Link Response: Consultation on UK REACH

July 2024

This response is on behalf of nature and animal welfare coalition Wildlife and Countryside Link (Link).

Introduction

This response addresses the proposed policy changes to UK chemicals regulation (UK REACH) as part of the last Government's Smarter Regulation programme. The response outlines why the new Government must discard the current version of the Alternative Transitional Registration model (ATRm) and enact a rapid process to adopt a pro-EU alignment approach, primarily due to the financial costs and human health and environmental risks associated with the last Government's proposal for the ATRm.

While there are benefits in granting the regulator new powers to request data, and there is a need to develop a system to meet the October 2026 deadlines under the current transposed regulations, these proposals are not fit for purpose. The current ATRm proposal presents long-term risks to human health and the environment as a result of the proposal's overall weakening of chemical safety data requirements. The proposal also places unnecessary costs and burdens an already slow, ineffective UK REACH system. Together, these risks far outweigh these limited benefits.

Watering down chemical safety data requirements weakens the ability of the regulator to effectively assess, prioritise, evaluate and control substances that present risks to human health and the environment.

Substances should not be eligible to be placed on the GB market without those making regulatory decisions having access to comprehensive, high-confidence hazard and chemical safety data. Responsibility for providing this information should remain with industry, whereas the ATRm places more responsibility on the regulator to chase industry for the information it needs to regulate and to ascertain gaps in information. The ATRm, or any proposals that supersede it, must instead be guided by a robust approach to the precautionary principle and need to match EU chemical safety protections.

The reasoning for this approach is set out in the response below.

Hazard Information Requirements

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

Based on the overarching principle of 'no data no market', we strongly disagree with the proposed removal of detailed elements of hazard information requirements would compromise protection of human health and the environment. The state of our water, marine and terrestrial environments are already in steep decline:

- Nearly one in six species threatened with extinction in Great Britain.
- No river has good chemical status.
- UK wildlife are already contaminated with toxic chemicals like PFAS and flame retardants, including otters and hedgehogs.
- In its latest report, the OEP indicated that the last Government has made limited progress and is largely off track in respect of its ambition to manage exposure to chemicals and pesticides.

It is also deeply concerning that the largest ever public screening on toxic chemicals (Europe Human Biomonitoring Initiative) found that significant numbers of the population, including children, in Europe are exposed to high levels of multiple chemicals.

Together, these pressing issues demonstrate that the pace of regulatory action on chemical pollutants needs to drastically increase to prevent further exposure and contamination. Yet, reducing the availability of detailed datasets and studies on chemical safety would slow down the ability of the regulatory system to quickly and effectively regulate chemical pollutants.

The Government remains accountable for:

- Delivering outcomes against the 25 Year Environment Plan, Environment Act 2021, Climate Change Act 2008 and Environmental Improvement Plan 2023 targets.

- International commitments contained in the Global Biodiversity Framework (particularly Target 7 to reduce the overall risk from pesticides and highly hazardous chemicals by at least half).
- Where making policy, the Government must consider the precautionary, prevention and polluter pays principles.

Slowing down the system is at odds with these commitments and ultimately creates undue risks for human health and the environment.

Achieving cost reductions on industry by deregulating information requirements would make it harder for Health and Safety Executive (HSE) and the Environment Agency (EA) to fulfil their duties as regulators and is not good value for money for the taxpayer who shoulders the burden of hazardous chemical pollution – financially and through the health and environmental consequences of exposure.

There are plenty of examples that demonstrate environmental deregulation doesn't work, including sewage pollution by private water companies, which is exacerbated by the presence of chemicals.

- Deregulation has been demonstrated to be an unattractive option amongst the UK public given that well-enforced regulations provide certainty, a level playing field, fairness, and promoting trust in society.
- 79% of UK voters indicated they understand the importance of regulation for protecting the public and the economy.
- Global trends in chemicals regulation attitudes indicate more than 4 out of 5 people in a recent OECD survey indicated they thought authorities needed to take stronger action on chemicals.

Analysis shows that a precautionary approach through a Swiss-style model of chemicals regulation, which is almost entirely harmonised with the EU, provides certainty and low costs on business, while upholding high chemical safety standards.

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

We disagree with this assessment, as well as with the notion that regulatory action should be based on incomplete hazard data.

Chemical classification is contingent on hazard data. This data is crucial to appropriately classify chemicals as Substances of Very High Concern or otherwise. If a replica set of hazard data is not required, and the hazard information that industry is required to provide is reduced to a bare minimum, it is unclear how the regulator intends to fulfil its statutory purpose. For this reason, the regulator ***does*** need to hold a replica set of hazard data. The pinnacle of effective chemicals regulation rests upon adequately understanding and being able to access information on the hazards presented by specific chemicals.

As the consultation document acknowledges (p. 16), "there is no need to completely replicate the ECHA's database of hazard information". Indeed, the EU system already encompasses extensive risk management analysis and an established system for identifying substances of concern. However, as a separate UK REACH system has been established, registration dossiers still remain a crucial element of assessing and mitigating risks from the manufacture, use and placing on the market of chemicals. The easiest way to reduce the costs with submitting a registration dossier under UK REACH is to align with the EU system.

In accordance with the precautionary principle, this data ***should*** be replicated in the UK REACH system, as opposed to the regulator picking and choosing chemicals from the EU hazard data registry based on industry information, voluntary targets or lack of GB-specific information. Regulators need data to make regulatory decisions and companies need data to manage chemicals. A lack of data hampers these functions.

If the UK wants to make UK specific regulatory decisions, it must begin replicating EU registration dossiers and develop UK REACH/regulator capacity to build upon these. Developing an effective system for building up the availability of hazard information means a better understanding of the full human health and environmental impacts of potentially hazardous chemicals. In turn, this reduces long-term costs of dealing with the consequences of otherwise preventable pollution and impacts on human health from this pollution or workplace exposure.

Equally, there is a possibility that UK companies may not have to register if they are EU registered and the UK aligns with EU restrictions.

The previous framework known as the 'Existing Chemicals' regime was based on the model of requiring full safety data for priority substances, whereas the EU REACH system introduced the 'no data no market' principle. It is unclear why a return to a model similar to this aspect of the Existing Chemicals regime is being proposed, considering delays in regulatory action was one of the primary reasons that EU REACH was created.

Should the UK instead pursue alignment with EU chemical restriction decisions (where restriction decisions are based on the fuller EU datasets), there may be ways to reduce UK data registration requirements for those companies who are registered in the EU, as these companies will have access to the chemical data needed to manage chemicals. However, this can only be explored if the UK restrictions align with EU restriction decisions.

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

    For the reasons outlined above, revised hazard data requirements actually risk increased costs to businesses over the long term, particularly if businesses are subject to the full application of the polluter pays principle and extended producer responsibility where avoidable chemical pollution occurs.

Use and exposure information requirements

11. **To what extent do you agree that requesting more detailed, Great Britain-specific use and exposure information will meet the aims of improving industry's risk management of chemicals and the regulatory capability for the regulators?**
12. **To what extent do you agree with the proposed trigger points and corresponding information requirements for registrants? (see Annex B)**

13. **What is your estimate for the length of time it will take to complete the necessary tasks for the registration process under UK REACH? Particularly, considering the revised ATRm requirements for use and exposure information?**
14. **Please comment on the extent to which you expect the revised use and exposure data requirements will increase costs to business. Where possible, please provide supporting quantitative evidence.**

Although we note the importance of assessing chemicals risk generally, we do not agree with the proposal to undertake specific risk assessments as a condition for restriction. We are concerned regulatory action on harmful chemicals will be significantly delayed by the movement by the previous Government towards a 'risk based approach', where substantial evidence on risk is required prior to classifying a specific chemical as a priority for regulation.

The consultation document suggests that specific risk assessments would increase the overall quality of assessment, management and control of risk. However, it is unclear what evidence there is to support this claim (as none has been provided) or how this would operate in practice.

Many of the regulatory priorities identified in the 2022-23 and substantially delayed 2023-24 (released in February 2024) work programmes, have not come to full fruition. The strongest example is PFAS, despite substantial, publicly available evidence proving these chemicals to be hazardous to humans and nature.

Yet, the UK still has yet to bring forward a restriction (other than the PFHxS ban adopted internationally) following the Regulatory Management Option Analysis (RMOA) on PFAS, which did not go far enough and set out recommendations for a narrow range of PFAS for a limited range of uses.

Presently, the only coherent consideration of a PFAS restriction in the current work programme relates to PFAS in firefighting foams, though a restriction itself is still yet to emerge. This means that the UK is increasingly lagging behind while the EU and other countries such as the US plough ahead with restrictions in food packaging, drinking water limits and textiles.

Far more effective policies are needed, such as a default mechanism for adopting EU risk management measures as standard.

Chemical Safety Reports (CSRs)

15. **To what extent do you agree that the proposed reduction in hazard assessment data will not negatively impact a registrant's ability to undertake exposure assessment and risk characterisation in their CSA and communicate the exposure scenarios and risk control measures downstream (where Article 14 (4)) of UK REACH applies29?**
16. **To what extent do you agree with our assessment of which aspects of information should be required or should no longer be required for CSRs (see paragraphs 54 to 59)?**

We disagree with this proposal. The proposed reduction in hazard assessment data will compromise the robustness and quality of the exposure assessment and risk characterisation in Chemicals Safety Assessments/Chemical Safety Reports.

A robust understanding of exposure scenarios is particularly important for addressing the impact of chemical mixtures downstream. Link has highlighted how widespread chemical cocktails are in the environment, with 1,619 sites across England containing six different chemicals in 5 different hazardous mixtures that are known from lab tests to harm wildlife.

The previous Government committed to address the harmful impacts of chemical mixtures. However, no further plans were detailed on how this will be achieved. Conversely the EU is planning to introduce a Mixture Assessment Factor (MAF), although this work has been delayed.

The new Government has an opportunity to act ambitiously to introduce specific measures to address the chemical cocktail effect, incorporate a MAF assessment of possible interactions within GB risk assessments before any new chemical is allowed on the market.

ATRm regulator powers and duties

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

New regulatory powers for the regulator to obtain data is necessary for the smooth operation of the regulatory system. We welcome these proposals in principle, but further safeguards are required to ensure that the regulator fully delivers the statutory purpose of UK REACH. These powers should not supersede the general imperative for companies to provide robust, transparent data in the first instance, and without delay.

Further regulatory powers must be accompanied by stronger enforcement and compliance mechanisms, such as the power to obtain data from companies to fully assess chemical safety and prevent harmful chemicals from entering the market.

Substance groups, data sharing and joint data submission

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

No answer for these questions.

Improving the UK REACH restrictions process

22. **In your view or experience (including experience of contributing to the EU REACH restrictions process), what actions must a manufacturer, importer or affected stakeholder of a chemical proposed for restriction take (for example, confirming supply chain actors) in order to draft a response to the first consultation? (please specify how long in days/months each action takes)**
23. **In your view or experience (including experience of contributing to the EU REACH restrictions process), is there any SEA information you would usually provide in the second consultation that you would not/cannot provide in the first consultation? If so, why can this information not be provided in the first consultation?**

For the reasons outlined above, it is clear these proposals will be insufficient to address the intrinsic issues with the UK REACH restrictions process. The regulator needs to be sufficiently resourced with data and capacity and supported by effective processes to effectively identify and act quickly to regulate where chemical risks to human health and the environment arise. This is not currently the case, and the UK continues to fall behind the EU in adopting restrictions.

These proposals do nothing to address the problems inherent to the UK REACH regulatory system and regulatory stagnation that has been a feature of UK REACH since it was first established in 2021. It would be poor value for money to introduce further lags in the regulatory system considering the existing system of UK REACH is not currently fulfilling its statutory purpose, and the divergence chasm is continuing to grow. Since Brexit, not one restriction has been adopted. The two that have been initiated since UK REACH was established in over 3.5 years ago are still ongoing and are generally less protective than the EU counterparts.

The risk of significant regulatory gaps increases with the implementation of the EU restrictions roadmap that proposes restrictions of groups of chemicals of a high concern and is poised to ban thousands of chemicals by 2030.

A grouping approach to chemicals regulation in the UK is necessary to comprehensively prevent a wide range of harms to human health and the environment and avoid falling further behind the EU and elsewhere. However, the current proposals do not adopt such an approach and still fall well short of meeting EU chemical safety laws (e.g., grouping regulation of endocrine disrupting chemicals and PFAS).

For these reasons, reducing the amount of time or actions required to draft a response to the first consultation is not an appropriate material consideration or justification for eliminating 50% of the consultations in an already slow, poorly functioning regulatory environment. The consultation document proposal to shorten the 27 month period to 24 months by consolidating the 6 month consultation period fails to address the crux of the issue: that the UK REACH system is already facing system paralysis and unable to match the pace of international counterparts, largely due to capacity constraints and overarching deregulatory ambitions.

Risk assessment and socio-economic impact assessments must be kept separate to ensure independence and transparency when considering scientific evidence of the risk posed by a substance versus the socio-economic impact of a proposal.

24. **What information and/or engagement from UK government/the Agency would be helpful ahead of the publication of the restriction dossier (for example, information on similar restrictions in other jurisdictions or engagement to confirm supply chain actors that hold information that downstream users might not have) that may allow for a shorter, consolidated consultation period?**
25. **If the consultations are consolidated as outlined in paragraphs 78 and 79, are there any potential consequences (not outlined in paragraph 78 and 79) you expect or concerns you have? If so, are there any ways in which these concerns could be overcome?**

See above for views on the shorter consultation period.

The Government and regulator should be engaging with a broad range of stakeholders through open consultation processes. A shorter, consolidated consultation period is unlikely to enable this. It will compromise transparency in decision-making and incorporate bias in processes if a public consultation is replaced by informal engagement ahead of publishing a restriction dossier. There are already risks of regulatory capture under UK REACH as highlighted by the Lords Industry and Regulators Select Committee, based on evidence from eNGOs.

As a public body, HSE is accountable to the general public/civil society and the stakeholders that operate within this realm. Removing a process of fully public consultation in an already restricted environment for engagement (with few

opportunities to engage with the regulator directly and independently from Government) and replacing it with more informal engagement reduces transparency, as well as the role civil society and relevant stakeholders play in ensuring accountability.

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

See above answers. It is unclear why this is being proposed, except to limit the burden on the companies to fully engage with the regulatory process, which will inevitably contravene the statutory purpose to be upheld by the regulator.

We therefore strongly disagree with the recommended approach. We suggest that it is reconsidered and revised to ensure that the regulator is not taking up the obligations of the groups it is meant to regulate and is regulating in line with public and environmental interest.

Improving the UK REACH reporting process

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

We generally agree with the introduction of a fixed date for the Agency to report to Government, as this will provide a good basis for planning oversight and regular accountability.

However, we disagree with the consolidation of reports 2 and 3 (on the work plan). These reports are already not delivered on time, with the 2023-24 work programme being delivered 11 months into the year it was intended to cover. Based on the consultation document, it is not clear why these reporting changes are being proposed as it is not specified to what extent their removal will contribute to, as opposed to inhibit, the statutory purpose of UK REACH.

Reducing administrative burden and facilitating business planning are not part of this overarching obligation to reduce risks to human health and the environment, and should not be material considerations in revising the reporting process.

Generally, reporting on enforcement more regularly than 5 years would be a welcome improvement of the reporting process, given the rapidly changing understanding of the hazardous nature of chemicals on the market and state of chemical pollution.

Further protections against unnecessary animal testing

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

We are strongly supportive of reducing the number of unnecessary animal tests and increasing the animal welfare requirements where alternatives to testing are not available for the registration of new substances.

However, this approach must be carefully balanced with the overarching imperative to ensure chemical safety before substances are placed on the market. Here, a grouping approach and EU alignment can support decision-making on chemical safety while minimising unnecessary animal testing without duplicating processes.

UK REACH and Trade

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

The policy proposals amount to a further step in the unnecessary and avoidable pathway towards costly, less protective regulatory divergence from the EU system. The effect is that there will be a less protective set of standards in the UK and a more protective set of standards in the EU. This imbalance in standards will risk an influx of toxic products that are banned from the EU on the GB market.

Other trade consequences of chemicals divergence include:

- Obstructions to the flow of goods and services between the UK and EU due to lower standards (which may create unfair competition and hinder the UK/EU Trade and Cooperation Agreement).
- Impacts to the UK internal market due to increased GB/Ireland checks.

The human health and environmental impacts of hazardous chemicals are not likely to differ between the EU and GB. Therefore, beyond the political decision to pursue further divergence, it is unclear why the ATRm proposal is designed to cut costs to the chemicals industry in a way that would undermine access to European markets for GB goods.

The clearest and most cost-effective way to mitigate market or trade issues is to adopt a pro-EU alignment approach.

For questions or further information please contact:
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The following organisations have inputted into this briefing and support replacing the ATRm proposals with a pro-EU alignment approach:

Angling Trust
Fidra
Marine Conservation Society
The Rivers Trust
RSPB