Department
for Environment
Food & Rural Affairs

ATRm and UK REACH Improvement

Last updated 17/05/2024

What will this presentation cover?

The Alternative Transitional Registration Model (ATRm)

- Details of proposals for ATRm, including new use and exposure requirements and changes in hazard requirements
- Information on proposed registration timelines
- Reflections on the overall policy intentions
- Upcoming opportunities for further engagement

REACH Improvement

- Proposals for an amended restrictions and reporting process
- Details of plans to extend requirements before animal testing

What is ATRm?

- A transitional period post-Exit was initially given in order to avoid a “cliff edge”. However, the cost of completing registration afterwards was estimated at ~2 billion by 2030. Last year, we announced an ATRm to manage this.

- Defra, HSE and EA have ATRm within the framework of UK REACH to ensure high levels of protection for human health and the environment, while reducing the costs to industry of registration.

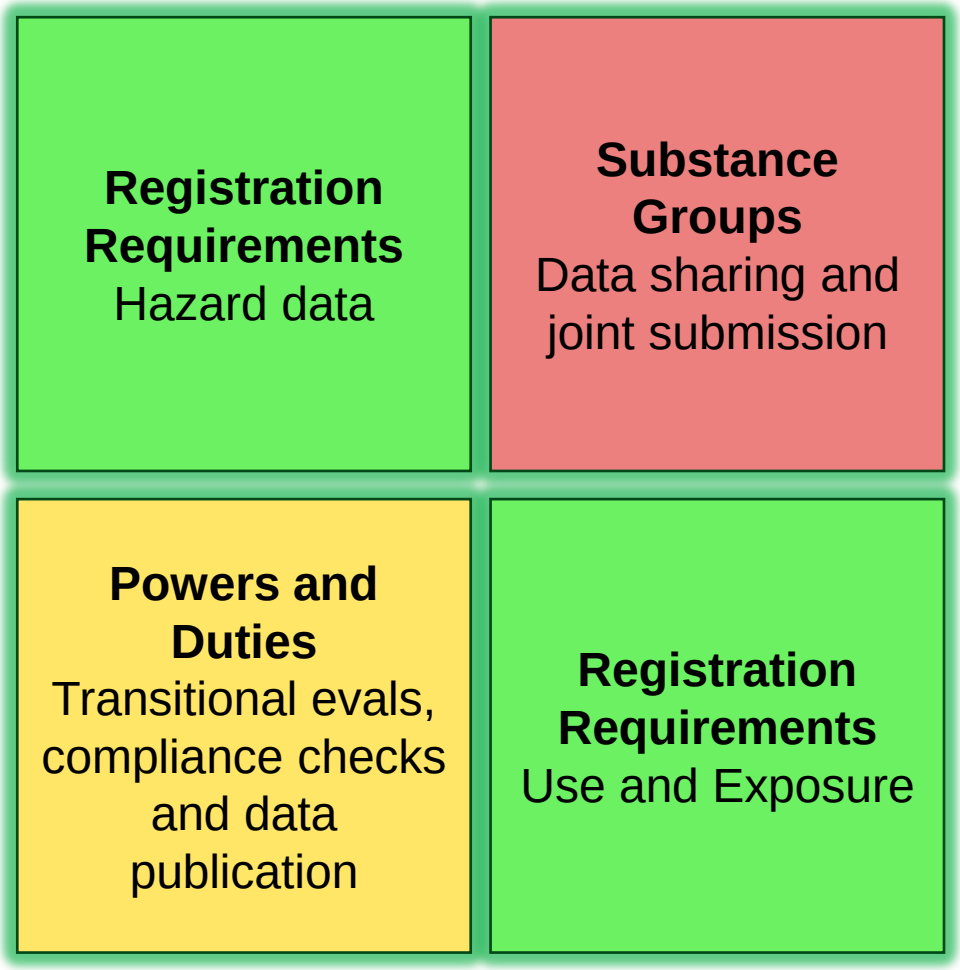
- The ATRm looks at hazard information and use & exposure information as two connected elements with the ultimate aim of risk management.

- The consultation is accompanied by an impact assessment which estimates that ATRm will reduce the total costs of the transition to UK REACH by around 70%. This figure takes account of both the reduction in hazard information and the enhanced use and exposure information.

What does the consultation cover?

We are now consulting on:

- Our proposals for the UK REACH, which will apply registrants of transitional substances.
- Initial UK REACH improvements, including proposals on UK REACH restrictions & reporting processes and furthering protections against unnecessary animal testing



Elements of ATRm- as covered in consultation

Use and Exposure

- Industry needs good use & exposure information to understand and manage risk and to ensure safe use of chemicals. The regulator also needs it to inform many regulatory activities. Collectively, it is an essential part of ensuring a high level of protection of human health and the environment.
- HSE/EA analysis of EU REACH registrations indicates that use & exposure information is often incomplete or otherwise not fit for purpose.
- The aim is to improve compliance and also build on the existing position with additional levels of information.

We want to understand:

1. How long you estimate it will take to complete the necessary tasks?
2. Whether you feel this information will meet the aims of improving industry's risk management and the regulatory capability for the regulators?
3. Whether you agree with the proposed trigger points and corresponding information requirements?

Use and Exposure- Levels

We are proposing 3 levels for use and exposure relating to **human health:**

Level 1: This is the existing set of requirements for use and exposure.

Level 2: In addition to level 1 information, registrants will need to provide information on: the percentage of substance in a mixture, its physical form, the number of sites or professional uses, number workers using the substance at an industrial site, exposure reduction methods and routes in which exposure could be regarded as 'negligible' and why.

Level 3: In addition to the information from level 1 and 2, registrants will also need to provide further information on potential levels of exposure and estimates of the totality of consumer user. This will only apply for 1-10 tonne registration as in higher tonnage bands CSA/CSRs will provide the necessary information.

Additionally, **all registrants** will now need to give 'level 2' data on **environmental use and exposure.**

Level 2: That will include: maximum level & frequency of use and annual use at both individual sites and cumulatively, information on sites related to potential levels of exposure and estimates of the totality of consumer use.

Use and Exposure Triggers

1-10 Tonnes		
Trigger	**Level of information (human health**	**Level of information (environment)**
Does not meet Article 14(4) criteria	Level 1	Level 2
Meets the Article 14(4) criteria	Level 2	Level 2
Meets the “T” criteria of PBT or is a respiratory or skin sensitizer (all categories)	Level 3	Level 2
>10 Tonnes		
All registrations	Level 2	Level 2

Hazard- what changes are we proposing?

- Under ATRm only hazard classifications would be required, for transitional substances. Along with similar information such as PBT assessment conclusions, DNELs and PNECs.

- Hazard will still trigger the exposure assessment and risk characterisation in the CSA/CSR. However, to ensure consistency the CSA/CSR should have to contain only the hazard conclusions.

The consultation seeks to understand whether:

1. For views on the removal of more detailed hazard information and its effect on human and environmental health.
2. For views on the opinion that the regulator does not need replicated hazard data to inform prioritisation of regulatory actions?
3. Views on the proposed hazard data requirements' impact on costs to business.

What information will be required?

Intermediates (isolated & transported)	Hazard classification and associated labelling			
All Substances below 10 tonnes	Hazard classification and associated labelling			
>10 tonnes if 14(4) doesn't apply	Hazard classification and associated labelling	PBT/vPvB assessment	Predicted no Effect Concentration (PNEC) + Derived No Effect Level (DNEL)	
>10 tonnes if 14(4) applies	Hazard classification and associated labelling	PBT/vPvB assessment	PNECs and DNELs	Some physical-chemical properties

Data Sharing- Substance Groups

- UK REACH did not carry forward the express provisions for Substance Information Exchange Forums (SIEFs). However, the UK REACH Service places registrants into “substance groups” and the intention is to put this on a statutory basis.
- A substance group should apply to all registrants regardless of their route into UK REACH and the provisions of the REACH Cost Sharing Regulation, e.g. fairness, transparency, non-discrimination, should apply to the substance groups.
- The substance group should agree the necessary hazard information, which is then submitted by a lead registrant. The right to opt out of a joint submission should remain.
- Responding to a transitional evaluation or other regulatory decision should be the joint responsibility of the substance group.

The consultation seeks to understand whether:

- Respondents are content with proposals for how substance groups will operate.
- If there any areas for improvement from the EU legislation on SIEFs which should be considered for UK REACH legislation?

Transitional Evaluations

- We intend to formalise a third type of evaluation called a “transitional evaluation”. A transitional evaluation would be a regulatory decision directed at duty holders and requiring them to supply the specified information within a set time.
- The scope would be any information which would be part of a standard registration under UK REACH, but which is no longer required under the ATRm proposal. Although, any individual transitional evaluation decision is likely to require only a subset of the total standard registration information.
- Existing evaluation procedures would be applied, e.g. chance to comment on a draft decision; legal time limits; right of appeal; subject to enforcement.
- We would expect the response time to be in the window of 3-12 months, depending on the nature and extent of the data concerned.

We would like to understand if:

You feel introduction of these powers is an appropriate way for regulators to request supporting information on an “as and when needed” basis?

How will ATRm affect new registrations?

- Existing hazard requirements will continue to apply for new/novel substances which were not registered in EU REACH before Exit,
- To ensure consistency, the new use and exposure requirements will also apply to new/novel substances.
- If the amount of an **ATRm substance** manufactured or imported exceeds the highest level registered under EU REACH the substance should revert to the standard hazard requirements.

New/Novel Registration	Full hazard information	New use and exposure (tonnage/hazard based)	Other information requirements in full, in line with new registration tonnage/hazard requirements

We are treating any substance registered after December 2020 as new/novel

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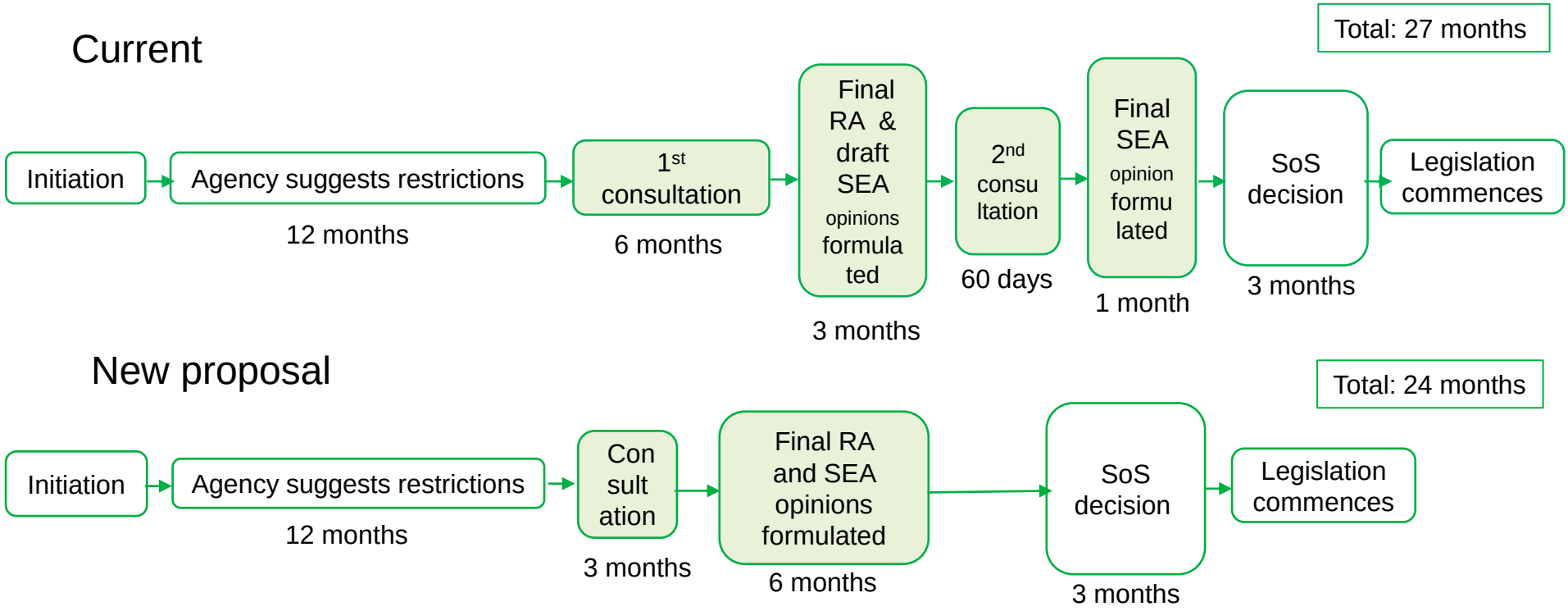
UK REACH
improvement

REACH improvement – of the restrictions process

To increase regulator capacity and accelerate the process



We would like feedback RE: the current restrictions process on:

- What actions need to be taken to draft a response to the 1st consultation? & how long do these take?
- Is there any information given in the 2nd consultation that cannot be given in the 1st?

REACH improvement – of reporting requirements

To increase regulator capacity

Remove reporting requirements where information is covered in other processes.

Reports the Agency produce each year	Deadline
1. Report of activities in the previous year (Article 83)	Each year (no specific deadline)
2. Work programme for the coming year (Article 83) ⊕	Each year (no specific deadline)
3. Multi-annual work programme (Article 83) ⊕	Each year (no specific deadline)
4. Annual accounts (Article 83) ⊗	Each year (no specific deadline)
5. Forecast budget (Article 83) ⊗	Each year (no specific deadline)
6. Rolling action plan (for substance evaluation) (Article 44)	Submit draft Rolling action plan by 31 May each year

We would like feedback on:

- Aligning the dates the Agency return these reports
- Consolidating reports 2 & 3
- Removing reports 4 & 5
- Removing a separate 5-year evaluation report (article 117(2), we have NOT proposed to remove the 3-year promoting non-animal testing methods report, 117(3) or the 5-year SoS evaluation report, 117(4))

Key: ⊗ report removed; ⊕ reports consolidated

REACH improvement - of animal testing

To ensure testing on animals is approached as a last resort

We want to support registrants exploring use of alternatives to animal testing to ensure unnecessary animal testing is avoided.

We would like feedback on:

Whether we should do this by

Non-legislative means	Legislative means
• e.g. guidance, on alternatives to animal tests/examples of adaptions.	• e.g. extending testing proposal requirements to manufacture/ import of substances from 1 tonne/year/registrant • Incentivises exploring non-animal tests and development of further non-animal tests.

Consultation process

- This consultation will last for 8 weeks
- Government response to consultation should be published within 12 weeks of end of consultation
- There will be a 2nd consultation focussed on the legislation under the powers in the Environment Act. This will be the formal consultation required by the Environment Act & will be accompanied by the Article 1 consistency statement.
- Our aim is to have legislation in place in 2025.

Further Engagement Opportunities

- To support the implementation of ATRm we will be developing new technical guidance and designing new UK IUCLID working contexts. If you are interested in being a part of stakeholder engagement groups on either of these topics, please let us know.