CTPA RESPONSE TO THE CONSULTATION ON THE DEADLINE EXTENSION FOR UK REACH

https://consult.defra.gov.uk/reach-policy/consultation-on-extending-the-uk-reach-submission/supporting_documents/Consultation%20Document.pdf

- **Proposed deadline extensions**

SUBSTANCES	CURRENT DEADLINES	OPTION 1	OPTION 2
1000 tonnes or more per year; CMR; Very toxic to aquatic organisms; candidate list substances (as at 27 october 2024)	27 October 2023	27 October 2026 (+3 years)	27 October 2026 (+3 years)
100 tonnes or more per year; candidate list substances (as at 27 October 2025)	27 October 2025	October 2028 (+3 years)	27 October 2027 (+2 years)
1 tonne of more per year	27 October 2027	October 2030 (+3 years)	27 October 2028 (+1 years)

- **Consultation response**

Questions 1-7 ask for the identity of the organisation responding to the consultation.

8. Which is the preferred policy option?

Option 1.

CTPA and the UK cosmetics industry would like to express support for option 1. In addition, CTPA would like to suggest the possibility of splitting the last tonnage band (1-100 tonnes) into two phases: 50-100 tonnes with a deadline of October 2029 and 1-50 tonnes with a deadline of October 2030.

The UK cosmetics industry is in favour of option 1 for the following reasons.

- A longer deadline maximises the opportunity for industry to produce as high-quality dossiers as possible, because there is additional time to gather more data and to provide training to businesses on building high quality dossiers. This would ensure high protection of human health and the environment, as well as a higher rate of compliance.
- The new UK REACH model is not yet in place, so the REACH registration requirements are not yet clear to industry. Without having an understanding of exactly what obligations will be in place for industry, and more importantly what has to be included to prepare high quality dossiers, it is harder for industry to commit to a shorter deadline. The longer deadlines of option 1 best account for the currently uncertainties on time and cost requirements of the future obligations.
- A longer deadline is more likely to harmonise the development of the new UK REACH model with other ongoing UK Government chemicals management initiatives, such as the UK Chemicals Strategy. It is important that all activities are developed in parallel to account for important cross-cutting topics, such as the use and acceptance of New Approach Methodologies (NAMs), the regulatory approach to suspected endocrine disrupting substances, and others, which require a holistic approach.

- Industry requires sufficient time to prepare for the new model and compile the registration dossiers, as well as to allow Downstream Users (DUs) which have become importers to familiarise themselves with the new obligations under UK REACH. Many companies submitting registrations under UK REACH did not have registration obligations under EU REACH and will need more time to receive relevant training. The training also has to be prepared and delivered by the UK Government and relevant stakeholders (e.g. trade associations), which will also require a significant amount of time.
- Longer deadlines will allow industry to spread the costs over a longer time period, increasing the opportunity to invest in other areas such as research, innovation and sustainability initiatives.
- A longer time frame will allow the supply chain to adapt to changes that may happen (e.g. change of supplier, formulation changes to substitute ingredients), thereby minimising disruptions.
- It is important to keep in mind that industry will still need time to negotiate data access, which is a complex task. At the same time, industry might still have to generate some new data to comply with the requirements of UK REACH. This can be done in two ways:
    - carrying out new tests, which do require a significant amount of time and costs;
    - using New Approach Methodologies (NAMs), which are faster to generate and are more cost-effective, but at the moment they require enough time to build expertise and promote a harmonised approach amongst industry and acceptance by regulators.

As mentioned, the new registration model for UK REACH is not yet in place, the deadline extension will give a timeframe by which the new model shall be ready. However, if any unforeseen circumstances occur which may delay the development of the new model, option 2 is unlikely to allow industry enough time to prepare. CTPA would like to propose the following solutions to help mitigate some of the challenges which exist with option 1.

- It is important for industry to have visibility of the existing substance groups, so that companies (especially DUs) know which substances are already being registered and by which suppliers. This will help industry prioritise and invest where there are gaps concerning particular ingredients.
- The cosmetics industry appreciates the current level of engagement from Defra and the HSE at the early stages of development of the new registration model under UK REACH. CTPA would like to see continuation of this constructive communication, especially in regard to, what information is expected to be submitted; so that education and preparations can begin well in advance. Transparency and clarity will also help swift decision-making on substance registrations by suppliers and manufacturers across the supply chain.
- As elaborated in detail in the answer to question 4, option 1 still ensures a high level of protection of human health and the environment because the HSE can still implement risk management measures for chemicals of concern, if needed. Furthermore, the substances of higher risk have the same deadline extension of 3 years in both options and the HSE will be able to investigate chemicals within this band as a priority, if required.

9. Do you think the reduced submission timeline for substances in the 100 tonnes or more bracket under Option 2 provides sufficient time to comply with the deadline?

No.

In general, shorter timelines are always more challenging for compliance.
It is difficult to give a definite answer without knowing the registration obligations of the new UK REACH model and the level of information and data that will be required to compile the registration dossier. This is not only in reference to the hazard data, but also to the use and exposure information. The collection of the hazard data still poses the challenges of the legality of using publicly available information that may be

intellectual property of other companies, as well as the possible need to conduct additional tests. Conversely, time is needed to provide education to industry on complying with REACH, gathering and providing use and exposure information and risk characterisation. In particular, this time will be most beneficial to those companies that have become importers from previously being DUs and which may not have completed a REACH registration before.
Early communication from Defra and the HSE on the structure of the new UK REACH model and what level of data will be expected will be very much appreciated by industry. CTPA welcomes the opportunities already provided by Defra and the HSE to input views from industry on the development of a new model. Clear and early communication will enable industry to start preparing as early as possible, even before the new UK REACH model is fully implemented into domestic law.

10. **Do you think the reduced submission time for substances in the 1 tonne or more bracket under Option 2 provides sufficient time to comply with the deadlines?**

No.

In general, shorter times are always more challenging for compliance.
As per the previous answer, it is difficult to give a defined answer without knowing the registration obligations of the new UK REACH model and the level of information and data that will be required to compile the registration dossier.

CTPA believes that this might be the most challenging tonnage band for the following reasons.

- For commercial reasons, some suppliers may not wish to replicate their EU registration under UK REACH, for a small tonnage band and for a small market such as the UK. This would mean that UK DUs using these ingredients would have to become importers and have to compile registrations for these raw materials.
- This has already been confirmed by the high number of Downstream Users Import Notification (DUINs) received, which was approximately 5400 (as of the beginning of 2022). However, CTPA is aware that companies are continuing to submit DUINs even after the October 2021 deadline. These DUs becoming importers are therefore more likely to be in the tonnage band of > 1 tonne. This means that education of these companies on REACH, their obligations, as well as registration dossiers is needed and
  may take a significant amount of time to be provided and achieve a high overall level of compliance.
- Assuming that this tonnage band may be more represented by DUs becoming importers and therefore having registration obligations, these companies may find it even more challenging to access data, compile registration dossiers, and sustain the costs related to these activities. This is because they are at the very bottom of the supply chain and may not have complete information on certain raw materials, nor access to hazard data.
- It is important to consider that, without clarity on what the requirements for registration under the new model will be, suppliers may not feel able to swiftly make commercial decisions on UK REACH. This will leave DUs in uncertainty for longer, providing less time for these companies to undertake their new responsibilities.

11. **To what extent do you think Option 1 impacts on the regulatory aims of UK REACH in achieving a high level of protection of human health and of the environment?**

Overall, options 1 and 2 provide the same level of protection to human health and the environment because the requirements have not changed; option 1 simply allows more time for industry to provide the dossiers.

The Evaluation, Authorisation and Restriction processes under REACH, which are the processes by which specific risk management measures are taken if there is a need to act to protect human health or the environment, are conducted separately and therefore not affected by either registration option 1 or 2.

In addition, the substances of higher risk (1000 tonnes or more per year; CMR; very toxic to aquatic organisms; candidate list substances as of 27 October 2024) have the same deadline extension of 3 years in both options and the HSE will be able to investigate chemicals within this band as a priority, if required. Furthermore, the EU has already been addressing chemicals of high concern over the past years and the subsequent risk management measures are already implemented within UK law, or the HSE is already prioritising their assessment within its work programme.

It is also important to consider that there is already a high level of protection for human health and the environment, comparing to when EU REACH first came into force in 2007. This is because there is much more data available for substances than 15 years ago; also, this information has been shared within the supply chain via SDS, therefore industry has good knowledge of how to manage risks.

12. **To what extent do you think Option 2 impacts on the regulatory aims of UK REACH in achieving a high level of protection of human health and of the environment?**

As per the answer to question 4, both option 1 and option 2 will achieve a high level of protection for human health and the environment. Neither option represents a weakening of protection or puts human health or the environment at risk.

13. **Do you agree with the Government's proposal to move the current dates for compliance checks until after the submission deadlines in either Option 1 or Option 2?**

Yes, compliance checks need to occur after dossiers have been submitted, so an extension to the submission deadlines will necessitate an amendment to the compliance check dates.

14. **Do you have a view on what the revised dates for compliance checks should be?**

The revised timeframe for the HSE to carry out compliance checks of 20% of the dossiers needs to be in line with the revised framework for companies to submit dossiers. It shall not be significantly delayed, compared to the deadlines given to companies.

15. **To what extent do you agree or disagree with the government's assessment of the impacts on human health and environmental protections in paragraphs 38-40 and paragraph 44 of the IA?**

CTPA agrees with the Government's assessment of the impacts on human health and environmental protection in paragraphs 38-40 of the IA (in regard to the implementation of option 1). The management options available during the timeframe of the deadlines will still allow the HSE to carry out its duties as a regulator, to ensure a high level of protection for human health and the environment. Furthermore, the HSE can still address and prioritise substances of concern using data from other sources, should that be needed. Indeed, industry is also capable of contributing to the protection of human health because there is a lot of data available on how to minimise risks, and this information is shared throughout the supply chain via the SDS.

Also, it is worth keeping in mind that the HSE has, to date, already addressed topics of concerns and is in the process of investigating and implementing regulatory management on those topics. For example, RMOAs, Restriction and Authorisation processes are already currently ongoing.

The above is valid also for option 2 (paragraph 44 of the IA); however, we are of the opinion that options 1 and 2 provide the same high level of protection for human health and the environment, despite the difference in deadlines. Please refer to the answer to question 4 for more details.

16. **To what extent do you agree or disagree with our risks and assumptions in paragraph 47- 48 of the IA?**

CTPA is in agreement with the information in paragraph 47-48 of the IA.

17. **To what extend do you agree with the public sector impacts in paragraph 45 of the IA?**

CTPA also agrees that the impact to the public sector would be negligible.

18. **To what extend do you agree with the business and consumer impacts in paragraph 42 of the IA?**

CTPA agrees that changing the registration timelines only affects the point in time at which costs occur, rather than the actual scale of the costs. However, it is CTPA's understanding that the new UK REACH model is intended to reduce the costs that businesses will have to face to comply with UK REACH.

The impact of UK REACH to businesses is not just monetary, but also practical. It is important to consider that the two options give a different timeframe for businesses to prepare for the requirements of the new UK REACH model. The amount of preparedness needed will depend on the level of data expected by regulators for the registration dossiers under the new framework. Companies may still incur some costs related to data access negotiations, repetition of tests and alternative methods to generate data.

Another point to consider is regarding supply chain arrangements. It is difficult to predict how the new UK REACH model may affect the supply chain, in particular whether suppliers will register substances under UK REACH or whether DUs will be required to do this instead if they wish to keep using a chemical. This will also incur in costs to businesses, as well as possible disruptions in the supply of chemicals.

The above possible disruptions in the supply chain and the uncertainties for businesses can ultimately have repercussions on consumers in relation to cost of finished goods and product availability and consumer choice.

19. **For substances that your company / the companies you act on behalf of have joint data ownership of under EU REACH: On average, what percentage of the price of generating a full dataset do you expect your company / the companies you act on behalf of to be charged by the EU consortium? For example, if you expect the consortium to charge full price, then please answer "100%". If you expect them to charge half of that amount, then please answer "50%".**

As a trade association, CTPA does not have visibility of information regarding costs and time needed to compile the UK REACH dossiers according to the new model.

However, CTPA understands from its members that the cost and time needed will vary depending on the substance. Some consortia may charge 100% of the costs, some others may charge 50% or less; it really depends on how much data is available, and on the commercial decision of the company(ies) owning the data. Consequently, companies will have to assess how much data can be used from existing resources, or shall be generated repeating tests or using NAMs.

20. **For substances that your company / the companies you act on behalf of does not own data under EU REACH: On average, what percentage of the price of generating a full dataset do you expect your company / the companies you act on behalf of to be charged by the EU consortium?**

As a trade association, CTPA does not have visibility of information regarding costs and time needed to compile the UK REACH dossiers according to the new model.

However, CTPA understands from its members that the cost and time needed will vary depending on the substance and how much data for is publicly available and can legally be used for registration purposes. UK REACH presents an important opportunity to increase the use and regulatory acceptance of NAMs, which constitute a faster and more cost-effective way to generate data compared to traditional methods. CTPA and the UK cosmetics industry is advocating for the use of NAMs for chemical safety assessment, as well as their regulatory acceptance by the relevant authorities, and cosmetics industry experts are ready to provide support the UK Government in any way which is required.