Hazard information under Article 127B

8. Does the proposed drafting in Article 127B clearly and accurately specify the information that must be submitted for transferred GB registrations where the reduced requirements apply? Please identify any potential ambiguity, unintended consequence or drafting issue.

Key points:

- The need to cross reference between provisions is complicated for readers. Therefore, A consolidated version of the legal text should be completed with all details in the relevant parts, supported by robust and detailed guidance to help companies (especially SMEs) navigate the complicated structure of the Schedule and promote compliance. Furthermore, the wording of the SI must reflect Defra's intended requirements as closely as possible.
- The legal text should clarify how registrants should choose the relevant self-classification, when there is no harmonised classification available.
- Clarity is needed on how the DNELs, PNECs and DMELs, as well as the PBT/vPvB assessment should be carried out and presented.

Article 127B outlines the information requirements for grandfathered registrations, which would be carried out mostly by raw material manufacturers. The grandfathered registrations are called 'transferred GB registration' in the SI and their criteria are outlined in Article 127A.

CTPA's understanding of the requirements for the information to be submitted for transferred GB registrations, as per Article 127B, is as below.

Paragraph 4(a) of Article 127B outlines the information that was submitted as part of the grandfathered registrations. Further to that, all other Article 10 information requirements have to be submitted, unless paragraph 4A applies (which outlines the conditions for meeting the requirements for the ATRm – discussed in the next question).

Where 4A applies, paragraph 4C outlines the information requirements for the ATRm.

- Article 10(a)(iv) → classification and labelling;
- Article 10(a)(viii) in relation to the above → an indication that the information submitted has been reviewed by an assessor chosen by the manufacturer or importer and having appropriate experience;
- The ATRm appears to require a statement confirming that, for each hazard class or differentiations not covered by a GB MCL, the registrant's classification is consistent with the EU harmonised classification. If there is no harmonised

classification, then the statement should compare if a self-classification is consistent with the information found on the EU lead registrant dossier. If the information on classification is not consistent with the ECHA database, a reasoning for this should be given.

- **In regard to the classification and labelling, the legal text should clarify how registrants should choose the relevant EU classification, when there is no harmonised classification available.** We ask Defra to clarify in the text, or supporting guidance, how the provisions should operate in the following practical situations:
    - the EU lead registrant's classification information is not publicly available on ECHA, or is incomplete;
    - if several different classifications are published in the EU for the same substance, which classification should a GB registrant use, and how should the registrant check which classification is the most relevant?
    - if the substance identity or composition differs, how will registrants assess if the GB substance composition differs or not from the substance covered by the published results on ECHA?
    - if the EU classification changes after the GB registration submission, GB registrants may not be informed of updates to the EU lead registrants' classification. The ongoing monitoring and updates of registrations to include new classifications will pose a significant administrative burden.
    - how should new hazard classes (currently not applicable in GB) be considered, in the event where these are not also implemented under GB CLP?
- Article 10(a)(v) → guidance on safe use of the substance, as per section 5 of Annex VI of UK REACH;
- Article 10(a)(x) → where relevant, exposure information as per section 6 of Annex VI of UK REACH (substances 1-10 tonnes).
- For substances above 10 tonnes, a Chemical Safety Report shall be provided containing the below:
    - classification and labelling human health (HH);
    - DNEL values (no justification for choice of DNEL needed);
    - physchem properties;
    - classification and labelling environment (ENV);
    - PNECs;
    - sentence on fulfilment of PTB/vPvB criteria + a statement confirming that the registrant conclusion is in line with the assessment on ECHA, or if not, why;

- statement to confirm that the DNELs and PNECs used are consistent with the information on the ECHA database, or if not, why;
- where it is not possible to derive a PNEC or DNEL, explain why;
- where Article 14(4) [hazard classes] applies, include exposure assessment and risk characterisation, state of the substance, melting/freezing point, boiling point, vapour pressure, water solubility, partition coefficient o/w, ready biodegradability.

- Because the text cross-refers to several articles and paragraphs, companies must move repeatedly between provisions to identify the applicable information requirements. **A consolidated version of the legal text, supported by robust and detailed guidance, is therefore needed.** Furthermore, EU-based suppliers may wish to register transferred GB registrations via a GB-based Only Representative (OR) under the ATRm to maintain continued supply to their Downstream Users (DUs). Clear legislation and requirements would support this process and possibly reduce the impact on DUs importing from the EU. The requirements must ultimately be set out clearly and accessibly to promote compliance; if companies cannot understand them, unintentional non-compliance is more likely.
    - The wording of the SI must reflect Defra's intended requirements as closely as possible. From our discussions with the Defra team, we understand that this is not always the case. For example, the SI refers to "derived DNELs", whereas the intended meaning is "obtained DNELs". Although guidance can help clarify interpretation, it should not be relied upon to resolve differences between the wording of the SI and its intended meaning. Ultimately, it is the SI, not the guidance, that is legally binding on companies.
- Paragraph 4E is ambiguous. It refers to the Annex 1 table, which outlines the information to be submitted as part of the Chemical Safety Report (CSR) within the ATRm, but states that the table is provided solely to inform registrants and that registrants are not necessarily required to follow its steps. The current wording therefore does not clearly explain what is intended by Defra, which is to demonstrate that the Annex I on CSR requirements are amended to reflect the reduced hazard information requirements. The SI should clearly reflect this meaning, which can be further explained in guidance.
- Paragraph 4F states that one registrant (the Lead Registrant - LR) shall submit the hazard information; whereas the other registrants shall submit individually their own uses and exposure information. In regard to the submission of the CSR, it is up to the registrants to decide whether it is submitted by one registrant, or by each registrant individually. This section also provides for registrants to submit the

hazard information and related statements separately if joint submission is significantly costly, or commercially sensitive information cannot be shared, or there is disagreement with the lead registrant; a justification for this decision must be submitted.

- The requirement for DMEL information is unclear. Article 127B(4D)(a)(ii) requires information under Annex I "subsection 1.4 (human health hazard assessment identification of DNELs, excluding…)", and does not expressly refer to DMELs. However, Article 127B(4D)(b)(ii) requires a consistency statement "for each DNEL, DMEL or PNEC derived". **The reference to DMELs within the text should be clarified.**
    - *Please note the same comment for Art. 127NA* applies.
- Furthermore, it is unclear from the proposed text how registrants should perform PBT/vPvB assessments.
    - **Art. 127B(4D)(a)(vi)**: "*the first sentence of subsection 4.1 (PBT and vPvB assessment: classification),*
    - **The first sentence of section 4.1 of Annex I**: *"This part of the PBT/vPvB assessment shall entail the comparison of the available information with the criteria given in Section 1 of Annex XIII".*

  The Schedule should clearly explain the requirements, rather than referring to a part in a subsection of Annex 1. The text should clarify whether the GB registrant must carry out their own comparison against the criteria by reviewing the supporting information in the EU dossier or rely on the published EU assessment conclusion. Registrants should be able to rely on published EU assessment conclusions. If a review of all the supporting information is still required, this will result in significant administrative burden.
- No fee is payable for the submission of information under the ATRm.

9. Do the eligibility conditions in Article 127B clearly identify the circumstances in which the reduced information requirements apply? Please identify any potential ambiguity, unintended consequence or drafting issue.

CTPA understands that the eligibility conditions for the ATRm are set out in paragraph 4B. The conditions apply when the substance is a 'transferred GB registration' and is registered under EU REACH at the same or a higher tonnage band than the tonnage manufactured or imported in GB. Alternatively, they apply where the substance is manufactured or imported in GB at 1–10 tonnes per year and is registered under EU REACH as a transported isolated intermediate in quantities of 1,000 tonnes or more per year. The drafting implies that the full information requirements apply where neither of these conditions are met. Such as, if the substance is manufactured or imported in GB

at a tonnage band above that covered by the EU REACH registration, and cases where the substance is manufactured or imported in GB at 10 tonnes or more per year and the only registration under EU REACH is as a transported isolated intermediate. **This should be stated expressly rather than left implicit, as well as explained in guidance.**

It should be noted that the ECHA website only provides estimated aggregate volumes of registered substances, rather than the tonnage band at which the substance is registered. It is therefore not possible for duty holders to check the registration tonnage under EU REACH for eligibility under the ATRm.

10. Are the classification consistency requirements in Article 127B clear and operable? In particular, please identify any potential uncertainty regarding the applicable comparator, the information to be provided, or the circumstances in which an explanation must be given.

As noted in response to question 8, CTPA understands that, for each hazard class or differentiation not covered by a GB MCL, companies must submit a statement confirming whether their classification is consistent with the EU harmonised classification. Where there is no harmonised classification, the GB registrant must compare its self-classification with the information in the ECHA database, submitted by the EU Lead Registrant. If classification information is inconsistent with the ECHA database, the GB registrant should provide the reasons. **CTPA considers that this information is clear**.

However, in the case where no harmonised classification is available, clarification is needed on how registrants are to identify and apply the relevant EU classifications in practice. We ask Defra to clarify in the text, or supporting guidance, how the provisions should operate in the following practical situations:

- if the EU Lead Registrant's information is not publicly available;
- if several self-classifications are published on the EU database;
- if the EU classifications change after the GB registration;
- how should companies assess if their substance composition differs or not from the substance covered by the published results;
- how should new hazard classes (currently not applicable in GB) be considered.

11. Do the links between the reduced information requirements in Article 127B and the transitional evaluation powers in Articles 127Q to 127U read clearly and without unintended gaps? Please identify any potential drafting issue, ambiguity or unintended consequence.

The link with Article 127Q is in section 4A of Article 127B. The way we understand the current wording is that the reduced information is to be submitted, unless Article 127Q is triggered.

CTPA has not identified any drafting issues or ambiguity here.

Chemical safety assessments and chemical safety reports

12. Does the proposed drafting clearly and accurately capture the chemical safety information and assessment outcomes that registrants must provide under Articles 127B(4C) to (4E) and 127NA(5) to (7)? In particular, please identify and explain any potential inconsistency or omission.

Key points:

- To improve comprehension of the requirements and therefore increase compliance, the requirements should be listed clearly alongside references to the relevant articles and paragraphs in the legal text and should also be set out clearly in the supporting guidance.
- Publicly available Information published on the ECHA website may be subject to intellectual property rights, as indicated in the legal notice on ECHAChem.
- Intellectual Property challenges may be encountered by registrants (especially those who are former DUs), because some LR may not accept their PNEC or DNEL values being used as part of a regulatory dossier in GB.

It is CTPA's understanding that the CSR is required for substances manufactured or imported above 10 tonnes/year; the information to be submitted is as per paragraph 4D of Article 127B and as outlined below

- classification and labelling (Human Health);
- DNEL values (no justification for choice of DNEL needed);
- physchem properties;
- classification and labelling (Environmental);
- PNECs;

- sentence on fulfilment of PBT/vPvB criteria and a statement confirming that the registrant conclusion is in line with the assessment on ECHA or if not, why;
- statement to confirm that the DNELs and PNECs used are consistent with ECHA or if not, why;
- where it is not possible to derive a PNEC or DNEL, explain why;
- where Art14(4) [hazard classes] applies, include exposure assessment and risk characterisation, state of the substance, melting/freezing point, boiling point, vapour pressure, water solubility, partition coefficient o/w, ready biodegradability.

As previously mentioned, the Annex 1 table, which outlines the information to be submitted as part of the Chemical Safety Report (CSR) within the ATRm, states that the table is provided solely to inform registrants and that registrants are not necessarily required to follow its steps. The current wording therefore does not clearly explain what is intended by Defra, which is to demonstrate that the Annex I on CSR requirements are amended to reflect the reduced hazard information requirements. The SI should clearly reflect this meaning, which can be further explained in guidance.

The legal text requires readers to move repeatedly between provisions because the information requirements are expressed through references to specific articles and paragraphs, rather than clearly stating the information to be submitted. This approach is time-consuming and can cause considerable confusion, particularly for EU-based suppliers that have grandfathered their registrations and may not be fully familiar with the ATRm. **The requirements should therefore be listed clearly alongside references to the relevant articles and paragraphs in the legal text and should also be set out clearly in the supporting guidance. Clear legal drafting will be essential to achieving compliance with the UK REACH provisions.**

The same feedback applies to Article 127NA paragraphs (5) to (7).

Publicly available information published on the ECHA website may be subject to intellectual property rights, as indicated in the legal notice on ECHAChem. Therefore, IP challenges may be encountered by registrants (especially those who are former DUs) because some LR may not accept their PNEC or DNEL values being used as part of a regulatory dossier in GB. If this situation is encountered, it should be made clear in the legal text or guidance that this is an acceptable justification for the GB registrant to not include this information in its submission. The information is still available for the GB Agency to access directly on the ECHA website.

13. Do the eligibility conditions in Article 127NA clearly identify the circumstances in which the reduced information requirements apply? In particular, please explain any potential unintended effect or other comments.

The conditions of Article 127NA apply to New Registrations of Existing Substances (NRES), and former DUs who became importers under UK REACH and submitted a Downstream User Import Notification (DUIN).

According to the draft legal text, the conditions apply to

- a GB company who starts or restarts manufacturing or importing a substance after EU Exit day, and where such substance is already registered under EU REACH and the registration was in place before EU Exit day; or
- a GB DU or distributor who was a GB DU or distributor under EU REACH before EU Exit day, and who is importing substances under UK REACH.

We understand that the former DUs' and the distributors' roles have been blended to refer to "P" within the legal text. It can be confusing to create additional roles (in this case P) with the same meaning and role as the GB company that falls under the provisions of Article 127NA. **It is important that the legal text is clear as to who "P" is, without too much legal jargon. This will ensure that companies understand what their role and obligations are.**

NRES and registrations following a DUIN

14. Does the proposed drafting of Article 127NA clearly and accurately define the registrants and registrations within scope and the registration information required? Please identify any potential ambiguity, unintended consequence or drafting issue.

Key points:

- CTPA can foresee a scenario where a former DU may import a substance into GB at a higher tonnage than is covered under the EU registration; for example, a retailer importing cosmetic products from several brands. Such a DU would not be able to access or generate the information to complete a full registration, so the legal text or guidance should exempt former DUs from the full registration requirement, regardless of import tonnage.
- DUs often do not have access to full composition information of a mixture or monomer information from their suppliers due to confidentiality. Many DUs also import finished products, which are exempt from SDS requirements. Therefore, they may have an SDS on a chemical mixture or parts of the finished product, but non-hazardous mixtures may not be accompanied by an SDS. A provision should

be made to address this challenge, for example: "*Downstream Users importing raw materials as mixtures or polymers who do not have access to information on the individual substances or monomers may submit a notification to the Agency that includes the identity of "P", the identity of the mixture or polymer, the SDS (where available) and information on their own uses*.". Further details of this option could be provided in guidance for DUs.

- Alternatively, permitting information to be submitted "*to the extent that it is available to Downstream Users*", as is currently required for DUINs, would also significantly reduce the challenges that the ATRm presents to Downstream Users.
- It should be made clear in the legal text or guidance that, if the EU registrant does not permit PNECs or DNELs to be used in regulatory submissions by GB registrants, this is an acceptable justification for the GB registrant to not include this information in its submission.
- Creating the CSR as is currently required under EU REACH will be very challenging for DUs. Therefore, we suggest that the CSR requirements within Article 127NA are removed or simplified as much as possible.
- A consolidated version of the legal text, supported by guidance, is needed to ensure ease of reference especially for new registrants, and increase compliance.
- An Article 26 inquiry requires substance identity information that may not be available to DUs, particularly for complex mixtures. We therefore request to add a provision for all potential registrants with a DUIN to get an automatic entry request into the substance group, to facilitate the registration process. The DUIN submitter can decide whether to join the joint submission group depending on their circumstances compared to the time where the DUIN was submitted.
- The actor directly supplying GB should be able to appoint the OR, reducing the need for GB DUs and SMEs to identify the original manufacturer or formulator.
- There is no exemption for payable fees for the NRES and DUIN registrations under the ATRm. Considering that the majority of companies fulfilling these obligations are former DUs and SMEs, we request for the fee to be removed in this instance too.

CTPA's understanding of the requirements for the information to be submitted for NRES or registrations following a DUIN, as per Article 127NA, is as below.

The Article 10 information requirements must be submitted unless the conditions in paragraph 4 apply; these set out when the ATRm requirements may be used. The conditions are that the substance is registered under EU REACH at the same or a higher tonnage band than the tonnage imported into GB. Alternatively, they apply where the substance is manufactured or imported at 1–10 tonnes per year and is registered under

EU REACH as a transported isolated intermediate in quantities of 1,000 tonnes or more per year.

The drafting implies that the full information requirements apply where neither of these conditions are met. Such as, if the substance is manufactured or imported in GB at a tonnage band above that covered by the EU REACH registration, and cases where the substance is manufactured or imported in GB at 10 tonnes or more per year and the only registration under EU REACH is as a transported isolated intermediate. **This should be stated expressly rather than left implicit, as well as explained in guidance.**

It should be noted that the ECHA website only provides estimated aggregate volumes of registered substances, rather than the tonnage band at which the substance is registered. There is therefore uncertainty around how duty holders can check the registration tonnage under EU REACH for eligibility of the ATRm.

It would be virtually impossible for former DUs to meet the full information requirements where a substance is imported into GB at a higher tonnage than under the EU registration. Although this scenario is unlikely because the GB market is smaller than the EU market, it is possible; for example, a retailer importing cosmetic products from several brands could have a high aggregate import tonnage for each individual ingredient in the finished products. CTPA has previously explained to Defra that former DUs do not have access to the full information requirements because the underlying information is the intellectual property of the data owner. DUs may also lack the financial resources and expertise needed to prepare a REACH dossier containing the full information requirements. They do not own complete substance data packages, which are the property of raw material suppliers. DUs would therefore be unable to obtain and submit the data promptly to access the GB chemicals market without risking infringement of legal terms and intellectual property rights, and they would be unable to invest in generating new data. The associated costs to purchase access to the data required under the ATRm would be significant to companies and prohibitive for SMEs. **The conditions therefore need amending, so that the ATRm and its reduced information requirements apply to former DUs regardless of import tonnage.**

A further challenge experienced by former DUs is that most raw materials used by cosmetic DUs are mixtures, and suppliers routinely do not fully disclose some components or include them in the SDS because of confidentiality. A similar issue arises for polymers. Although polymers are exempt from UK REACH registration requirements, their monomers are not. DUs import the final polymer into the GB market and are likely to find it extremely difficult to obtain information about the monomers from which it is formed. Many DUs also import finished products, and they would have an SDS on a chemical mixture, rather than the individual components of the product; furthermore, non-hazardous substance information is not required in an SDS. In this scenario, the DUs

would not know what individual substances make up the product, unless access to this information is negotiated with the brand owner, subject to disclosure of confidential information and IP rights. In these circumstances, DUs will be unable to meet the information requirements because they do not have access to information on the individual substances in a mixture or the monomers forming a polymer. **Provisions should therefore address this challenge, for example: "*Former DUs importing raw materials as mixtures or polymers who do not have access to information on the individual substances or monomers may submit a notification to the Agency that includes the identity of "P", the identity of the mixture or polymer, the SDS (where available) and information on their own uses*.". Further details of this option could be provided in guidance for DUs.**

Another way to support DUs in complying with the requirements and addressing the principal challenges would be to require information to be submitted "*to the extent that it is available to them*", as is currently required for DUINs. Information submitted on this basis would still give the HSE visibility of the substances placed on the GB market, their tonnage, the relevant SDS information and their uses. This would enable the HSE to identify and prioritise concerns as necessary. Receiving this information would provide greater protection for human health and the environment than receiving no information because companies are unable to comply with requirements that are impossible for them to meet.

Paragraph 5 outlines the information requirements for the ATRm.

- Article 10(a)(iv) → classification and labelling;
- Article 10(a)(viii) in relation to the above → an indication that the information submitted has been reviewed by an assessor chosen by the manufacturer or importer and having appropriate experience.
- The ATRm appears to require a statement confirming that, for each hazard class or differentiations not covered by a GB MCL, the registrant's classification is consistent with the EU harmonised classification. If there is no harmonised classification, then the statement should compare if a self-classification is consistent with the information found on the EU lead registrant dossier. If the information on classification is not consistent with the ECHA database, a reasoning for this should be given. The only challenge related to this for former DUs who have registration obligations because they become importers, is that suppliers are likely to provide an EU compliant SDS, with EU harmonised classification and labelling; additional burden may impact companies to check for any GB MCL vs EU classifications.
- Article 10(a)(v) → guidance on safe use of the substance, as per section 5 of Annex VI of UK REACH;

- Article 10(a)(x) → where relevant, exposure information as per section 6 of Annex VI of UK REACH (substances 1-10 tonnes).
- For substances above 10 tonnes, a Chemical Safety Report shall be provided containing the below:
    - classification and labelling (Human Health);
    - DNEL values (no justification for choice of DNEL needed);
    - physchem properties;
    - classification and labelling (Environmental);
    - PNECs;
    - sentence on fulfilment of PTB/vPvB criteria + a statement confirming that the registrant conclusion is in line with the assessment on ECHA, or if not, why;
    - statement to confirm that the DNELs and PNECs used are consistent with the information on the ECHA database, or if not, why;
    - where it is not possible to derive a PNEC or DNEL, explain why;
    - where Art14(4) [hazard classes] applies, include exposure assessment and risk characterisation, state of the substance, melting/freezing point, boiling point, vapour pressure, water solubility, partition coefficient o/w, ready biodegradability.
- CTPA has previously raised significant challenges for former DUs in compiling the CSR; this becomes more relevant especially when a substance group is solely formed by DUs. In particular, we would like to reiterate the two points below.
    - The PNECs and the DNELs may be available in the SDS, or in online databases. However, these are values generated through studies owned by companies. It is not yet clear if it is considered infringement of IPR to submit these values as part of a registration dossier to gain access to the GB market. Furthermore, not all PNECs or DNELs might be easily available, and not all companies have the expertise to derive these values. **It should be made clear in the legal text or guidance that if the EU registrant does not permit PNECs or DNELs to be used in regulatory submissions by GB registrants, this is an acceptable justification for the GB registrant to not include this information in its submission.**
    - Creating the CSR as is currently required under EU REACH (and as required under the ATRm) will be challenging for DUs, who have never had to do such documentation - this is both because DUs may not have the technical expertise, but also because they do not have access to all the information needed to compile the CSR as is currently required (due to the issues around access and use of information as outlined above). Therefore, we

suggest that the **CSR requirements within Article 127NA are removed or kept as simple as possible.**

- Because the text cross-refers to several articles and paragraphs, companies must move repeatedly between provisions to identify the applicable information requirements. **A consolidated version of the legal text, supported by guidance, is therefore needed.** This is vital for DUs who never had to deal with REACH registrations before and have no knowledge or experience on how to achieve this. In order to promote compliance with the requirements, these have to be clearly and easily outlined; if companies cannot understand the requirements, there is more likely to be unintentional non-compliance.
- The text in paragraph 7 refers to the Annex 1 table, which outlines the information to be submitted as part of the Chemical Safety Report (CSR) within the ATRm, but states that the table is provided solely to inform registrants and that registrants are not necessarily required to follow its steps. The current wording therefore does not clearly explain what is intended by Defra, which is to demonstrate that the Annex I on CSR requirements are amended to reflect the reduced hazard information requirements. The SI should clearly reflect this meaning, which can be further explained in guidance.
- Paragraph 8 states that one registrant (the lead registrant) shall submit the hazard information; whereas the other registrants shall submit individually their own uses and exposure information. In regard to the submission of the CSR, it is up to the registrants to decide whether it is submitted by one registrant, or by each registrant individually. This section also provides for registrants to submit the hazard information and related statements separately if joint submission is significantly costly, or commercially sensitive information cannot be shared, or there is disagreement with the lead registrant; a justification for this decision must be submitted.
- There is no exemption for payable fees for the NRES and DUIN registrations under the ATRm. Considering that the majority of companies fulfilling these obligations are former DUs and SMEs, we request for the fee to be removed in this instance too.

There are a few additional challenges that we would like to raise specifically for former DUs importing substances on their own or within mixtures in GB.

- It is CTPA understanding that an Article 26 inquiry will be the first stage of the formation of substance groups. Submitting an Inquiry requires substance identity information that may not be available to DUs, particularly for complex mixtures. DUs will not be able to submit this information to enter the joint submission groups, if they cannot determine which substance needs to be

registered, because **DUs do not have the substance identity data to allow them to submit an article 26 Inquiry or access to the pure substance to allow them to conduct testing to generate the data**. This would also mean DUs cannot register their substances, even if they have the remaining data requirements from the SDS, as they do not have the analytical data required to complete an Article 26 inquiry.

  - Therefore, a solution could be to **add a provision for all potential registrants with a DUIN to get an automatic entry request into the substance group, to facilitate the registration process.** The DUIN submitter can decide whether to join the joint submission group depending on their circumstances compared to the time where the DUIN was submitted. If an Inquiry is needed to join the substance group, then this significantly delays progress for most potential registrants. This could force registrants with 'transferred registrations' having to become lead registrant by default, just because they are already in the substance group disproportionally impacting some companies.

- In an ideal scenario, the EU registrant may choose to appoint a GB-based Only Representative (OR) to cover for the UK REACH registrations for their GB-based DUs. However, there is no guarantee that this will happen and members have already obtained feedback from their suppliers about this: due to the small GB market viability, the EU supplier will not complete the UK REACH registration for their DUs; sharing of relevant information for the DU to complete the registration is also not a guarantee. Assuming that EU-based suppliers will register under UK REACH via an OR is not a reliable solution because suppliers are not obliged to do so; it is a commercial decision for each individual business.
- Another point in relation to OR: the current definition of OR under UK REACH does not reflect common supply chain arrangements in which an EU supplier supplies finished products to GB. Currently, only the manufacturer or the formulator of a substance or mixture can appoint an OR; however, within the current supply chain, it may be one or more EU distributors, or a cosmetic manufacturer (rather than a substance manufacturer) supplying substances or products to a GB importer. **Therefore, amending the OR definition and who can appoint an OR under UK REACH can support former DUs and SMEs. A new definition of OR can allow the actor directly supplying GB to appoint the OR, reducing the need for GB DUs and SMEs to identify the original manufacturer or formulator.**

- The current OR definition under UK REACH is "*A natural or legal person established outside **[F52**Great Britain**]** who manufactures a substance on its own, in **[F2**mixtures**]** or in articles, formulates a **[F2**mixture**]** or produces an article that is imported into **[F52**Great Britain**]** may by mutual agreement appoint a natural or legal person established in **[F52**Great Britain**]** to fulfil, as his only representative, the obligations on importers under this Title*.". This can be amended to "*A natural or legal person established outside **[F52**Great Britain**]** who manufactures a substance on its own, in **[F2**mixtures**]** or in articles, formulates a **[F2**mixture**]** or produces an article, supplies a substance on its own, in mixtures or in articles that is imported into **[F52**Great Britain**]** may by mutual agreement appoint a natural or legal person established in **[F52**Great Britain**]** to fulfil, as his only representative, the obligations on importers under this Title*."

On-site and transported isolated intermediates

16. Does the proposed drafting of Articles 127L, 127M and 127NB clearly and accurately specify the information required for existing and new on-site and transported isolated intermediate registrations? Please identify any potential ambiguity, unintended consequence or drafting issue

CTPA does not provide feedback on this question, as isolated intermediate registrations do not affect our members.

17. Does the condition determining whether Article 18(3) information is required for transported isolated intermediates read clearly? Please identify any potential ambiguity, unintended consequence or drafting issue

CTPA does not provide feedback on this question, as isolated intermediate registrations do not affect our members.

Transitional evaluation powers

18. Does the proposed drafting of Articles 127Q to 127U provide a clear and workable process for requesting, deciding on, submitting and reviewing additional information where the reduced dataset is insufficient in line with the policy intention? Please identify any potential drafting issue, ambiguity or unintended consequence.

Key point:

- The phrase "*whether or not that information has been submitted to ECHA under EU REACH*" is of significant concern to the cosmetics industry. New data generation would be highly challenging for DUs joint submission groups and risks requiring new animal testing, incompatible with the UK Cosmetics Regulation ban and inconsistent with the UK Government's strategy to phase out animal testing. This provision should be removed.

CTPA understands Article 127Q to provide that, in a transitional evaluation, the HSE may require the full information specified under Articles 10 and 12 for non-intermediate substances (intermediate substances do not affect our members, therefore we do not refer to this in our response). The provisions state that the HSE may request study summaries of information derived from the application of Annexes VII to XI; robust study summaries of information derived from the application of Annexes VII to XI where required under Annex I; and testing proposals listed in Annexes IX and X. In that case, the registrant would also be required to conduct the full chemical safety assessment and compile the chemical safety report in accordance with Annex I. It is unclear whether this is an additional requirement that applies when the HSE requests specific information, as distinct from a request for the full information requirements, or whether it is additional to a request for the full information under Articles 10 and 12. Article 127R(2) may clarify this point. **Depending on their role in the supply chain, companies may find it difficult to obtain study summaries and robust study summaries because these are the intellectual property of EU registrants. This difficulty would be particularly significant where a joint submission group is composed solely of former DUs.**

The phrase "*whether or not that information has been submitted to ECHA under EU REACH*" is of significant concern to the cosmetics industry. If information has not been submitted to ECHA under EU REACH, it will not be available for GB registrants to provide unless new data are generated to meet the information requirements. This could impose substantial costs on companies, particularly where a joint submission group consists solely of former DUs importing finished cosmetic products. Furthermore, the process in the case where no data was submitted to ECHA has to be clarified, in regard to whether companies need to submit a testing proposal and follow the typical registration process. Finally, **the provision also creates a risk that new data generation**

could lead to unnecessary animal testing. This is highly undesirable for chemicals also used as cosmetic ingredients, and not possible for substances only used in cosmetics, because of the animal-testing ban under the UK Cosmetics Regulation and would be inconsistent with the UK Government's strategy to phase out animal testing. This provision should therefore be removed because it is not practicably achievable.

19. Do the proposed prioritisation criteria for transitional evaluation dossiers in Article 127Q read clearly? Please identify any potential drafting issue, ambiguity or unintended consequence.

Key points:

- Separate submission should be removed as a prioritisation criterion for transitional evaluation.
- Alternatively, separate submission could be used as a prioritisation criterion only where the reason given is disagreement between registrants; in that case, the HSE could review the hazard information submitted and assist the registrants in reaching agreement.
- Enough time must be built into the process of formalising a joint submission group during transitional evaluation and 30 days is insufficient time to respond to requests.

CTPA understands that the HSE may prioritise a dossier for additional information where classification and labelling information has been submitted separately by registrants, or where the dossier meets at least one of the substance-evaluation criteria in Article 44(1): hazard information, including specific hazards of concern; exposure information; or tonnage. **CTPA is concerned that using separate submission as a prioritisation criterion conflicts with the provisions allowing registrants to submit information separately to minimise costs under Articles 127B 4F(1) and 127NA (8)(1).** This concern would become particularly relevant if the proposal were adopted under which each registrant could submit the information requirements individually and the substance group would be formed only in the event of a transitional evaluation. Registrants may submit information separately to minimise costs, protect intellectual property or record disagreement with the lead registrant. It would be unfair and not scientifically robust to prioritise their dossiers for choosing an expressly permitted option on any of those grounds. **The prioritisation criteria should therefore remain those currently specified in Article 44(1), as these provide the most relevant basis for the HSE to prioritise substance review for the protection of human health or the environment.**

Alternatively, separate submission could be used as a prioritisation criterion only where the reason given is disagreement between registrants; in that case, the HSE could review the hazard information submitted and assist the registrants in reaching agreement.

20. Do the provisions in Article 127R governing draft transitional evaluation decisions provide a clear and workable process for registrants? Please explain any potential drafting concerns or other comments.

CTPA understands that, if the HSE requests additional information, it will notify the registrant, who will then have 30 days from notification to comment on the request. The method of notification is not clear. **The response period should be considered in relation to the notification process; for example, if notification is sent by post, 30 days may not give the registrant sufficient time to prepare and submit comments. If the response period starts from the receipt of the letter by the registrant, then this should be made clear.**

Furthermore, it is important to consider that during a transitional evaluation, a formalised joint submission group will need to be set up to cover cost sharing, legal contracts specifically for this instance. Therefore, it is vital that enough time is built into this process to allow registrants to set up and formalise the legal agreements in addition to the time needed to address the evaluation questions. This underlines why 30 days will not be sufficient time to respond to requests.

In the event where the registrant has ceased to manufacture or import the substance for which the HSE requested additional information, then the registrant does not need to provide this information and the HSE will update the tonnage of the substance to be null. Should the registrant restart manufacturing or importing the substance, then the HSE has to be notified and the request for submission of full information fulfilled. We welcome this option.

Overall, the process for the transitional evaluations is not clearly outlined. It will be valuable for companies to have more clarity on this, to provide constructive feedback. **If it is not possible to provide more details within the legislation, then this needs to be clarified in guidance.**

21. Do the provisions in Article 127R on cessation and recommencement of manufacture or import during the transitional evaluation process read clearly and as intended? Please identify any potential drafting issue, ambiguity or unintended consequence.

Clarification is needed as to what tonnage qualifies as a cease of manufacture/import; for example, 0 kg/year or when the tonnage is less than 1 tonne/year.

Article 127R appears to repeat most of the provisions covered by Articles 50 (preparation and notification of draft decision under the standard regime) but appears to introduce some differences concerning the cease of manufacture. The purpose and intention of these differences should be clearly explained. Such as, Article 50(3) states that if the registrant stop import after receiving a draft decision, its registration "shall no longer be valid", whereas Article 127R does not say that the registration becomes invalid.

22. Do the proposed time limits in Articles 127R and 127T for the transitional evaluation process provide a workable framework for regulators and registrants? Please identify any potential drafting issue, ambiguity or unintended consequence.

CTPA remains concerned about the 30-day period for registrants to respond to an HSE notification requesting information, as explained in response to question 20. Whether this period is workable will depend on the method of notification; for example, notification by post would require additional time. The legislation also states that the HSE will set a time limit within which the registrant must submit the full information requirements requested. Although the absence of a fixed timeframe allows flexibility, the HSE and the registrant should be able to agree an appropriate period. The time needed to fulfil a transitional-evaluation request will vary depending on whether the relevant data are already available, must be generated through new testing, or require negotiations with an EU registrant for access to existing data. This flexibility and the need for mutual agreement between the HSE and the registrant should therefore be reflected in the legislation.

Again, we would like to reiterate our concerns that generating new data will lead to performing unnecessary animal testing.

Substance groups, data and cost sharing, and joint submission

23. Does the proposed drafting of Articles 3(46), 25A and 127OA clearly establish who will be required to participate in substance groups and how information, access rights and costs need to be shared for registration and evaluation purposes? Please identify any potential drafting issue, ambiguity or unintended consequence.

Key points:

- Clarity should be provided in the case where no company can act as a Lead Registrant within a joint submission group.
- Flexibility should be introduced to allow companies to submit information either as part of substance groups, or individually.

- A common data/cost-sharing regime should be established which adds the specific changes needed for transitional submissions.
- The text should be amended so that the data owner is required to make every effort to provide proof of the cost of information to registrants.
- The text in Paragraph 6(b) should be amended to not mix the negotiation with the data and cost allocation with all co-registrants.
- Clarification is needed as to how data sharing will be done in a fair, transparent and non-discriminatory way in case of a dispute.

The definition of substance group in Article 3(46) is "substance group: means a forum of registrants and potential registrants who manufacture or import, or intend to manufacture or import, the same substance, established with the aim of agreeing the classification and labelling of the substance and facilitating the exchange of information between registrants for any of the purposes mentioned in Article 25A(3).". **It is unclear what is meant by potential registrants, and it should be explained that potential registrants are those who submitted an Article 26 inquiry as explained in Article 25A.** Consolidating the information rather than scattering it in different places of the legislation provides clarity. Furthermore, it is our understanding that Article 127ZA amends the information requirements to be submitted by the lead registrant, rather than the role of the lead registrants.

Exchange of information within the substance group covers: classification and labelling, as well as study summaries, robust study summaries and proposal for testing where applicable (in the event of a transitional evaluation); guidance on safe use and chemical safety report if the registrants decide to submit it all together; the statement that the information has been reviewed and assessed by an expert assessor. Members raised concerns in the instance where no company can act as a Lead Registrant within a joint submission group; clarity for this scenario should be provided. This can occur when a joint submission group is solely made by former DUs with no data owner or clear expertise to act as a LR.

CTPA is aware of a proposal of retaining substance groups as a mechanism for communication between registrants, but allow the registration information to be submitted individually. We believe that the legislation can be amended to allow flexibility for the joint submission group to decide whether to submit the information as a group or as individual companies. Submitting information as individual companies may reduce the administrative burden from contractual and data-sharing arrangements. However, some former DUs consider it may be more burdensome to submit information individually, which is why flexibility to allow either approach should be introduced. CTPA supports the retention of joint submission groups in the event of a transitional evaluation.

Art. 127(OA)(3) and (4) concerns the sharing of information and costs if the data is owned by a participant of the Substance group (SG), unless the participant has opted to submit information separately. In this case, the following is required:

- Proof to be provided of the data cost by the data owner.
- Cost sharing should be in a fair, transparent and non-discriminatory way.
- If there is a disagreement in cost sharing amongst the registrants, the cost is to be divided equally. Thus, replacing the existing dispute mechanism under Art. 27
- If the data owner refuses to provide proof or the information itself, registrants must determine whether the information from another source outside the SG.

Art. 127(OA)(5) and (6) concerns sharing of information and costs if the data is owned by a company outside the Substance group. In this case, the following is required:

- An agreement on access to the information on terms acceptable to all registrants
- Cost sharing should be in fair, transparent and non-discriminatory way, agreed between data owners and relevant registrants.
- If there is a disagreement in cost sharing, the cost is to be divided equally between registrants. Thus, replacing the existing dispute mechanism under Art. 27

The Schedule creates two different data and cost sharing regimes for standard registration or transitional registrations. For transitional registrations, Article 127OA replaces the existing dispute mechanism under Article 27 with a requirement to equally share the cost amongst registrants. This adds unnecessary complexity and could negatively impact registrants, especially where existing vertebrate studies are available by a data owner that is also a participant within a substance group. **A common data/cost-sharing regime should be established which adds the specific changes needed for transitional submissions.**

However, if Defra's intention is to indeed regulate the external owner's price or access conditions to substance group within UK REACH, the legal basis, the scope and the enforcement mechanism must be explained.

Paragraph 4(e) requires the participant who is the data owner to provide proof of the cost of the information to the registrants. If this is not provided, then registrants must determine whether the information is available from another source outside the substance group. The data owner may not be able to provide proof of the cost because this information is no longer available to them, for example for studies performed a long time ago. If the cost information is not available this should not prevent registrants from accessing and using the information. If the cost of the negotiated data access is considered acceptable to the lead and registrants, then registrants should still be able to

use this data in their registration. The text should be amended so that the data owner is required to make every effort to provide proof of the cost.

Additionally, Articles 127OA(5) and (6), concerning information owned by companies outside the substance group, do not clearly distinguish between negotiations with external data owner from cost sharing/allocation between all the registrants. Paragraph 6(b) states that the data owner will decide how the costs are shared between the members in the substance group. However, an external data owner is not subject to UK REACH obligations. Data access (price and terms) depends on negotiation with the data owner. The relevant registrants must then ensure the final cost, as set and agreed with the data owner, is shared in a fair way amongst registrants. **The text in Paragraph 6(b) should be amended to not mix the negotiation with the data and cost allocation with all co-registrants.**

Furthermore, it is not clear how replacing the existing dispute mechanism with a process to share equally the cost will be fair for all registrants. **Clarification is needed as to how data sharing will be done in a fair, transparent and non-discriminatory way in case of a dispute.** For example, in the event there is a dispute in a substance group containing registrants with a 1-10 tonnage band and others with a 10-100 tonnage band, it will not be fair for the 1-10T registrants to pay equal cost for data required for the 10-100T dossier. For the sharing of data costs to be fair, the cost for access to data required for a 10-100T dossier, should be shared only amongst 10-100T registrants.

24. Do amended Articles 11 and 19, as modified for each transitional route, clearly describe the arrangements applying to joint and separate submission? In particular, please identify any potential drafting ambiguity, omission or unintended consequence.

It is CTPA's understanding that the requirements on joint or separate submissions of information have been included into the transitional provisions correctly as per the existing requirements under Article 11 and 19.

25. Do the proposed cost-sharing provisions in Article 127OA clearly and effectively provide for the allocation of costs on a fair, transparent and non-discriminatory basis? In particular, please identify any potential drafting ambiguity, omission or unintended consequence.

There are provisions related to cost sharing when generating new data. **Generating new data to meet information requirements under the provisions of transitional evaluations may lead to performing unnecessary animal testing,** which is highly undesirable for chemicals also used as cosmetic ingredients, and not possible for

substances only used in cosmetics due to the animal testing ban under the UK Cosmetics Regulation. This would also not be aligned with the UK Government strategy for phasing out from animal testing.

Fees

26. Do the proposed fee exemptions in Articles 127B(4F), 127L(4) and 127M(4) clearly identify the transitional information submissions for which no fee is payable? In particular, please identify any potential drafting ambiguity, omission or unintended consequence.

It is CTPA understanding that no fee is payable for the submission of information under the ATRm for transferred GB registrations. There is no exemption for payable fees for the NRES and DUIN registrations under the ATRm – it is unclear if this omission was intentional or a mistake. Considering that the majority of companies fulfilling these obligations are former DUs and SMEs, **we request for the fee to be removed in this instance too. If this is not correct, then then legal text is not clear on this point.**

Other comments

27. Are there any provisions within the proposed drafting that you believe could create unintended practical, legal or operational consequences that are not addressed elsewhere in your response?

While CTPA has responded to the UK REACH Alternative Transitional Registration model (ATRm) technical consultation, **our response should not be interpreted as an endorsement of the proposed approach. We remain concerned that the proposed ATRm does not deliver the level of simplification needed to reduce the regulatory and administrative burden associated with UK REACH, especially for Downstream Users**, and we continue to support more fundamental reform of the regime.

Our consultation response is therefore intended to provide constructive feedback on the proposed legal text, highlighting areas where the requirements lack clarity, identifying provisions that are likely to be particularly challenging for companies, especially downstream users, to interpret and comply with, and suggesting practical improvements to enhance the workability and effectiveness of the proposal should it be taken forward.

Key points:

- The substantive requirements should be set out alongside the references to the relevant articles and paragraphs, and a consolidated text created, to promote ease of understanding requirements.
- The majority of the GB market comprises of former DUs importing chemicals from the EU. In many cases, they will have registration obligations, which cannot be met due to resource or expertise gaps. This will reduce availability of products on the market for GB consumers and reduce competitiveness of the GB market.
- Key challenges remain for DUs because they, particularly SMEs, are unlikely to have access to the data required under the ATRm, creating significant practical, legal and cost barriers to compliance.
- DUs may not have access to mixture composition or monomer information from suppliers due to confidentiality.
- It should be made clear, either in legislation or guidance, that DUs do not need to submit information on manufacturing process of the raw material or waste quantities.
- PNECs/DNELs and CSR requirements present significant challenges for DUs.
- The ATRm may pose significant challenges in regard to enforcement, and it is important that a robust and transparent enforcement process is published, to ensure a level playing field for all companies.
- A Working Group should rapidly be established between Defra, the HSE and industry representatives to ensure that the requirements are feasible and can address the challenges outlined in this consultation response.

CTPA reiterates that the legal text is complex and relies heavily on cross-references to articles and paragraphs rather than directly stating the relevant information requirements. Although an official legal text must use appropriate legal drafting, this approach may be highly confusing for companies and creates a risk that readers will lose track of the applicable provisions, consult the wrong line or paragraph, or misunderstand the requirements. We therefore recommend setting out the substantive requirements alongside the references to the relevant articles and paragraphs. A consolidated version should also be created. The requirements must be stated clearly and accessibly to promote compliance; where companies cannot understand them, unintentional non-compliance is more likely.

Finally, CTPA would like to reiterate the key challenges for DUs to meet the ATRm information requirements.

- Based on the number of Downstream User Import Notifications (DUINs) received, **the majority of the GB market comprises DUs importing chemicals from the EU** – for chemicals placed on the EU/GB market and already registered under EU

REACH prior to Brexit. As such, these formerly DUs are now classed as importers into the GB market. In an ideal world, EU or overseas suppliers may appoint an Only Representative to carry out the ATRm registration for their DUs; but this does not always occur. Certainty cannot be provided by suppliers until there is no clarity in the public domain on the ATRm requirements, and **some suppliers have already confirmed that the GB market is not commercially viable to justify the appointment of an OR and carry out a registration. The latter scenario will leave DUs with registration obligations,** which comes with significant challenges in meeting the ATRm requirements; or worst case, this leaves DUs losing the supply of a chemical substance, if they cannot afford taking the role of a registrant**. It is important to highlight that a lot of DUs are SMEs, who do not have the administrative or financial resources to take on the role of a registrant under UK REACH. This will reduce the choice of products available on the GB market to consumers, or increase the cost of finished products to consumers, as well as discourage investment and reduce competitiveness for businesses.**

- **Former DUs importing chemicals into the GB market do not have direct access to the detailed information required to be submitted under the ATRm.** The key consideration in this scenario is that **DUs only have the Safety Data Sheet (SDS) as readily available documentation** containing most (but not all) relevant information on a substance. DUs do not own full data packages on substances, as these are property of raw material suppliers. Therefore, **DUs would not be able to promptly access and submit data to access the GB chemicals market without infringing legal terms and IP rights;** nor they would be able to invest in generating new data. Some companies may be able to set a letter of access in place to obtain the information to be submitted under the ATRm; **but SMEs are very unlikely to be able to have these arrangements, as the cost will be too significant for them to cover.**

- Furthermore, not all DU companies have internal resources (administrative, cost and technical expertise) to carry out the ATRm registrations. Some companies may be able to outsource these, but SMEs would not be able to cover such costs.

- Most raw materials used by cosmetic DUs are mixtures, **and some of the components might not be fully disclosed by the suppliers,** nor included in the SDS due to confidentiality.

- A similar challenge has to be raised for polymers. Whilst polymers are exempt from UK REACH registration requirements, their monomers are not. DUs import the final polymer into the GB market, and **it may be extremely challenging to obtain information on the monomers forming that polymer.**

- In regard to the uses and exposure information, the requirements under Annex VI of REACH cover: manufacturing process; tonnage; form and physical state under which the substance is made available to DUs; concentration ranges of the substance in mixtures; general description of identified uses; information on waste quantities from the manufacture or use of the substance; uses advised against; exposure scenarios. Of these:
    - the manufacturing process is only required for UVCB materials (these are Unknown or Variable composition, Complex reaction products, or Biological) --> DUs do not have access to the manufacturing process of the raw material;
    - waste quantities may not be relevant if the entire substance group is composed of former DUs, as they would have no or very minimal manufacturing waste. This information may therefore not be applicable in these cases and should not be mandatory.
- **It should be made clear, either in legislation or guidance, that DUs do not need to submit information on manufacturing process of the raw material or waste quantities.**
- The PNECs and the DNELs may be available in the SDS, or in online databases. However, these are values generated through studies owned by companies. **It is not yet clear if it is infringement of IP to submit these values as part of a registration dossier to gain access to the GB market.** Furthermore, not all PNECs or DNELs might be easily available, and not all companies have the expertise to derive these values.
- Creating the CSR as is currently required under EU REACH will be challenging for DUs, who have never had to do such documentation - this is both because DUs may not have the technical expertise, but also **because they do not have access to all the information needed to compile the CSR as is currently required** (due to the issues around access and use of information as outlined above).

CTPA and the cosmetics industry would like to also request more **clarity on the enforcement process of these provisions under UK REACH.** In particular, the evidence that would be requested, the mechanism for addressing incomplete registrations, how authorities intend to support companies towards becoming compliant and how roles and responsibilities throughout the supply chain will be assessed by the enforcement agency.

Finally, it would be very helpful to establish a Working Group between Defra, the HSE and industry to ensure that the requirements are feasible and can address the challenges

outlined above. This would also provide an opportunity to explore specific flexibilities or practical solutions for DUs, as only a workable model will support effective compliance.

The chemicals industry would also like to reiterate its practical proposal to simplify the ATRm further while fulfilling the UK REACH legislative requirement of 'no data, no market'. The proposal is to recognise all EU registrations, consistently with the UK's overarching objective of aligning with EU regulatory decisions and with the UK Government's use of a similar approach in other areas of chemicals regulation.

Lighter reporting mechanism

A significantly simplified ATRm based on key information requirements such as substance identity, volumes, classifications, and uses would be satisfactory. This lighter reporting mechanism can ensure that the UK Government receives the information it requires, and industry can comply in a cost-effective way which supports the UK's competitiveness on a global stage.

Compliance with primary legislation

This proposed solution also satisfies the requirement for GB companies to have sufficient information to effectively manage risks from chemicals because hazards, risks, how to manage them and sharing information down the supply chain are features in place already by virtue of the substances having been registered under EU REACH. This is all already communicated in substance Safety Data Sheets (SDS).

Continuing safety

Recognition would not remove the continuing obligations on manufacturers, importers, and downstream users to understand hazards, assess risks, and communicate appropriate risk-management measures through the supply chain. As mentioned above, this already happens by virtue of the SDS.

Within the industry's proposal, regulators can retain risk-based powers to trigger the transitional evaluations where needed for prioritisation, compliance and enforcement. This would maintain protection for health and the environment and avoid the cost and duplication of creating a separate UK database of more than 22,000 dossiers, especially when the overall UK Government position is to align with EU decisions on authorisations and restrictions.