UK REACH: Extending data submission deadlines

Lead department	Department for Environment, Food and Rural Affairs (DEFRA)
Summary of proposal	The UK REACH (the Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation) sets out requirements relating to the use of chemicals in Great Britain. The proposal extends the current data submission deadlines to ensure sufficient time to develop and implement an alternative transitional registration model.
Submission type	Impact assessment (IA) – 01/03/2023
Legislation type	Secondary legislation
Implementation date	27 October 2023
Policy stage	Final
RPC reference	RPC-DEFRA-5210(2)
Opinion type	Formal
Date of issue	03 April 2023

RPC opinion

Rating[1]	RPC opinion
Fit for purpose	The IA provides a good discussion of direct costs to businesses and assessment of potential impacts on small, micro and medium sized businesses. The RPC suggests some improvements could be made around assumptions underpinning the EANDCB figure and conducting sensitivity analysis to test the robustness of assumptions used for the cost-benefit analysis (CBA). Nonetheless, the Department has transparently communicated the weaknesses in the data used. Wider impacts could be discussed further, specifically the Department's assessment that the Health and Safety Executive's ability to conduct its regulatory duties will not be hindered by the proposal.

[1] The RPC opinion rating is based only on the robustness of the EANDCB and quality of the SaMBA, as set out in the Better Regulation Framework. RPC ratings are fit for purpose or not fit for purpose.

Business impact target assessment

	Department assessment	RPC validated
Classification	Qualifying regulatory provision (OUT)	Qualifying regulatory provision (OUT)
Equivalent annual net direct cost to business (EANDCB)	-£17 million (final IA estimate)	-£17 million (2019 prices, 2020 present value)
Business impact target (BIT) score	-£85 million	-£85 million
Business net present value	£170 million	
Overall net present value	£170 million	

RPC summary

Category	Quality[2]	RPC comments
EANDCB	**Green**	The Department appears to have used the consultation to improve the discussion of direct impacts to businesses. The IA also presents a good counterfactual that considers preparations that businesses may have already made, to meet the current submission deadlines. The IA would benefit from sensitivity testing this area and the 0.67 cost reduction factor.
Small and micro business assessment (SaMBA)	**Green**	The SaMBA appears to appropriately cover the necessary points set out in the RPC's SaMBA guidance[3], including the affected sector(s), the number of businesses in scope of the regulation, the market share of the businesses in scope and the impact on businesses (or lack thereof), of the proposal.
Rationale and options	**Good**	The rationale for intervention and options under consideration are sufficient, as they clearly set out the objectives of the proposal and provide a justification for ruling out non-regulatory alternatives.
Cost-benefit analysis	**Weak**	The IA does not present a complete cost-benefit analysis, due to limitations in the underpinning data sources, which the Department has transparently communicated. It appears that the main difference between figures presented in the consultation stage IA and final stage IA, are the inclusion of very small familiarisation costs in the latter.
Wider impacts	**Weak**	The 'Wider impacts' section in the IA is largely identical to what had been presented at consultation stage. The IA appears to have included a number of unsubstantiated claims and conclusions, for example, that the proposal will have no direct impact on innovation and competition or impede the HSE's ability to conduct its regulatory duties. This section should be improved regarding these claims by way of seeking support from impacted stakeholders.
Monitoring and evaluation plan	**Satisfactory**	The IA sets out a brief monitoring and evaluation (M&E) plan on page 20, and it explains that there is already a plan in place for the transition from EU REACH to UK REACH which sets out the data collection plan and evaluation methodology. The

[2] The RPC quality ratings are used to indicate the quality and robustness of the evidence used to support different analytical areas. Please find the definitions of the RPC quality ratings here.
[3] Link to RPC SaMBA guidance.

	Department explains that the proposal will be evaluated as part of this wider M&E plan.

Summary of proposal

Under the European Union (Withdrawal) Act 2018, the EU REACH Regulation was brought into UK law and is known as UK REACH. UK REACH requires safety information on substances that are manufactured in, or imported into Great Britain, to be compiled in a dossier and submitted to the Health and Safety Executive (HSE) for review.

The Government introduced transitional provisions in UK REACH pursuant to reduce disruption to industry as the UK moves to the new system (UK REACH). These provisions allow companies to submit initial 'notification' data to continue trading and then provide the complete registration data after a further two, four or six years from 28 October 2021, depending on the tonnage and hazard profile.

The proposal extends the current registration submission deadlines as follows:

<u>The current and proposed UK registration submission deadlines</u>

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	

The IA considers the following options:

- Option 0: Do nothing and leave the current submission deadlines unchanged. (27 October 2023, 27 October 2025, and 27 October 2027).
- Option 1 (preferred option): Extend all the current submission deadlines for each tonnage band by three years (to October 2026, October 2028, and October 2030).
- Option 2: 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.

The IA explains that the preferred option (Option 1) will be given effect through secondary legislation using the UK REACH amending powers in the Environment Act 2021. The primary objective of deferring the current submission deadlines is to provide industry with sufficient time to prepare for and adhere to any new information requirements in the alternative transitional registration model.

For the preferred option, the IA estimates an indicative net present value of £170 million over 10 years (2022 present value and price base year). The only monetised impact is the change to the net present value of registration costs to firms, which arises from changing the submission deadlines. The estimated present value of the cost of registration declines from £1.73 billion to £1.56 billion, under Option 1. The IA has identified other costs and benefits of the proposal but has not monetised these (other than very small familiarisation costs).

With regards to the benefits, the proposal will mean that businesses will submit registration information once an alternative model is in place and therefore reducing the likelihood of companies making nugatory spend in complying with current deadlines and data requirements. The extended deadlines are also intended to allow for a smoother distribution of resources over time, providing more time for activities such as planning, recruitment and training.

With regards to costs and risks, there is a possible small reduction in the ability of the Health and Safety Executive (HSE) to conduct its regulatory obligations in providing high levels of protection of human health and the environment, regarding chemicals which are already on the market.

EANDCB

The Department reports an EANDCB figure of approximately £17 million. The methodological approach to calculating the EANDCB figure could be made clearer, as the use of the EANDCB calculator to monetise impacts is currently not intuitive. The IA could also provide further details on the origin of the estimated overall costs of REACH (such as the £1.73 billion figure in paragraph 59).

There are two factors affecting the EANDCB where the IA acknowledges particular uncertainty.

The benefits captured in the IA are present value cost savings arising from the delayed registration dates. However, the costs associated with the registration process seem to have been derived from current activities (based on EU REACH) such as preparing a dossier (paragraph 42), and subsequently adjusted by 0.67

(paragraph 43). The IA explains why costs are expected to be significantly lower than the EU REACH figures and why an adjustment is therefore appropriate. It outlines how it used the consultation to obtain evidence for the size of this adjustment. However, this was unsuccessful, and the IA acknowledges this as a particular area of uncertainty (footnote 20 and paragraph 46). Whilst the IA has attempted to address the rationale for this figure, it would benefit from discussing further the "analytical judgement" behind the 0.67 adjustment and from sensitivity testing it.

Secondly, the IA considers whether some businesses would have already started taking the necessary measures to adhere to the current submission deadlines (paragraph 61, fourth bullet). The IA reports little evidence of this, likely influenced by the government publishing its intention to extend the deadlines in December 2021. However, the IA would benefit significantly from providing more evidence in this area to provide reassurance on this issue or explaining why it would not be proportionate to do so. The IA could also benefit from sensitivity testing the assumptions on this.

The IA has attempted to disaggregate direct and indirect impacts to consumers and businesses, and has provided sufficient justifications where impacts could not be monetised. For example, the indirect impact of businesses not registering substances has not been monetised, with the justification for this being explained in paragraph 61.

The IA provides a good description of the counterfactual (page 10), with a very small proportion of consultees in favour of proceeding with this 'Do Nothing' option (paragraph 25). Uncertainty around the proportion of businesses that may have already started taking measures to meet the current submission deadlines, could be addressed via sensitivity analysis as mentioned above.

SaMBA

The SaMBA presented, appears broadly in line with the RPC's SaMBA guidance. The IA captures the number of SMBs in scope of the proposal and states that no disproportionate impacts on micro, small or medium sized businesses are foreseen (paragraph 63). The Department has explained that this assessment is supported by consultation responses in which small, micro and medium sized businesses had expressed a preference for Option 1, with many respondents (the exact proportion of respondents is not cited) noting that small firms would struggle disproportionately with shorter timelines. The reasons for this appear intuitive, as the flexibility of having longer timelines, would most likely help smaller businesses more. The SaMBA could be improved by considering whether any reduction in the HSE's ability to carry out its regulatory obligations could indirectly affect small businesses.

As the proposal is expected to benefit businesses and not place disproportionate costs upon SMBs and MSBs, as stated in the IA, it appears appropriate that the Department has not considered mitigating actions.

Rationale and options

Rationale

The IA includes a clear set of policy objectives, citing two intended outcomes: (1) to provide sufficient time for the government to develop and introduce the new transitional registration model; and (2) to defer the current submission deadlines to provide industry with sufficient time to prepare for and adhere to any new information requirements under the new model. The IA explains that intervention is required to defer the current data submission deadlines to meet these objectives and avoid businesses making nugatory investments to comply with the current data deadlines and requirements.

Options

The IA considers two options against the 'Do Nothing' baseline position, including a discussion on why non-regulatory options would not be sufficient in meeting the policy objectives. The IA briefly explains the criteria that underpinned options analysis (paragraph 23). The IA discusses whether enabling the regulator to apply EU risk management decisions during the extension period, would be appropriate for limiting data gaps for the HSE. A strong justification is provided for EU risk management decisions not being appropriate in this instance, however, the IA could benefit from exploring other ways or proxies, to mitigate against data gaps and the potential consequences for HSE in conducting its duties (discussed further in 'Wider impacts' below).

Furthermore, the IA outlines how consultation responses and stakeholder engagement helped to inform the preference of options. Prior to the consultation stage, the Department had noted Option 2 as the preferred option, however the consultation brought to light, a strong overall preference for Option 1. The IA provides evidence to support the assessment that the preferred option strikes the right balance between cost savings to businesses and non-monetised risks.

Cost-benefit analysis

Assumptions

The IA provides indicative analysis of the potential cost savings to businesses from changing the registration timelines, which it estimates to be £170 million over ten years under the central scenario. The IA explains that this estimate reflects changes to the time at which costs occur, rather than the actual scale of the costs. However, the IA would benefit from setting out clearer evidence to support the assumption that the registration cost in undiscounted terms will remain the same.

Evidence and data

The Department has attempted to take a proportionate approach to justify the level of analysis used in the IA. Data sources underpinning different components of the analysis have been clearly identified and weaknesses in these data sources have been pinpointed, with justifications made for why these pieces of data remain

appropriate for use in this context. The CBA could benefit from strengthening as the figures presented have not changed since the consultation stage IA, apart from the addition of a relatively small familiarisation cost. The IA should clarify why the figures have not changed since the earlier stage, if strengthening them is not possible.

The CBA is primarily informed by two main data sources, the UK REACH Service data on grandfathered registrations and Downstream User Import Notifications. The IA provides a good description of these data sources, including assessing their robustness. The IA briefly discusses the findings of the eight-week public consultation, which was used to strengthen its evidence base. Furthermore, the IA attempts to address one evidence gap from the consultation stage IA; the Department transparently communicates its limitations in attempting to fill this gap via consultation. Additionally, the Department explains that the impact of introducing an alternative transitional registration model is out of scope for this IA; the RPC expects to see an IA submitted for scrutiny in due course.

Moreover, it appears unclear how the low and high scenarios in the sensitivity analysis, were created. It seems that the cost reduction factor assumption of 0.67 was not adjusted (paragraph 62) as part of the sensitivity analysis, which appears to be an oversight, as adjusting this assumption would make a significant difference.

Wider impacts

The IA presents a near-identical assessment of impacts of the proposal on human health and environment, public sector, businesses and consumers, as what was presented in the consultation stage IA. A brief addition to this section is the conclusion that implications on the distribution of chemicals to the public sector, are expected to be negligible. The IA should seek to provide further discussion around how this conclusion was reached. In addition, the IA could be improved by including a discussion on the implications on human health and environmental protection, from delaying the submission deadline for registration data; this is a point that the IA covers briefly when discussing the concerns of NGOs (paragraph 21).

The Department has reached the conclusion that the extension of the submission deadlines will not directly impact innovation, trade, competition or market opportunities and access to the EU market; however, it is unclear how this conclusion was reached. The IA should elaborate on the competing deadlines mentioned in paragraph 68 and why there is expected to be no impact on access to the EU market. With regards to the EU, the IA would benefit from discussing what the proposal would specifically mean for UK exporters to the EU and what this would mean for the EU as a result (e.g. potential prohibition of exports or increased compliance costs). The IA states that the current registration data requirements under UK REACH are identical to those that applied under EU REACH (paragraph 3); the Department should make clear if this applies to dates also. Additionally, the IA should provide more discussion around the wider benefits of avoiding risk, to the continuity of chemical supply, mentioned in paragraph 32.

The Department used the consultation responses to cover potential unintended consequences of the proposals, in the form of member companies of industry associations, having to meet an additional regulatory commitment. The IA would benefit from discussing how the new deadlines may incentivise businesses to wait before they begin the process of complying with REACH registration; this could unintentionally weaken the UK's future REACH system and encourage bad business practices as a result.

Furthermore, the IA concludes that the policy proposals will have no impact on the HSE's ability to carry out its regulatory duties or assess new chemicals; however, the IA would benefit from explaining further how this conclusion was reached, including any input from the HSE. In addition, the IA has not sufficiently addressed proportionate mitigation actions to minimise the risks outlined in paragraph 60. The IA has also not considered additional risks such as potential advances made in the EU's database in the interim.

Monitoring and evaluation plan

The IA sets out a brief monitoring and evaluation (M&E) plan on page 20, and it explains that there is already a plan in place for the transition from EU REACH to UK REACH which sets out the data collection plan and evaluation methodology. The Department explains that the proposal will be evaluated as part of this wider M&E

plan. The IA explains the means through which data will be collected to evaluate possible unintended consequences and mitigating actions to minimise risks associated with the proposal.

Regulatory Policy Committee

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