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How to read the Assessment of Regulatory Needs (ARN) reports?

Purpose of this document

This is a communication to chemical suppliers, consortia and downstream users to explain the purpose of the ECHA ARNs, what they are and how to understand and use them.

What is ARN?

ARN is a preliminary step taken by the European Chemical Agency (ECHA) to explore the need for potential regulatory risk management for (groups of) substances. The groups from ARN are built upon available information and use a practical approach to prioritise areas of interest based on common attributes like uses, hazards, and chemical structure, which differs from methods from grouping as defined in Annex XI; ARN does not aim to validate read across and category approaches. During 2019-2022, ECHA assessed around 5 000 substances in groups. Based on group assessments, around 60 % of substances do not need further regulatory risk management ¹. For the remaining 40%, further data collection and generation is required, possibly through a compliance check (CCH), before potentially moving towards regulatory risk management.

How ARN Works:

- **No legal implications:** ARN outcomes have no legal or regulatory relevance as they are not part of any formal regulatory management and decision-making processes
- **Voluntary action:** The ARNs are developed voluntarily by the Agency. The process uses selected information and assumptions for a screening-level assessment to help the Commission and Member States to understand if and where regulatory action might be needed.
- **Not a Definitive Assessment:** ARN reports offer screening-level assessments and assumptions. They do not give a final evaluation; robust justifications by authorities are needed for regulatory risk management.

Why ARN Reports are Useful:

- **Transparency:** Publication provides insights into authorities' focus, though it's limited to a screening level, and the industry responses to ARN outcomes are currently not publicly available.
- **Prioritisation:** Helps companies focus on substances needing further investigation or clarification, streamlining efforts.
- **Proactivity:** Allows the industry to prepare for potential regulatory actions based on informal signals.

Recommendations for Chemical Suppliers, Consortia and Downstream Users:

- 1. **Read Carefully:** Understand assumptions in the report, considering missing information and the screening level nature.
- 2. **Update Dossier:** Keep your registration dossier up to date by correcting outdated information and filling identified data gaps. ARNs are based on current dossier information on chemical composition, tonnage and uses; if the right information is not updated, the ARN screening will provide wrong information.
- 3. **Feedback to ECHA:** Find errors? Inform ECHA via the <u>feedback button</u>. Stakeholder input may trigger updates.
- 4. **Prepare for Action:** Collect data for upcoming public consultation and evidence gathering, e.g. more detailed use information or critical uses, anticipating potential regulatory actions and updating the dossiers proactively (if needed), especially where there's a perspective for further regulatory action.
- 5. **Inform Customers:** Keep customers informed about potential regulatory actions.
- 6. **Stay Informed:** Timelines for regulatory actions vary. Stay alert through relevant channels like the <u>PACT list</u>, <u>ECHA Newsletter</u>, Restriction Roadmap, and the <u>Registry of Intention</u>.

ARN is a tool for **early awareness** and **industry preparation**. <u>Keep informed, update dossier information, and proactively engage in the process</u>.

¹ Integrated Regulatory Strategy Annual Report- July 2023