Regulatory Policy Committee

UK REACH (Registration, Evaluation, Authorisation & restriction of CHemicals)

Department for Environment, Food & Rural Affairs

RPC rating: fit for purpose

Description of proposal

The policy objective is to introduce the necessary statutory instruments to ensure the UK has an operable chemicals control system following the UK's withdrawal from the EU in a no-deal scenario. Specifically, the policy aims to convert existing EU REACH regulations into national law.

The Department aims to build UK regulatory capability to ensure that the UK continues to have a highly-integrated regulatory system for chemicals. It plans to do this by creating a UK regulatory authority, which will combine functions carried out by the European Chemicals Agency (ECHA) with those of the UK Competent Authority. Powers which are currently exercised by the European Commission would move to the Secretary of State for Environment, Food and Rural Affairs.

These powers with the Secretary of State will include powers to introduce new or amended restrictions and add to the list of chemicals that are subject to the authorisation procedure, as well as to grant authorisations to applicant companies.

Impacts of proposal

Costs

Direct Costs to Business

Additional Costs Compared to the status quo baseline:

The Department plans to 'grandfather' 12,000 registrations held by UK companies into the UK system. This will not impose any direct costs from re-registration or fees. These will have the status of "retained EU law".

The Department expect firms using the new system to incur familiarisation costs, but expects these to be relatively small as the UK REACH IT system will aim to replicate the EU REACH IT system as closely as possible.

There will, however, be a requirement on UK registrations and authorisation holders to transmit supporting data to the new UK agency. The Department notes that UK companies may not be in a position immediately to re-send all the data held by EU REACH to the UK regulator, due to EU REACH industry joint registration procedures. This SI includes provisions for partial transition in which data items within the UK company's sole ownership (including evidence of the EU registration) must be provided within 60 days and data items that are part of a joint submission musty be provided within two years. The Secretary of State will have power to alter submission dates if the relevant evidence justifies such a change. Firms may incur additional costs as a result, depending on ownership of the relevant data.

Firms will be expected to face the same data requirements under the proposed system as under the status quo. They will, however, incur costs from seeking access to data that the firms submitted to ECHA. This could include labour and time costs. If the firms are unable to gain access to their old data, they would need to submit new testing proposals and conduct new data tests, and the IA states they "*may incur substantial costs for doing so*" (paragraph 44, page 11).

UK businesses wishing to access the UK market for the first time after exit will also face costs from new registrations and authorisations to the new UK authority, including any relevant fees and administration costs. The UK authority would take the same approach to fees and charges as ECHA, so the IA assumes these will be the same as they would have been under the baseline. The IA expects there to be familiarisation and transition costs incurred by firms using the new UK REACH IT system but expects these to be low as the system will aim to mimic the EU REACH IT system. The assessment correctly identifies that costs incurred by seeking access to the EEA market are out of scope of this SI.

UK based Only Representatives (ORs) who can register with ECHA on behalf of third country companies to access both the UK and wider EEA market, would lose the ability to serve third country exporters in the EEA market. This is also correctly identified as out of scope. However, the Department notes the possibility that UK based ORs could adapt their services and offer their services to non-UK firms (including EEA based firms). This occurrence could create a benefit which would be in scope of this SI, however, the net impact is not known.

Direct costs to government

The preferred option (Option 1) would lead to the following three direct costs to government:

1) Increased staff costs at DEFRA, the Environment Agency (EA), and the Health and Safety Executive (HSE), as proposed ownership of the onshored responsibilities from ECHA will fall on these agencies.

2) The costs related to building and maintaining the new UK REACH-IT system.

3) Additional costs of funding evidence budgets, scientific advice and providing helpdesk services.

Additionally, the UK authorities would not be able to reap income from the fees ECHA has incurred from charging businesses for registrations of substances, for which the deadline was May 2018[1].

The RPC cannot currently verify the estimated equivalent annual net direct cost to business (EANDCB), as one has not been provided. This will be a non-qualifying regulatory provision that will not score under the business impact target.

Benefits

Benefits to Business, Government and Society

The SI will enable the necessary legislative amendments to make the chemical regulatory system operable in the UK 'after Day 1' and continue to provide stability and legal certainty for businesses and UK regulatory authorities. It will also ensure there is a functioning and safe chemicals management system.

The Department expects that businesses will benefit from legal certainty of regulatory controls on chemicals, due to the existence of a functioning chemicals management system. Businesses that produce chemicals and businesses that use chemicals will also benefit from the certainty that the chemicals they are using have been through a safe management system.

The Department expects that the SI will bring about a large benefit versus the 'do nothing' scenario, as the regulations will mitigate the significant risks of the do-nothing scenario.

The SI also aims to continue to provide the health and environmental benefits that are currently present in the status quo baseline. In particular, the measure gives UK authorities the power to respond to new and emerging risks chemicals could pose to human health and the environment. It does this by allowing them to investigate

[1] "ECHA's main source of fees to date is from registrations, which will largely not be available to the UK authorities following the final deadline for phase-in registrations in May 2018" (paragraph 35, page 10)

outstanding concerns, introduce appropriate controls, and to take enforcement action where necessary.

Small and Micro Business Assessment (SaMBA)

The RPC notes that the SaMBA mistakenly focuses on small and medium business, as opposed to small and micro businesses. It has identified that small, medium and micro businesses comprise 97.5% of the market, and that the measure must impact all businesses to enable the policy to work effectively.

The new UK regulator will adopt a range of fees that are proportionate to both business size and volume of chemicals traded. This is already done by ECHA and is a proportionate approach.

Further, businesses will be required to provide data on substances; the Department expect this cost to be 'substantially higher' than fee costs, and notes "*that this may place a disproportionate cost on smaller businesses*" (paragraph 56, page 17). The size of this cost depends on the amount of chemicals manufactured or imported – for example, smaller business who manufacture under 10 tonnes would face lower costs of providing data through a smaller sized registration dossier. The risk of disproportionate costs for smaller businesses could also be mitigated through firms sharing costs of testing substances through joint registrations.

Wider Impacts

Compared to the 'do nothing' scenario, the Department expects the SI to have a positive impact on competition, on health and safety, and on the environment, by mitigating the risk of a non-functioning chemical framework.

Compared to the status quo, there may be a negative impact on animal welfare as a consequence of these measures. This is envisaged in a scenario where data sharing with ECHA is not established, and firms may be required to duplicate animal testing with the EEA, resulting in a loss of animal welfare.

The Department also expects the SI to have a positive regional impact compared to the 'do-nothing' scenario. Chemical production firms in the UK are concentrated in regions with economic deprivation and protecting these firms will provide stability for the firms in these regions.

The overall net present value (NPV) has not been provided.

Quality of submission

The Department's assessment of the overall impacts of the proposal, including the impacts on business, is fit for purpose. The IA sets out clearly the rationale for the proposal and uses a proportionate level of evidence to support estimates of the impacts. The IA sets out clearly the rationale for the policy but does not currently provide estimates of the costs.

A clearer evidence base for cost estimation, however, would improve the IA significantly. The Department has analysed 1 option alongside two counterfactual options. The first counterfactual was a static acquis scenario. The second counterfactual focuses on a do-nothing scenario.

The assumptions that the Department has made appear realistic, but the Department should seek, where possible, to test assumptions via continuing consultation with stakeholders. Specifically, it should aim to collect more accurate information surrounding data transfer/collection costs, familiarisation costs, labour costs and time costs.

The Department's planned charging structure is proportionate.

The IA would also benefit from clarification of its no-deal counterfactual. Although this is a no-deal measure, the IA relies consistently on the assumption of an implementation period, which would only be the case in a scenario where a deal is reached, and the Department should set out clearly why it feels this is an appropriate approach.

The IA would benefit from providing:

(a) further discussion of how the overall balance of cost and benefits would be affected by a no-deal scenario, and how a no-deal scenario would impact trade in chemicals covered by REACH to and from the EEA.

(b) a clearer explanation of how the overall costs and (particularly) benefits weigh up against each other in the differing scenarios.

(c) a more clearly informed SaMBA. Although the Department has clearly thought through its approach to mitigation of impacts on small and micro businesses, a clearer focus upon small and micro (as opposed to medium) businesses would have been valuable.

(d) Clarity on the costs surrounding data, specifically in reference to the following:

- If the data have changed, the most recent data should be provided, meaning that new data will need to be generated (amounting almost to a (duplicate) de novo registration). The IA would benefit from clarifying how much of the relevant data falls into this category;
- If the data have not changed, and are the sole property of the company, it is not clear why they cannot simply provide copies from their own records. The IA would benefit from clarifying whether it has included data cost when referring to data that falls within this category;
- Data that are jointly owned by more than one company or by the company and the EU REACH authority may involve further cost and/or delay – the IA would benefit from assessing the balance between cost and delay;
- Finally, as the UK entity has (presumably) been acting as the local competent authority, it may well have access to these data already – the measure would benefit from clarifying how these CA data assets will be apportioned in the event of a no deal scenario.

(e) The IA would benefit from providing clarity on whether the costs firms will face from new registrations and authorisations to the new UK authority are solely to provide access to UK markets. This will make it whether the revenues used to offset the costs of REACH procedures will be UK-only or will include EU access only under existing third-country procedures.

Departmental assessment

Classification	Non-qualifying regulatory provision (EU exit)
Equivalent annual net cost to business (EANCB)	NQ
Business net present value	NQ
Overall net present value	NQ

RPC assessment

Classification	Non-qualifying regulatory provision (EU exit)
EANCB – RPC validated[2]	NQ
Business Impact Target (BIT) Score[1]	NQ
Small and micro business assessment	sufficient

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[2] For reporting purposes, the RPC validates EANCB and BIT score figures to the nearest £100,000.