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**Via email:** [ATRmConsultation@defra.gov.uk](mailto:ATRmConsultation@defra.gov.uk)

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## **Fuels Industry UK response to consultation on UK REACH**

Fuels Industry UK represents the eight main oil refining and marketing companies operating in the UK. The Fuels Industry UK member companies – bp, Essar, Esso Petroleum, Petroineos, Phillips 66, Prax Refining, Shell and Valero – are together responsible for the sourcing and supply of product meeting over 85% of UK inland demand, accounting for a third of total primary UK energy<sup>1</sup>.

As reflected in our responses to questions posed in the consultation document, Fuels Industry UK has a number of concerns with the proposals set out in the consultation:

- The assumption that businesses will be able to retrieve and submit the required hazard information from publicly available sources (including the ECHA website) without infringement of copyright and other intellectual property rights.
- Key information required for the second stage of registration such as PBT assessment conclusions and DNELs/PNECs are derived from proprietary studies. If an exposure and risk assessment is triggered, the fate hazard data required is also

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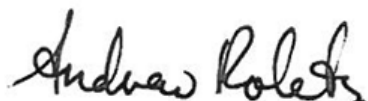
<sup>1</sup> [DESNZ Digest of UK Energy Statistics \(DUKES\) 2023](#).

derived from proprietary studies, along with the study summaries and robust study summaries. In practice, for the majority of petroleum substances (of which there are around 150 registered in UK REACH and EU REACH) the relevant studies have largely been carried out by a range of companies and consultants located outside the UK. This will require negotiation of access to data by the Substance Group or individual registrants – the cost of securing data access has not been determined.

- The requirement to provide detailed, Great Britain-specific use and exposure information goes far beyond the use category and brief general description of identified uses under EU REACH and as previously required under UK REACH. As such much of this information is not held by registrants, Fuels Industry UK believe this would take considerable resources to obtain and compile, with risks that the deadlines for transitional registrations to provide full registration data are not met for the higher tonnage bands.

Fuels Industry UK welcomes the opportunity to respond to the consultation – our responses to the questions posed are given in Attachment 1.

Yours faithfully,



Dr Andrew Roberts

**Director – Special Projects**

Cc	Emily Reves	Department for Energy Security and Net Zero
	Michael Duggan	Department for Energy Security and Net Zero
	Simon Stoddart	Department for Energy Security and Net Zero
	Emilio Marin	Department for Energy Security and Net Zero

## **Attachment 1**

### **Fuels Industry UK response to consultation on UK REACH**

#### **Part one: standard consultation questions**

Question 1. Would you like your response to be confidential?

No

Question 2. What is your name?

Andrew Roberts

Question 3. What is your email address?

[andy.roberts@fuelsindustryuk.org](mailto:andy.roberts@fuelsindustryuk.org)

Question 4. Are you responding as an individual or on behalf of an organisation?

Organisation

Question 5. What type of organisation are you responding on behalf of?

Industry association

Question 6. If you are responding on behalf of an organisation, what is the name of the organisation?

Fuels Industry UK Ltd.

Question 7. For organisations that have legal responsibilities as a result of UK REACH, what is your role?

Not applicable

#### **Part two: ATRm policy proposals and consultation questions**

##### **Hazard information requirements**

Question 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?

Agree. The submission of hazard conclusions, hazard classifications and labelling information should be sufficient to enable hazard assessment and risk management – it is considered unlikely that assessment of detailed hazard data for UK REACH would lead to different hazard conclusions to those found under EU REACH.

The removal of the automatic requirement to provide study summaries and robust study summaries under Article 10(a) (vi) and (vii) for full registration under the UK REACH transitional arrangements is a welcome and pragmatic approach. In general, UK registrants of petroleum substances no longer have access or rights of access to the supporting hazard data used to compile study summaries and robust study summaries.

There is also no guarantee that access can be secured at reasonable cost through negotiation with the data owners.

For petroleum substances (of which there are around 150 registered in UK REACH and EU REACH) the relevant studies have largely been carried out by a range of companies and consultants located outside the UK. In the absence of a well-established UK Substance Group, identification of the data owners and data access is likely to take considerable resources over an extended time period. (See also response to Questions 17 and 10).

Question 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?

Fuels Industry UK supports the view that the UK REACH 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, as the hazard assessment identified under the hazard conclusions, hazard classifications and labelling information should be the same as under EU REACH. Prioritisation of regulatory actions should therefore also be similar to that adopted under EU REACH.

Question 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.

Fuels Industry UK and its member companies are unable to comment on the extent to which the revised hazard data requirements will reduce costs to businesses, as these costs have not yet been quantified for petroleum substances.

Although Fuels Industry UK recognise the potential for cost savings, little information has been provided in the Impact Assessment on how these have been estimated and we have concerns regarding a number of assumptions that have been made in the development of the ATRm:

- The assumption that businesses will be able to retrieve and submit the required hazard information from publicly available sources without infringement of copyright and other intellectual property rights.
- Key information required for the second stage of registration such as PBT assessment conclusions and DNELs/PNECs are derived from proprietary studies. If an exposure and risk assessment is triggered, the fate hazard data required is also derived from proprietary studies, along with the study summaries and robust study summaries.
- The apparent assumption that use of information obtained from the ECHA website for the purposes of UK REACH registration will not breach the terms and conditions for its use, in particular, intellectual property rights held by ECHA and third parties<sup>2</sup>.

Despite the above concerns and the likelihood that registrants will need to negotiate access to the required data and information for the majority of petroleum substances, we believe the costs associated with UK REACH registration and setting up a Substance Group

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<sup>2</sup> [ECHA Legal Notice](#), Section 5.

would be reduced significantly below those incurred in setting up and operation of Concawe's activities as the SIEF for petroleum substances under EU REACH, including development of risk assessment methodologies<sup>3</sup>. Individual registrants licensing costs are also likely to be reduced if letters of access excluding detailed hazard data are available at reduced cost, but this remains uncertain.

### **Use and exposure information requirements**

Question 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?

Strongly disagree. Fuels Industry UK strongly believes that placing a requirement on manufacturers and suppliers to provide more detailed Great-Britain specific use and exposure information will introduce an onerous requirement that will be impossible to meet. For companies importing for subsequent sale in the UK or for Only Representatives (ORs) of non-UK companies, obtaining the level of detail required may be challenging and a more pragmatic approach will be required. (See also response to Questions 17 and 18).

UK Inland demand for petroleum products amounted to just over 59.5mt in 2022<sup>4</sup>, covering around 150 registered substances but the number of registrations and downstream users is not known. The majority of petroleum substances are classified as being of unknown or variable composition, complex reaction products or of biological materials (UVCBs). A significant proportion of this demand was for consumer products such as petrol and diesel, with distributors also playing an important role in the supply of key products to the end user.

With most (if not all) registered petroleum substances exceeding the 10-tonne threshold and many classified as hazardous substances, registrants would be required to provide Level 2 or Level 3 information for all substances covering thousands of industrial users and consumers.

We would therefore contend that the premise that requesting more detailed, Great Britain-specific use and exposure information will improve risk management of chemicals and the regulatory capability for the regulators is invalid for the majority of petroleum substances.

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

Strongly disagree. As advised in the response to Question 11, Fuels Industry UK believe that placing a requirement on manufacturers and suppliers to provide more detailed Great Britain-specific use and exposure information will introduce an onerous requirement that will be impossible to meet. The requirements to provide Level 2 human health and environmental information for substances meeting Article 14(4) criteria and Level 2 environmental information for "non-hazardous" for substances manufactured or imported in quantities between 1 and 10 tonnes are considered grossly disproportionate.

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<sup>3</sup> [Concawe](#) is a division of the European Fuels Manufacturers Association.

<sup>4</sup> [Digest of UK Energy Statistics \(DUKES\) Table 3.2](#), 2023.

Fuels Industry UK doubt whether any of the site related information identified under Level 2 “Environment” for “Manufacture, Formulation and Industrial Uses” and “Professional, Consumer and Service Life Uses” under Annex B is available to registrants. This is likely to render the proposals to base risk management of chemicals and regulation on more detailed, Great Britain-specific use and exposure information completely unworkable.

Question 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?

The requirement to provide detailed, Great Britain-specific use and exposure information goes far beyond the use category and brief general description of identified uses under EU REACH<sup>5</sup> and as previously required under UK REACH. As such much of this information is not held by registrants. Fuels Industry UK believe this would take considerable resources to obtain and compile – a matter of years with the current level of available resources. Consequently, there is very high risk that the deadlines for transitional registrations to provide full registration data are not met for the higher tonnage bands. (See also response to Question 12.)

Supply chains from importer or UK producer through to the end user are extended and complex where substances are used in formulated products, where detailed information is commercially confidential. Substances including petroleum substances can be placed on the market as components in hundreds of different products and supplied to hundreds or thousands of customers and end users for different uses.

Registrants will therefore face challenges in obtaining specific use information for a substance that is several steps down the supply chain and where sharing of information may be commercially sensitive (in particular for formulated products) or a user or supplier simply unwilling to provide information where they have no legal obligation to do so.

In view of these issues, we believe expectations concerning the level of detail associated with the required use and exposure information must be made more realistic and comply fully with the principles set out in the Government white paper “Smarter regulation: Delivering a regulatory environment for innovation, investment and growth”<sup>6</sup>.

Question 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.

Fuels Industry UK and its member companies are unable to comment on the extent to which the revised use and exposure data requirements will increase costs to business based on any relevant experience in collecting site-based use and exposure data at the level of detail identified. However, given the issues identified in the responses to Questions 11 to 13, we believe very significant costs would be incurred to the point that these are not justified.

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<sup>5</sup> As specified under the REACH Regulation (EC) No 1907/2006 Annex VI.

<sup>6</sup> Department for Business and Trade, “[Smarter regulation: Delivering a regulatory environment for innovation, investment and growth](#)”, May 2024.

We also note that the proposed approach on extended use and exposure information will introduce additional costs to the cost of data access, introducing new administrative burden to request, collate and interpret data from downstream supply chains. Again, the associated costs will be dependent on the level of accuracy and completeness demanded by the regulator.

In many cases, the UK REACH proposals on use and exposure data requirements go further than currently required under EU REACH. This will result in a loss of competitiveness in comparison to registrants under EU REACH and is against the principles set out in Government white paper "Smarter regulation: Delivering a regulatory environment for innovation, investment and growth"<sup>6</sup>.

### **Chemical Safety Reports (CSRs)**

Question 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<sup>7</sup>)?

Disagree. On balance, Fuels Industry UK does not 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. This premise assumes that data required for exposure assessment and risk characterisation if triggered is available from data owners, which is not necessarily the case. (See also response to Question 8.)

Question 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)?

Neither agree or disagree. Whilst Fuels Industry UK recognise the simplification that the proposed changes in information required for CSRs would bring for some substances, in practice this would be of no value for the majority of petroleum substances which fall under the Article 14(4) criteria or for most hazardous substances as identified in Annex B of the consultation document<sup>8</sup>.

Greater clarity is also necessary on whether only the information identified in Annex A of the consultation document is required in the CSAR or whether the supporting studies are also required for substances which fall under the Article 14(4) criteria or for most hazardous substances as identified in Annex B of the consultation document.

Guidance is also required on hazard endpoints and tools provided for risk assessment.

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<sup>7</sup> Classified as dangerous in accordance with GB CLP or assessed to be a PBT or vPvB.

<sup>8</sup> Those which meet the "T" criteria of PBT for high hazard classification (Annex 13 Section 1.1.3 points (b) and (c)) – covering carcinogenic category 1, mutagenic category 1 and toxic for reproduction category 1 and 2, as well as specific target organ toxicity after repeated exposure (STOT RE) category 1 and 2) and, in addition, respiratory and skin sensitisers (all categories).

## **ATRM regulator powers and duties**

Question 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?

Disagree. Fuels Industry UK does not 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, as this would assume that the supporting information and data is either held by registrants or is readily available from data owners. In practice, we believe preparation of a response to a transitional evaluation could take far longer than 3-12 months where access to data held by a number of overseas data owners must be negotiated by the registrant. (See also response to Question 8.)

Question 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?

Neither agree or disagree. Fuels Industry UK agree in principle 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 document. However, in practice, it may be some considerable time before the use and exposure information specified elsewhere is available. (See also responses to Questions 12 and 13.)

## **Substance groups, data sharing and joint data submission**

Question 19. Do you have any concerns with Substance Groups operating in the manner proposed in this consultation?

Yes. Fuels Industry UK welcomes the proposals for Substance Groups, data sharing and joint submission of data, which we have been calling for since early 2019. However, we have concerns regarding the costs associated with setting up and operation of Substance Groups where licenses for access to data must be negotiated and costs shared amongst UK registrants and the resources required to complete registrations before the deadlines for transitional registrations, in particular substances in the higher tonnage bands. (See also response to Question 10.)

To facilitate the establishment and effective operation of Substance Groups, greater clarity is required on which registrants are subject to which information requirements and Substance Group provisions in the context of registration and evaluation.

It is also unclear whether the proposed cost sharing provisions under UK REACH also cover development of use and exposure information. Although SIEFs have prepared use category and CSRs under EU REACH, this activity and any subsequent cost sharing is not covered by Articles 29 and 30 of the REACH Regulation (EC) No. 1907/2006.



Question 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?

Fuels Industry UK is not aware of any areas for improvement from the EU legislation on SIEFs which should be considered for UK REACH legislation.

Question 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.

Fuels Industry UK is currently unable to quantify the costs associated with securing licenses for access to data or the setting up and operation of a Substance Group for petroleum substances or for compiling Great Britain-specific use and exposure information. It would be helpful if Defra could publish the basis for the cost benefit analyses presented in the Impact Assessment, such that these could be validated by industry.

It is anticipated that registrants will need to rely on the services of third parties/external consultancies to collect information from the supply chain and to work with the Substance Group to include this information in the registration dossier avoiding disclosure of confidential or commercially sensitive information.

### **Part three: Improving the UK REACH restrictions process**

Question 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).

Businesses affected by the proposed restriction will review the reasons for any restriction and consider whether suitable alternatives to replace the substance exist, taking into account supply availability and sustainability impacts. Companies will start their initial assessment on the socio-economic impact of the proposed restriction and consideration of potential alternatives, the need for derogations and transition periods at the start of the consultation when the Annex 15 dossier is published. This process takes time and the six-month period allowed under the current UK REACH restrictions process is already short. The proposal to shorten this to three months may well prove to be unworkable, especially where extended supply chains are found.

Question 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?

Fuels Industry UK note that under the current UK REACH restriction process, the first consultation seeks information to allow refinement of the risk assessment (RA) supporting the proposed restriction, along with information to allow assessment of the socio-

economic impacts of the restriction. The second consultation on the final RA and draft socio-economic assessment is important, as it allows stakeholders to comment on the impacts to society if specific sector and use derogations are not agreed or if the RA or use restriction is changed from those initially proposed.

Although Fuels Industry UK understand the objective to streamline the restriction process, limiting the consultation period in line with standard policy consultation periods, the first and second consultations cover information requirements that have a different purpose to standard policy consultations and between each other. We also note that any revisions to the process should comply with the principles of transparency and engagement with businesses set out in Government white paper "Smarter regulation: Delivering a regulatory environment for innovation, investment and growth"<sup>6</sup>.

Question 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?

Information on the justifications taken to initiate the restriction, including a full insight on the Risk Management Option Analysis (RMOA) carried out, would be helpful to understand the concerns that drive any proposed restriction.

If a restriction for the same chemical has already been proposed for the EU, it would be useful to understand whether the UK REACH Authority intend to adopt the same proposal as in the EU or whether differences - minor or major - may be expected.

We would also welcome closer coordination between Defra, the environmental regulators and the UK REACH Authority on information requests related to proposed restrictions, for example, the recent development of the regulatory framework controlling poly- and per-fluoroalkyl (PFAS) and related substances. Here, the regulators have focussed on different elements of PFAS regulation, introducing duplication in requests for information, along with policy uncertainty. A more coordinated approach would have provided greater policy certainty and the opportunity to reduce replacement costs for the use of alternatives to PFAS in firefighting foams and reduce disposal costs for unused PFAS-based concentrates and PFAS-contaminated tank washings.

Question 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. If the consultations are consolidated as outlined in paragraphs 78 and 79, Fuels Industry UK believe there are risks that:

- Risk assessment does not fully consider all uses and exposure.
- The SEA is less robust and does not properly consider the steps required by industry to identify and source suitable alternatives to replace the substance subject to the restriction, disposal routes and costs or any technical constraints

involved in making the substitution (e.g. reformulation, changes in equipment, cleaning and disposal of contaminated flushing media).

There is no opportunity for businesses to seek derogations against the restriction where these have not been proposed in the consultation.

These issues could be addressed through better engagement with stakeholders during development of the restriction proposal (a 12-month period) and closer alignment with the timeline and content of EU REACH restriction proposals.

Question 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. There is insufficient information in the consultation document to form an opinion on whether the proposed change could work in practice, in particular surrounding the process that would follow the “post-consolidated” consultation period.

See also responses to Questions 24 and 25.

### **Improving the UK REACH reporting process**

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

Agree with all of the proposed changes. Fuels Industry UK supports the proposed changes to make UK Agency and DEFRA reporting more efficient, while ensuring transparency and providing advance notice of the annual work programme. This helps companies to understand priorities and anticipate additional regulatory requirements.

### **Further protections against unnecessary animal testing**

Question 28. To what extent do you agree that the legislative approach (paragraph 94) will reduce unnecessary testing on vertebrate animals?

Disagree. Fuels Industry UK and its member companies believe strongly that requirements for animal testing should be avoided and that alternative methods including read-across should be supported. However, extension of the current testing requirements to low tonnage substances (Annex VII and VIII) would not be an effective measure to avoid unnecessary animal testing under UK REACH.

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

Agree. Fuels Industry UK and its member companies believe strongly that legislated requirements for animal testing should be avoided and that alternative methods including read-across from existing studies should be supported via additional guidance on alternative methods/approaches and their reasonable application.

Question 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?

No. Neither of the approaches proposed in the consultation document would adequately promote the development of non-animal alternatives to testing. The proposals introduce additional administrative burden and detailed guidance will be required to clarify the information required in any proposal submitted to the Agency for approval.

Fuels Industry UK member companies are active in the development of non-animal alternatives to testing, both as individual companies and through Concawe, the SIEF facilitator for the majority of petroleum substances registered in EU REACH<sup>9</sup>. However, to support the development and adoption of non-animal alternatives, more flexibility is required under Annex VI to use non-validated non-animal approaches.

Question 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. The majority of hydrocarbon substances are of unknown or variable composition, complex reaction products or biological materials (UVCBs). The precise identity and composition of every constituent is most of the time unknown and the composition may vary across samples of the same substance. Petroleum substances registered under UK REACH are a sub-set of those registered in EU REACH.

The challenge in applying EU and UK REACH to hydrocarbon substances is to account for their UVCB nature. The complexity of UVCB substances, their variability and their large number of potential constituents (which can reach over a million of molecules), makes it impossible to determine the precise chemical composition to the level of each constituent for the majority of hydrocarbon substances.

For many applications, a detailed chemical composition is not necessary, because industry practice is to manufacture and market hydrocarbon substances according to physicochemical parameters specified in European and/or UK Standards. Different samples from the same process in a refinery will show some variability in detailed composition, whilst still remaining within the specifications that identify the substance.

A risk-based approach is therefore preferred to a more “data-driven” approach, which often required data generation without a link to uses and exposure.

Read-across (RA) is a commonly used alternative approach for data gap-filling. RA involves the use of relevant information from analogous “source” substances to predict the properties of the “target” substances under consideration. Relevant information requires primarily structural or compositional characterisation, as well as physical-chemical properties and biological activity profiles. In addition to reducing animal use, the proper application of RA can improve the quality of the hazard assessment by

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<sup>9</sup> Further information and examples are available in [Concawe Review Volume 31 Number 2](#), September 2022.

bringing into consideration the weight of evidence of closely related substances and reducing the time required to provide compliant information for a substance<sup>10</sup>.

Question 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.

Fuels Industry UK has no response to this question.

#### **Part four: UK REACH and Trade**

Question 33. Do you anticipate any impact on trade from the ATRm policy proposals, and if so, what do you think this impact will be?

Fuels Industry UK has no response to this question.

Question 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?

Fuels Industry UK has no response to this question.

Question 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.

Fuels Industry UK has no response to this question.

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<sup>10</sup> Further information about hydrocarbon space mapping to support gas oil read-across for human health hazard assessment can be found in [Concawe Review Volume 31 Number 2](#), September 2022.