a downstream user to UK REACH will be registered.
- 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.
- It is assumed that EU REACH registration costs, as evaluated, are a reasonable predictor of UK REACH registration costs.

- It is assumed, in the central scenario, that each substance is registered only once. This is
 a simplifying assumption in reality, multiple firms will separately register their usages and
 tonnages and will then co-ordinate on the submission of full data packages. For substances
 which have been reported in multiple tonnage bands, only the instance with the highest
 tonnage band is used. Substances for which no tonnage was reported were apportioned
 to tonnage bands in line with the distribution of substances for which tonnage is known.
- It is assumed that a cost reduction factor of 0.67 provides an appropriate proxy for the
 otherwise unquantified factors likely to lead to lower costs 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).
- These uncertainties are addressed through the presentation of a sensitivity analysis which assesses the costs of UK REACH as it stands under "high-cost" and "low-cost" scenarios (generating the range of £1.1bn to £3.0bn given in paragraph 35 above). 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 the "high-cost" scenario 15. In addition to this change, the "high-cost" scenario incorporates multiple registrations per substance, including all grandfathered registrations and downstream user impact notifications for which a tonnage is reported. This scenario applies per-registration costs, rather than persubstance costs, as reported in the EU REACH evaluation. Both of these scenarios apply the same cost reduction factor as the central scenario.

Impact on small and micro industry

49. Of the 3,160 firms registered in the chemical sector, 98% (3,085) are SMEs¹⁶. SMEs are responsible for 55% of employment (total: 93,000), and for 40% of turnover (total: £42bn). No disproportionate impacts on SMEs are foreseen, in line with the broader assessment made above that the policy is not expected to have a negative effect on businesses of any size. It is expected that savings, in discounted terms, would accrue to SMEs in a proportional way relative to larger businesses. Further info on the possible impacts of these policy options on SMEs is being sought through the associated consultation, which disaggregates responses by firm size.

A summary of the potential trade implications of measure

50. There are not expected to be any trade impacts as a result of this measure that are distinct from the more general impacts discussed above.

Monitoring and Evaluation

- 51. 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. The evaluation methodology includes management information, trade data, interviews and surveys with industry, and interviews with authorities and NGOs. The changes to the deadlines can be readily incorporated into the strategy and will be monitored and evaluated as part of this.
- 52. Data collection is already underway as part of the evaluation of the first year of the transition. This has included interviews with industry and a survey to chemical businesses, which has received over 550 responses. At this point we have been evaluating emerging impacts on industry of the current data requirements, as well as gathering opinion on the government's review of these. The evaluation will provide a useful baseline to benchmark future years against.

¹⁵ This assumption has been used in the high-cost scenario because it allows a plausible data-driven high-cost scenario to be generated while relying on a concise and transparent list of assumptions.

 $[\]frac{16}{\text{https://www.gov.uk/government/statistics/business-population-estimates-2021}}, \text{ Detailed Tables, Table 6, SIC Code 20}$