**CTPA response to the UK REACH consultation on the ATRm and policy proposals**

**Executive Summary**

- For UK REACH to be an innovative, exposure-led chemicals framework, it is imperative that uses of substances are clearly identified and exposure is estimated. Exposure can be informed by known as well as foreseen uses of the substance from downstream users, or predicted using computational tools (there are many available, such as ECETOC, TRA, PACEM, etc.). We believe that the proposal under this consultation has the potential to become an innovative, exposure-led UK REACH which will meet its objective of effective protection of human health and the environment.
- CTPA supports the removal of the more detailed information requirements for hazard data, because a high level of protection for human health and the environment can be achieved through the proposed requirements. These requirements for hazard data under the ATRm will enable more EU REACH registrants to consider also registering the substance under UK REACH (via appointing a UK-based Only Representative or affiliate); in turn, this will also ensure a competitive chemicals market in the UK and a stable supply chain. It is important to highlight that CTPA members raised concerns about the legality of using data from publicly available resources, as well as any risk of infringement of Intellectual Property rights. It is important to clarify this matter to ensure that companies can comply with the ATRm requirements.
- CTPA supports the principle for the additional requirements on uses and exposure information, as well as having trigger points for these additional requirements. However, not all companies are already familiar with the use descriptors; therefore, education for industry will be needed.
- The chemicals and cosmetics supply chains are extremely complex. It is important to consider that every substance is used in many different ways and product categories; manufacturers and suppliers of chemicals supply to a lot of different companies operating in many different areas of the chemicals sector. This implies that there may be hundreds/thousands of Downstream Users (DUs), as well as registrants, submitting an extremely high volume of information on uses and exposures. It is therefore important to identify a feasible and practical way to implement these requirements.
- CTPA supports the provision of giving powers to the regulator to request additional hazard information "as and when needed" (so called "transitional evaluation"). However, there is no clarity yet as to what criteria will trigger a "transitional evaluation"; it will be important to have visibility of this.
- CTPA supports the streamlining and simplification of the restriction processes under UK REACH, but it should not hinder the opportunity for industry to input critical information into the restriction proposal. It is important that regulatory management processes under UK REACH are transparent and provide opportunity for industry and stakeholders to provide any relevant information. Informal modes to submit additional information are not transparent and they are not always well known, therefore do not provide the opportunity to all stakeholders to submit any additional information. We would therefore request that a second consultation step is not removed from the process.
- CTPA strongly supports that UK REACH is at the forefront of promoting the use of Non-Animal New Approach Methodologies (NAMs) for chemical safety assessment. NAMs are cutting-edge scientific methods to chemical safety assessment that do not use animal testing. This provides an opportunity for the UK to be a global leader in animal free chemical

safety assessment. The proposals to further protect against unnecessary animal testing which are found in this consultation have both positive and negative aspects. Their implementation shall take place only if the challenges outlined in this response are addressed in an appropriate manner. CTPA also made other proposals to address this matter within this response.

- The new Government is committed to a closer relationship with the European Union and to regulatory cooperation, which is extremely welcome. Enhanced regulatory cooperation and data sharing may be achieved, which would mean that the burdens and costs on UK businesses of the ATRm can be further reduced. We would urge both the UK and EU authorities to seek to work together on regulatory cooperation and on data sharing, as per the legal terms under Annex VI on chemicals of the Trade and Cooperation Agreement (TCA). This will improve chemicals management both in the UK and the EU, ultimately benefitting consumers, the environment and businesses on both sides.

**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?

Strongly agree

- It is important to consider that there is already a high level of protection for human health and the environment, because since EU REACH first came into force in 2007, there is now much more data available for substances. This information has been shared within the supply chain via the safety data sheets (SDS), therefore industry has increased knowledge of how to manage risks for these substances and replicating the same data again will provide no benefit.
- The removal of the more detailed information requirements for hazard data does not compromise on a high level of protection for human health and the environment. The EU has already been addressing many chemicals of high concern over the past decade, based on the hazard data already provided for these chemicals to EU Authorities, and the subsequent risk management measures are already implemented within UK law. Furthermore, the hazard classification itself, rather than the detailed elements justifying the classification, is used to decide risk management measures therefore the high levels of protection to human health and environment would not be compromised.
- The HSE can still address and prioritise substances of concern using data from other sources, should that be needed. Where necessary, we support the proposed provision of 'transitional evaluation' to request more information from the registrant if needed.
- It is important to highlight that CTPA members raised concerns about the legality of using data from publicly available resources, as well as any risk of infringement of Intellectual Property rights. It is important to clarify this matter to ensure that companies can comply with the ATRm requirements.
- The ATRm also aims to improve the use and acceptance of Non-animal New Approach Methodologies (NAMs) and Next Generation Risk Assessment (NGRA) which give the opportunity to industry to generate hazard data and/or carry out exposure-led risk assessment in a way that is more relevant for, and protective of, human health and the

environment. Should further information on hazards or risk be needed, this can be provided by companies to the regulators also using these approaches.

- CTPA supports a chemicals framework that maintains a risk-based approach focussing on uses and exposures for Great Britain (GB) specific and real-life relevant regulatory management of chemicals. The ATRm is proposing greater consideration of uses and exposures, which will support more targeted risk characterisation. This will help chemicals management to become as realistic and specific as possible, relevant to real life scenarios.

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?

- It is important that the registration dossiers contain information which allows the HSE to effectively identify chemicals of potential concern according to the prioritisation criteria available on the HSE website.
- The hazard criteria to prioritise substances for evaluation are based on hazard classes that are of most concern. The other criteria for prioritisation outlined on the HSE website are uses and exposures and risk assessments. According to the ATRm proposal, the hazard classes and associated labelling of chemicals are part of the information that shall be submitted to the regulator as part of the UK REACH dossier. Furthermore, substances with higher tonnage bands will also require submission of the Predicted No Effect Concentration (PNEC) and the Derived No Effect Level (DNEL) and physico-chemical properties, depending on tonnage band and hazard category. This will address any specific concerns that can arise with substances manufactured or imported in high quantities.
- The HSE can still address and prioritise substances of concern using data from other sources, should that be needed. In addition, we support the proposed provision of 'transitional evaluation' to request more information from the registrant if needed.
- The new Government is committed to a closer relationship with the European Union and to regulatory cooperation which is extremely welcome. Enhanced regulatory cooperation and data sharing may be achieved, which would mean that the burdens and costs on UK businesses of the ATRm can be further reduced. We would urge both the UK and EU authorities to seek to work together on regulatory cooperation and on data sharing, as per the legal terms under Annex VI on chemicals of the Trade and Cooperation Agreement (TCA). This will improve chemicals management both in the UK and the EU, ultimately benefiting consumers, the environment and businesses on both sides.

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.

- The proposed requirements for hazard data under the ATRm will enable more EU REACH registrants to also consider registering the substance under UK REACH (via appointing a UK-based Only Representative or affiliate); in turn, this will also ensure a competitive chemicals market in the UK and a stable supply chain. CTPA membership comprises both DUs, at the end of the supply chain, as well as registrants. DUs will mostly rely on their suppliers to hold registrations under UK REACH and, therefore, may not be involved in substance registration.

However, some members will be involved in registration of chemicals under UK REACH , who will need clarity on the legality of using certain publicly available information.

- Our members are reassured by the proposed hazard requirements, as these are likely to encourage companies to register chemicals under UK REACH, as the ATRm is not prohibitive. This will help ensure continuity of supply of cosmetic ingredients to companies, especially SMEs, which will be disproportionately impacted by any burdensome requirements of UK REACH. A member provided an estimate of their cost saving from these revised hazard requirements: the cost would be reduced by around £20 million either directly or indirectly by suppliers passing on registration costs via raw material prices. Although expert resources will still be needed to create the registration dossier, this resource will not be tied up in legal discussions regarding consortium agreements/data sharing agreements. This will save a great deal of time due to the reduced complexity.
- The information requested to be submitted as hazard data under the ATRm is feasible for companies. The information requested for hazard classification and associated labelling can be more easily accessed by companies from publicly available resources. For example:
    - The hazard classification and labelling of the substance may be found in the SDS of the raw material, as well as in other reliable online sources.
    - The same applies to physico-chemical properties, which may also be found in the SDS of the raw material.
    - The PNEC and DNEL may be more difficult to find, as they may not always be provided in the SDS. The EU and UK requirements provide for these parameters to be included within the SDS for the exposure scenarios applicable to that substance.
- If a PNEC or DNEL is not available, it could be derived from studies or databases available online. However, this may still raise legal issues on the use of data if that data is protected by intellectual property or specific legal terms of an online database.
- It is important to consider that some chemicals now have different mandatory classifications in GB vs in the EU; there might be a different set of information in the EU SDSs and chemicals database, as well as other publicly available resources. It is important to provide clarity to registrants on what information is expected to be submitted under UK REACH. This means there is always a cross check required for the information found in SDS.
- The above feedback is applicable for substances manufactured or imported in the UK and EU, where there are specific extensive requirements to compile SDS. However, meeting the ATRm requirements may be more challenging if the substance is manufactured outside of the UK/EU where the SDS may not contain the same extensive information. In this case, if it is a former DU (now importer) which needs to submit the registration dossier, the DU who is now the registrant will need to liaise with the overseas manufacturer to access relevant information to be submitted under the ATRm.
- The general view of CTPA members is that the new hazard requirements are likely to reduce the cost of the Letter of Access (LoA) from the Lead Registrant. However, it is not possible for CTPA members to share quantified cost savings without knowing how the preparation and submission of these dossiers will work in practice.
- As mentioned in the previous question, we would encourage UK authorities to seek further regulatory cooperation with the EU authorities, as stipulated under Annex VI on chemicals of the TCA. This can further support access to data on chemicals.

**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?

I don't know

*[An explanation for this answer is given within the answer to the next question]*

12.To what extent do you agree with the proposed trigger points and corresponding information requirements for registrants? (see Annex B)

Agree

- It's important to keep in mind that for substances used in cosmetic products, information on uses and exposure for consumer use (this would include professional use in salons or hairdressers) is exempt from REACH requirements. The only uses and exposure information covered by REACH for substances used in cosmetic products refers to occupational health (worker exposure in the context of manufacturing cosmetic products or ingredients) and environmental safety.
- CTPA supports the additional uses and exposure requirements and the principles of having trigger points for requesting these. The trigger points are currently broad and could be made more granular. For example, the additional uses and exposure information may be requested only for particular hazard categories (e.g. CMRs, PBT/vPvB, respiratory sensitisers, STOT), but not all hazard categories in Article 14(4).
- We would like to clarify why we answered 'I don't know' to the previous question. The majority of our members are also supportive of these additional requirements, but we could not find a unanimous consensus and our response has to therefore reflect the feedback from all membership. There is overall agreement in principle with the uses and exposure information and their aim to improve risk management of chemicals. However, some members raised concerns about the practicalities of the proposals. We expand on this in the following bullet points.
- Level 1 uses and exposures information consists of what is already required under Annex VI of UK REACH. We therefore do not foresee any issues in providing this information.
- We have reviewed thoroughly the level 2 and 3 enhanced requirements. We believe that the proposed additional information on uses and exposure should be feasible for companies to collect. The proposed level 2 and 3 requirements should already be supplied by DUs to registrants, as they are included in the guidance on 'use descriptors' developed by industry's associations for EU REACH. For the cosmetics sector, we specifically use the Cosmetics Europe's 'use descriptors' (Specific Environmental Release Category – SPERCs, and Specific Workers Exposure Descriptions - SWEDs). These existing use descriptors were developed for EU REACH to provide more detailed guidance to DUs and registrants as to what should be submitted as part of the broad Annex VI requirements. Furthermore, Cosmetics Europe's

SWEDs and the SPERCs already have default values; they are relevant for the EU market so they may need to be adapted to a smaller market such as GB.

- However, not all companies are already familiar with the use descriptor, especially if they have not had such obligations under EU REACH previously; therefore, education for industry will be needed. Members flagged that one of the reasons why communication on uses and exposure didn't work for EU REACH is because there was confusion around what these are and why they are needed. It is important to highlight that the different sectors have different use descriptors, and each sector will have to become familiar with their specific requirements. As these are now becoming legal requirements, it is key that industry is properly trained on what the information requested covers and why it is requested. Trade associations can help with education in their respective sectors.
- From the cosmetics industry perspective, we would like to highlight that it will be extremely challenging to collect level 2 information for the environment, in relation to professional and consumer uses. This is because it will be extremely difficult to track the daily use and average use of products in each professional hair or beauty salon; release fractions from consumer use. We believe that companies may be able to calculate estimate values for these points, but they will not be able to have the exact value. For example, brand owners can calculate the estimated values based on the concentration of the ingredients in the product and the number of units sold to salons, as well as assuming 100% release down the drain for rinse off hair products (as examples). Therefore, we would suggest that the expectation is to work around estimates of uses and exposure information, or create a framework with a range of values to allow submission of this information.
- Furthermore, the chemicals and cosmetics supply chains are extremely complex. It is important to consider that every substance is used in many different ways and product categories; as well, manufacturers and suppliers of chemicals supply to a lot of different companies operating in many different areas of the chemicals sector. This implies that there may be thousands of DUs, as well as registrants, submitting an extremely high volume of information on uses and exposures. It will be highly challenging for registrants to collate all this information from all their different DUs into the exposure assessment of the registration dossier. It is therefore important to identify a feasible and practical way to implement these requirements, as well as ensure that the UK REACH IT functionalities allow for submission of this type of information from a complex supply chain. CTPA offers its support to the Government in developing a suitable mechanism; and we would suggest further engagement with industry to ensure that the mechanism properly works in practice.

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?

- It is difficult to provide an estimate of the time that companies will take to complete the collection, submission and assessment of the additional uses and exposure information that may be required under the ATRm. This is because there is no clarity at this stage on how this will work in practice, nor on the accuracy required. On the latter, it is important to

highlight that companies are likely to provide worst-case estimates of the additional uses and exposure information, as it is not always possible to have exact figures. If more accuracy reflecting actual use is required, data collection should be repeated continuously, and this will have a significant impact on the amount of work required to meet these requirements.

- However, some members reported that collecting and providing the additional uses and exposure information to the registrant is likely to require an additional several hours of work per substance. Other members may be using Only Representatives (OR) to register under UK REACH; therefore, administrative time and cost to manage OR contracts and the additional information on uses and exposure also has to be considered.

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.

- It is difficult to provide an estimate of the costs that companies will face to complete the collection, submission and assessment of the additional uses and exposure information that may be required under the ATRm. This is because there is no clarity at this stage on how this will work in practice.
- However, some members reported that the additional cost to business is likely to be related to increased staff time. Another member was able to provide an estimation: assuming that the company is a DU of approximately 1500 substances and that 5% of these substances require the level 2 or 3 information, and assuming that the default values defined within the Cosmetic Europe SPERCs and SWEDs are not accepted, the company would need an additional 7.5 full time equivalent to meet these requirements.

**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 applies?

Strongly agree

- Exposure assessment is mainly carried out looking at the uses of a chemical and its fate. To calculate the risk level associated with a chemical, the assessor needs both the hazard and exposure. The uses and exposure information (especially considering the additional requirements) will allow the registrant to carry out an extensive exposure assessment, which in combination with hazard information can allow robust risk characterisation.

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)?

Strongly agree

**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?

Agree

- We support the provision of giving powers to the regulator to request additional hazard information "as and when needed" (so called "transitional evaluation"). However, there is no clarity yet as to what criteria will trigger a "transitional evaluation"; it would be important to have transparency and available guidance on this.
- The regulator has to be able to carry out its duties and prioritise chemicals for regulatory management, should there be an identified risk to human health or the environment. There can be instances where the submitted hazard information may not be sufficient to carry out effective evaluation and prioritisation; therefore, the regulator has the right to request targeted additional information. It is important to highlight in this point that the regulator has the duty to carry out dossier evaluation to allow prioritisation of substances of concern and this is what should trigger the "transitional evaluation". The additional information should be requested to companies after a thorough evaluation and prioritisation exercise; these criteria shall be clarified so that companies know what can trigger the "transitional evaluation".
- The fact that additional information may be requested "as and when needed" will significantly reduce burden on industry; this is because the negotiation to gain data access from companies, or generate new data, is targeted to specific chemicals and in specific occasions, rather than all chemicals available on the GB market.
- Publicly available information, including sources such as online databases or international regulators, may be useful to inform regulatory decisions. As mentioned above, when this is the case, it will also be important to provide alongside the rationale of how international activities might be relevant to the UK.
- The consultation document states that a response from the registrant to submit additional information is expected within 3-12 months. This deadline may not be feasible in all cases: data negotiations and/or data generation can take a significant amount of time, depending on the type of substance, data available and other factors. We suggest including the possibility for the registrant to negotiate a longer deadline if needed, with clear justification for it and a roadmap of the steps to be taken towards data submission.

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?

Strongly agree

- We would like to highlight that the uses and exposure information is published in an anonymised and aggregated way, to maintain confidentiality of uses of chemicals throughout the supply chain.

**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?

No

- CTPA supports the possibility to form "substance groups" that include registrants, former DUs and any other relevant actor in the supply chain wishing to join the registration for a specific chemical. It is important that companies have the possibility to come together to work on the registration dossier and share data, costs, and resources. We also support:
    - the possibility to identify a lead registrant to submit the dossier on behalf of the substance group;
    - the possibility for registrants to be entitled to opt out of the joint submission for a specific reason;
    - the possibility for the joint group to work on a transitional evaluation, if it applies.
- The ATRm must provide an appropriate environment for the Substance groups and industry consortia to operate according to legal contracts, to ensure compliance with Competition Law. Such contracts allow members to reach agreement in regard to cost and resources sharing, as well as any other operational terms to allow the correct functioning of the group.
- Whilst the substance groups govern themselves and should have a suitable legal agreement in place, Defra/HSE should publish guidance on best practices for the functioning of the substance groups and principles to ensure that the substance groups operate in a transparent, fair, non-discriminatory matter.
- Furthermore, members suggested that the UK REACH IT system has to be improved to allow these functionalities.
- We also would like to make a comment in regard to the process of submitting an Article 26 inquiry to join a joint submission group. A number of companies who will go through this process are likely to be former DUs which are now importers under UK REACH. These companies may not be able to assess whether any information requirement may require new testing, which is part of the information that needs to be submitted within the inquiry. It is important that such process is made flexible, to allow the submission of an inquiry without including this level of detail.

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?

- Members support the mode of operation of SIEFs under EU REACH. Therefore, they have no suggested improvements in this area.

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 further comment

**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)

- Typical actions that companies need to take to prepare a response to the first consultation include:
    - suppliers to understand the downstream uses of an affected chemical and ensure the supply chain is informed of the restriction proposal;
    - DUs to work with suppliers to understand availability of technical data and any plans in regard to defence of the chemical;
    - information about the usage and exposure of the chemical is prepared. This may include information from an industry survey, environmental exposure modelling, or other information;
    - technical hazard information is prepared, for example, based on existing supplier data and/or a literature search;
    - information about societal benefits of the chemical and why it is used will be prepared;
    - a socioeconomic analysis may be prepared at this stage;
    - additional testing may be commissioned to address specific questions.
- Technical submissions take a minimum of 6 months to prepare, and this time will be extended if a socioeconomic analysis is required. Additional testing will require 18 months or longer. Important aspects, such as industry surveys, require several months because they are very resource intensive for companies.
- Suppliers and DUs will usually closely collaborate on these submissions, because each actor has specific information which is required to prepare a full picture of the hazards and usage of a chemical in order to characterize a risk.

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?

- This depends on a case-by-case basis. There have been instances where further information is submitted at a second consultation. This is because a Trade Association may need to carry out a member survey, or additional research to inform a consultation to a restriction proposal under UK REACH. These surveys, or other extensive research, can take a significant amount of time; furthermore, we would know whether to run such projects, and how they should be conducted, only when detailed information about the restriction proposal or the Socio-Economic Assessment (SEA) are issued.
- Furthermore, industry and stakeholders may have more detailed responses, or additional information to submit based on how the Risk Assessment (RA) and SEA have been conducted. For example: as part of the process that led to the microplastics restriction under EU REACH, Cosmetics Europe and the cosmetics industry had additional information to

contribute to a refinement of the socioeconomic analysis prepared by the Authorities, in particular to counter some assumptions that has been made. Industry must have the opportunity to challenge any relevant aspects of the RA and SEA which are supposed to be carried out after the first consultation step (according to the proposal in paragraph 78 of this consultation).

- CTPA supports the streamlining and simplification of the restriction processes under UK REACH, but it should not remove the opportunity for industry to input into the restriction proposal. We also would like to provide feedback on paragraph 79, which states that further information can be informally submitted on a draft RA and SEA and removes the second consultation. It is important that regulatory management processes under UK REACH are transparent and provide opportunity for industry and all stakeholders to provide any relevant information. Informal modes to submit additional information are not transparent and they are not always well known, therefore do not provide the opportunity to all stakeholders to submit any additional information, creating the possibility of an uneven playing-field.
- CTPA therefore would recommend maintaining the second consultation step; however, this may be shortened compared to the processes inherited from EU REACH. The second consultation would be issued publicly, allowing for transparency and equal opportunities for responses.

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?

- CTPA agrees that providing industry and stakeholders with any information, or engagement ahead of the publication of a restriction proposal will be helpful. These can include similar dossiers or restriction proposals from other jurisdictions, as well as any related supporting documentation; as well as industry engagement in a way that Defra has already carried out to present any proposals and plans. The visibility of substances on the Registry of Intentions and the engagement between authorities and interested stakeholders during the priority setting process is welcomed as an important and valuable part of the process.
- In order to allow industry to prepare ahead of a consultation on a restriction proposal, it will be helpful to have access to the summary of the justifications for that restriction, and data that will be used to compile the dossier for the proposal.
- It will be important to request industry to submit any already available publications or data that can help inform the restriction proposal at the early stages, rather than doing this at consultation stage. Allowing this could help form a restriction proposal that considers all available information, including that which is not in the public domain.

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?

Yes

- As mentioned in Q23, CTPA supports the streamlining and simplification of the restriction processes under UK REACH, but it should not hinder the opportunity for industry to input into the restriction proposal. We also would like to provide feedback on paragraph 79, which states that further information can be informally submitted on a draft RA and SEA and removes the second consultation. It is important that regulatory management processes under UK REACH are transparent and provide the opportunity for industry and relevant stakeholders to provide any relevant information. Informal modes to submit additional information are not transparent and they are not always well known, therefore do not provide the opportunity to all stakeholders to submit any additional information.
- CTPA therefore would recommend maintaining the second consultation step; however, this may be shortened compared to the processes inherited from EU REACH. The second consultation would be issued publicly, allowing for transparency and equal opportunities for responses.

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?

Disagree

- As mentioned in the previous questions, industry and stakeholders may have more detailed responses, or additional information to submit based on how the RA and SEA have been conducted. If there is no formal consultation step after the publication of the draft RA and SEA, then industry and other stakeholders do not have transparent and equal opportunities to submit any additional relevant information.
- It is also not currently clear what the content of the additional information from the UK Government/the Agency would be.

**Improving the UK REACH reporting process**

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

Yes

- We would suggest that, as part of the Article 83 requirements, the HSE also publishes a report on the statistics of NAMs or NGRA approaches used within registration dossiers and testing proposals, both accepted and not accepted. This can help to effectively monitor industry's duty to use NAMs and NGRA approaches to fulfil their information requirements

and duly apply the "last resort" requirement, and the regulator's acceptance of these approaches.

**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?

Neither agree nor disagree

- CTPA strongly supports UK REACH being at the forefront of promoting the use of Non-Animal New Approach Methodologies (NAMs) for chemical safety assessment. NAMs are cutting-edge scientific methods to chemical safety assessment that do not use animal testing. This is an opportunity for the UK to be a global leader in animal free chemical safety assessment.
- The proposal in paragraph 94 of the consultation which suggests introducing the requirement for submitting testing proposals also for information requirements in Annex VII and VIII of UK REACH may be a way for the regulator to ensure that industry indeed applies the "last resort" requirement to their testing, and would allow the regulator to better enforce the "last resort" requirement. This proposal is likely to encourage the chemicals industry to apply NAMs and Next Generation Risk Assessment (NGRA), if their testing proposals on vertebrates are being rejected where there is an alternative approach available. However, to encourage the chemicals industry to apply NAMs and NGRA approaches, regulators will need to support industry in the transition away from animal testing through a willingness to discuss proposed approaches during their development and a fast and thorough review of proposals.
- This proposal does carry a risk that testing proposals based on NAMs and NGRA approaches may be rejected by the regulator (especially if the assessor is not an expert in the field). This could lead to the opposite outcome, as currently companies can implement safety dossiers based on NAMs and NGRA directly into the registration dossier without the need for approval. This highlights the need for discussion between industry and regulators.
- Furthermore, the process for preparing/submitting testing proposals by companies and for reviewing/approving by the regulator may take a significant amount of time which can delay the placing on the market of substances. On this point, the registration dossier that will be submitted while waiting for the testing proposals to be approved may be data-poor. Therefore, if this requirement is implemented, the regulator will need to ensure it is sufficiently resourced to be able to review and assess a significantly increased number of testing proposals; also taking into account that the assessment of data from NAMs and NGRA approaches requires specific expertise in this field. Should this proposal be implemented, these points must be addressed.
- Another legislative proposal that can be considered is to expand Annex XI of UK REACH, which covers "General Rules For Adaptation Of The Standard Testing Regime Set Out In Annexes VII To X". This Annex allows the use of historical data, weight of evidence approach, qualitative or quantitative structure-activity relationship (SAR/QSAR) models, *in-vitro* methods, grouping and read across, exposure driven testing to meet the information requirements under UK REACH. All these methods are extensively used by the cosmetics industry as part NAMs and NGRA approaches. It may be worth giving more flexibility and

weight to these requirements in Annex XI, in order to encourage companies to use these approaches to fulfill their information requirements. Expanding the remit of Annex XI can also help companies put together a greater amount of data to meet the information requirements for those toxicity endpoints that do not have yet a validated alternative method. This can help the shift of mindset from validation of alternative methods to regulatory acceptance of NAMs and NGRA approaches that are already available, but have not yet been through the lengthy validation process.

- A longer-term alternative (or additional) legislative change that can be introduced in UK REACH is to extend the information requirements to include validated NAMs and non-animal approaches (including NGRA), as well as reinforce the "last resort" requirement within the Annexes covering the information requirements. However, as science in this area continues to develop, it is important that such changes are future-proofed to ensure that suitable future methods are automatically incorporated. This suggestion is applicable to Annexes VII, VIII, IX and X. This proposal would also improve efficiency for the Agency, as it may not receive as many proposals for animal testing that could be rejected and reduce the "back and forth" between the applicant and the Agency.
- Another suggestion is to introduce within UK REACH a dynamic link ensuring that future validated or accepted NAM and NGRA approaches are accepted within the UK REACH framework.
- As per Articles 13 and 25 of UK REACH, companies do have the legal obligation to fulfil the information requirements "whenever possible by means other than vertebrate animal tests, through the use of alternative methods" and to "testing on vertebrate animals only as a last resort". However, as these are legal requirements, it is important that the regulator enforces them. We would therefore support robust enforcement of the 'last resort' requirement for conducting any animal testing that is currently in the text of UK REACH. Whilst the legislative proposal would support this, we have outlined in previous points why such proposal may be challenging in practice. We would recommend setting clear processes to determine the absence of suitable NAM/NGRA approaches and a mechanism to appeal regulatory requests for animal testing. The process should ensure industry and regulators apply the 'last resort' requirement. This outcome can be achieved through a policy statement and/or guidance which is complementary to existing regulatory frameworks will support the use and regulatory acceptance of these approaches.

29.To what extent do you agree that the non-legislative approach (paragraph 97) will reduce unnecessary testing on vertebrate animals?

Strongly agree

- CTPA supports the publication of official guidance on NAM/NGRA approaches for addressing certain types of safety decisions. Guidance which is complementary to existing regulatory frameworks will support the use and regulatory acceptance of these approaches without the immediate requirement to amend legislation. Health Canada's approach of publishing Science Approach Documents (SciAD) is a clear example on how the regulator can assist with confidence-building for regulatory use over time.
- The guidance should also clearly outline which existing test methods have a validated alternative non-animal method to raise awareness and encourage application. For those

toxicity endpoints for which there isn't yet a validated alternative method, the guidance should outline which non-animal approaches (such as NGRA or others) can be applied to reach a safety outcome – even though these approaches may not yet be validated by a body (such as the OECD), they may be scientifically valid and their use should be encouraged, together with promoting open dialogue between the registrant and the regulator to collaboratively evaluate and accept the data submitted.

- Finally, the guidance should offer a clear interpretation of the "last resort" requirement, how it should be applied by industry and the regulator, in practice.
- However, guidance alone does not have the same weight as legislation. If the non-legislative approach alone is implemented following this consultation, incorporating NAMs and NGRA approaches into UK REACH should still be considered in the near future.

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?

Yes

- CTPA would like to highlight that rather than the development of new methods, this opportunity to introduce NAMs/NGRA into UK REACH should focus on the acceptance and uptake/use of these alternative approaches. This is the main challenge that industry is currently facing.
- The suggested proposals are very likely to promote the use and uptake of NAMs/NGRA in registration dossier and safety decisions. Please refer to the feedback and other suggestions in the answers to questions 28 and 29.
- However, acceptance of the alternative methods for safety decisions should also be a key focus of the outcome of this consultation. In order to promote the acceptance of NAMs and NGRA approaches, especially for those toxicity endpoints for which there isn't a validated alternative yet, we suggest creating a forum or a task force to increase the implementation of using NAM/NGRA approaches to fulfil regulatory requirements, and increasing the acceptance by the regulator, by providing an opportunity for both parties to discuss the proposed approach prior to testing and data submission.
- Another suggestion on this point could be to launch regulator-led demonstrator projects designed and operated by a cross-functional group including regulatory scientists, industry safety scientists, academics and other stakeholders who will work together to develop common approaches, and build confidence in moving through the process from regulatory question, to data generation, to safety decision-making.

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?

Yes

- In addition to the suggestions shared in the answers to questions 28, 29 and 30, we add the below proposals for consideration.

- Establish partnerships between regulators and other safety scientist stakeholders, to develop exposure modelling and assessment case studies.
- Enable cross-sector acceptance of data to remove any requirement to repeat animal testing for a different regulatory or sector purpose.
- Empower and support the existing UK Government scientific advisory committee structure, working with NC3Rs, to act as change enablers for the development and uptake of NAMs.

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.

- Our concerns are raised in the previous questions and Defra also took these into account in the IA.
- It is important to highlight that there is a ban for the Home Office to issue licenses for animal testing for chemicals exclusively intended to be used as cosmetic ingredients under UK REACH. This was issued in May 2023 to address the regulatory dilemma raised by the animal testing ban under the UK Cosmetics Regulation and the information requirements under UK REACH.
- Therefore, it is imperative that Defra implements one of the proposals on this matter, also to allow cosmetic ingredients suppliers to meet the UK REACH information requirements, in a situation where they wouldn't be issued a license for any other type of testing.
- A consideration should be made for NAMs and NGRA requirements to be compatible with EU trade.

**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?

- The additional requirements for companies to provide uses and exposure information under UK REACH could be a deterrent for companies to enter the GB market. However, the additional uses and exposure requirements reflect use descriptors that should already be used by industry under EU REACH – so this aspect should be made very clear so that companies understand what the additional requirements are and realise that these are (or should be) already used.
- As far as we understand, the ATRm would not prevent the submission of an EU dossier under UK REACH if a company prefers to do so. However, the registrant would need to integrate the dossier with the additional uses and exposure information if these are not already up to the standard required under UK REACH.
- Due consideration must be given to the interaction for companies operating across the whole of the UK, including Northern Ireland and the need to ensure that companies are able to benefit from as much compatibility as possible.

- To minimise any risk of impact to trade in the future, we would encourage the UK regulators to seek further cooperation with the EU authorities for chemicals, as stipulated under Annex VI on chemicals of the TCA.
- Further, as many countries around the world implement their own approaches to chemical management, due cooperation with authorities outside of the EU may also prove valuable to ensure there is no creation of artificial barriers. This could be through formal mechanisms such as Free Trade Agreements and bilateral cooperation agreements, or informal, such as providing opportunities for companies based outside of the UK to engage in education and training around the new framework and its operation.
- Dedicated SME support should be considered in the implementation of the new model.

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?

- It may be challenging if the Annex VII and VIII requirements also need submission of testing proposals, as these can delay placing a chemical on the market and can be quite an admin burden for both companies and the HSE. The points raised in question 28 apply here too.
- Removing a consultation step from the restriction process, or having an informal/non-transparent mode of submitting feedback to the RA and SEA, may not allow overseas companies/regulators/stakeholders to input as they may not be aware of the informal way to submit additional feedback. This point further supports the need for a transparent process and second consultation step, significantly shorter than the EU second consultation.

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.

- CTPA agrees that the ATRm could facilitate trade, because it is a simpler process. However, the above reflections on the additional uses and exposures requirements are still relevant.