Progress made with the evaluation of Petroleum Substances under REACH

A regulatory perspective

Online workshop on testing and assessment of petroleum UVCB substances

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Aims of REACH

- Ensure a high level of protection of human health and the environment
- Promote alternatives to animal testing
- Ensure the free circulation of substances on the internal market
- Enhance competitiveness and innovation

Petroleum substances and authorities

- **2013 – SVHC Roadmap to 2020** - EU policy commitment
  - **To have all relevant currently known SVHCs included in the Candidate List by 2020**
  - SVHC Roadmap highlights need to start working on regulatory risk management (RRM) for petroleum stream substances and coal stream substances in particular due potential **PBT** and **CMR** properties of those substances
- **2020** – SVHC Roadmap closure*
  - PetCO works not finalised and need to be continued under the **Integrated Regulatory Strategy (IRS)**

2020 – Chemical Strategy for Sustainability (CSS)

- Commission communication of October 2020
- Objectives:
  - better protect citizens and the environment which includes increased protection against most harmful chemicals such as
    - extension of generic risk management approach to ensure **consumer** products do not contain (**CMR**), **PBT**, ED
    - Extend this to **professional** uses and potentially other hazards
  - boost innovation for safe and sustainable chemicals

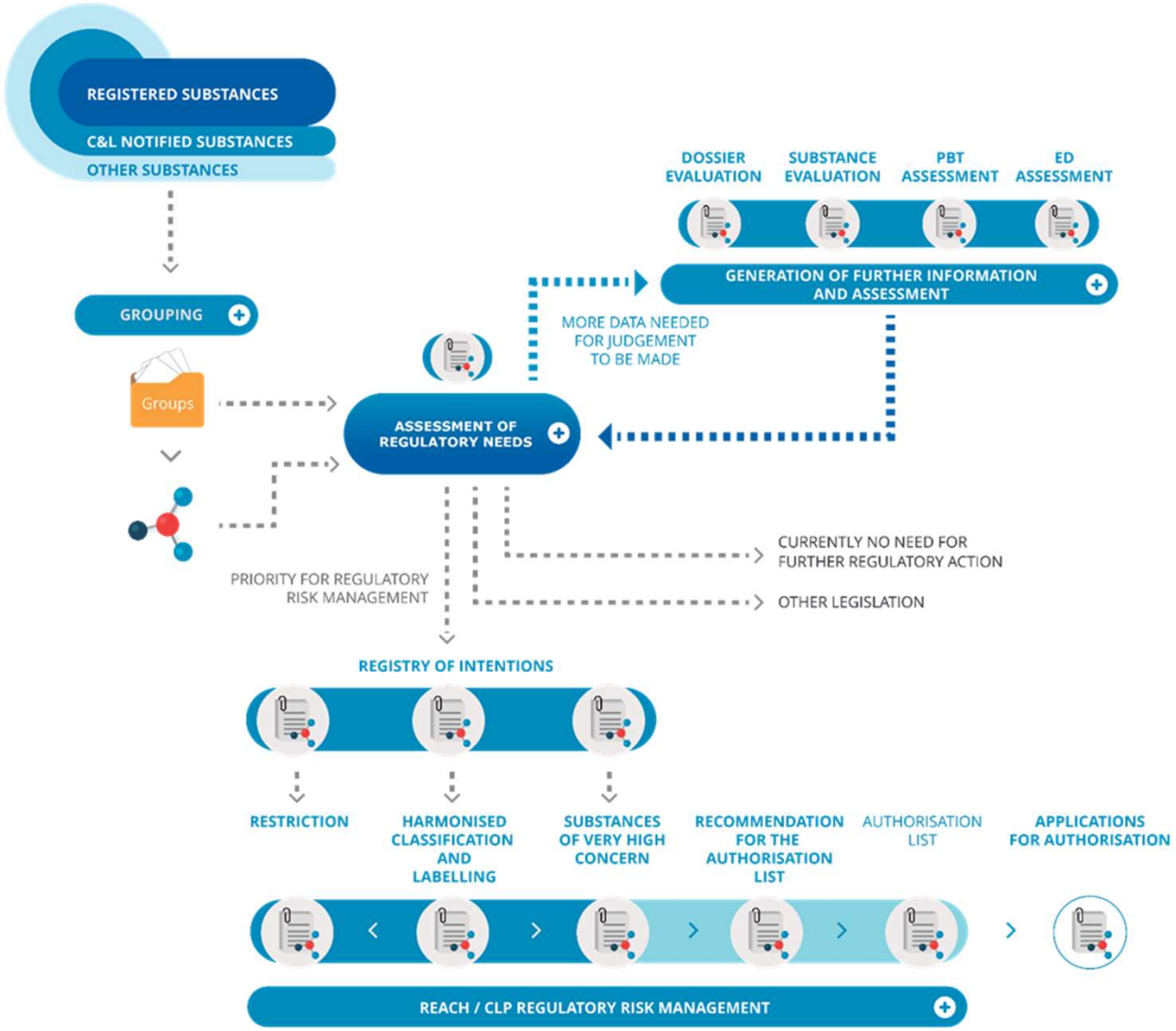
Integrated Regulatory Strategy (IRS) - Aims

- **Efficiently select (groups of) substances that raise potential concern. Generate information needed to assess their safety so that any remaining concerns can be addressed through the most suitable regulatory risk management measures (asap).**

- Ensure appropriate and timely intervention by all actors – ECHA, Member States, the European Commission and industry

- Provide confidence among stakeholders that registrants meet REACH information requirements, promoting improved communication on safe use in the supply chain.

Integrated Regulatory Strategy



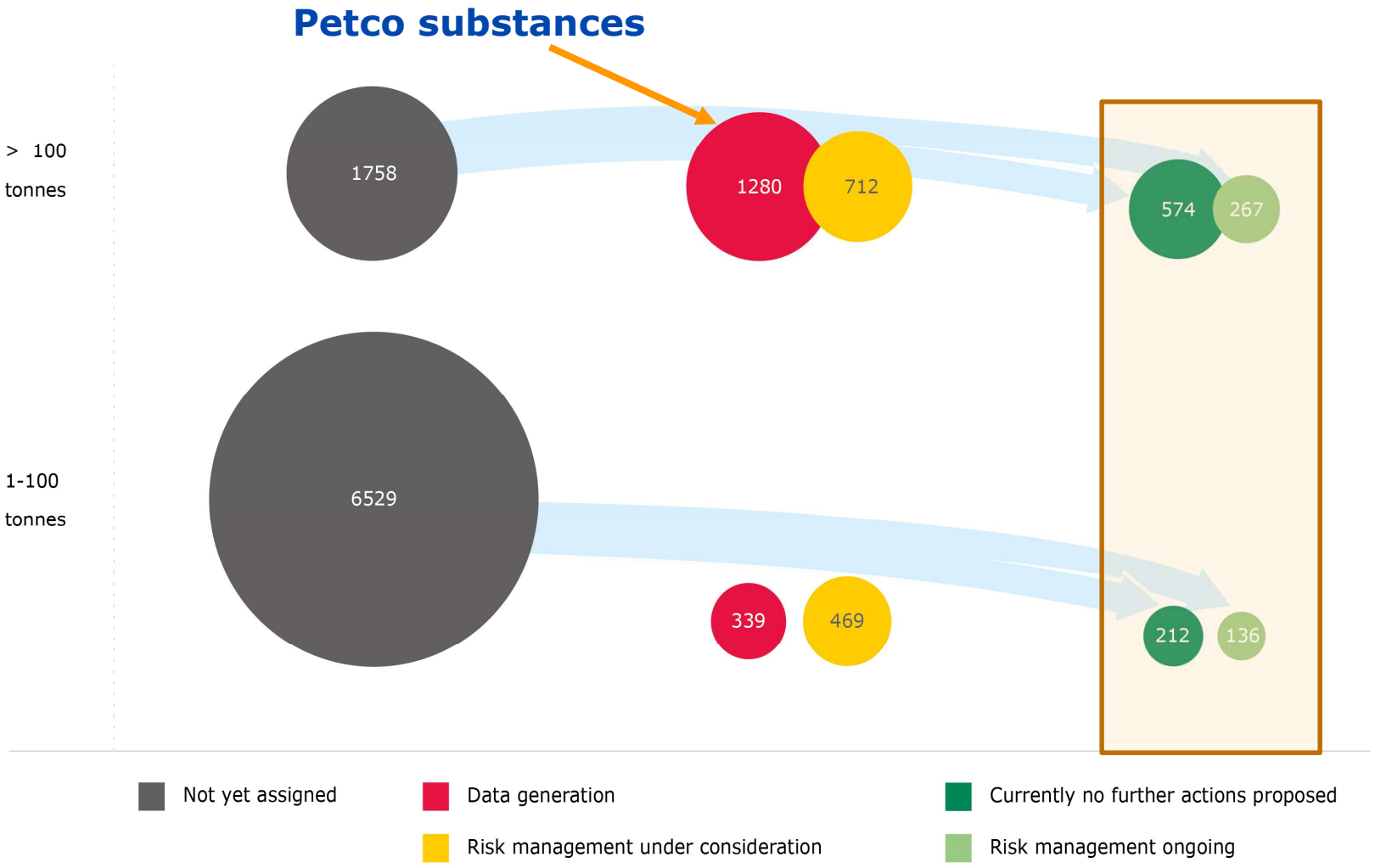
Integrated Regulatory Strategy - Targets

- To conclude, **by 2027**, on all registered substances whether they are:
  - of priority for EU level regulatory risk management or
  - currently of low priority for further EU level regulatory action

Targets in line with REACH Evaluation Joint Action Plan

Link to IRS annual report

Chemical universe mapping*



*universe of registered chemicals

Petroleum substances of high concern - composition?

- **Substance Identity Profile (SIP)** describes the composition(s) (and manufacturing process(es) for UVCBs) that are covered by the data that is jointly submitted.

- **Boundary composition** refers to the technical reporting in the IUCLID dossier of all the compositions of the substance covered by the registration.
  - Boundary composition was not designed as a tool for only sameness assessment.
  - The level of detail should be linked to **hazard assessment** purposes (this may be different from level of detail needed for substance identity purposes).

- **Variability** in composition could be accommodated in terms of SID (especially for process defined UVCBs), but challenging for hazard assessment

Petroleum substances of high concern - hazard?

- Because of the nature of the products, there is suspicion for **CMR** and/or **PBT properties**

- Assessing the CMR and PBT properties of petroleum substances is a challenging task
  - Complexity and variability of composition
  - Starting data-set is 'thin', specifically for environment and higher tier human health
  - Need to find the right balance between developing new approaches for hazard assessment and not delaying action
  - Acknowledge that many challenges that require scientifically sound work

Petroleum substances of high concern - exposure?

- Initially focus on prioritisation of substances based on uses.
  - Consumer and professional uses at highest priority
  - Medium priority industrial uses other than intermediate uses
  - Lower priority: intermediate and fuels uses only

- Note that migration of constituents through the supply chain is an issue for intermediate uses

Petroleum substances of high concern – Regulatory risk management?

- Starting point to consider when regulating a substance is **confirmation of the hazard properties** (CLH, Candidate listing)
  - Need meaningful hazard information to support **further regulatory risk management**
  - Constituent versus whole substance

- High **variability** in composition means that same substance may have different hazards
  - How to regulate such substance in a proportionate and efficient manner?
- UVCBs imply a certain level of **unknown** and therefore uncertainties around the hazard of those substances
  - Which level of uncertainties authorities and industry are willing to accept to ensure the safe use of those chemicals?

Progress made

- Use information was clarified (consumer, professional, industrial, intermediate uses)
- Analytical work has enhanced the understanding of the chemistry
- For Human Health, additional testing proposals have been submitted
- For Environment, the block approach has been a good pragmatic starting point

Progress made … but much more to come

- Use information was clarified (consumer, professional, industrial, intermediate uses). The information needs to be maintained, also in light of potential additional registrants – some concerns on migration through supply chain from authorities

- Analytical work has enhanced the understanding of the chemistry, but more work is needed especially to ensure optimal testing, a solid implementation of the block approach and to substantiate read-across

- For Human Health, additional testing proposals have been submitted, but there are still quite some categories/ substances to work through

- For Environment, the block approach has been a good pragmatic starting point. Some chemicals should already be handled as PBT because of the known PBT constituents above 0.1%. Number of higher tier studies insufficient – what testing strategy? False negatives?

Sustainability

- Your substances are under attention:
  - Urgency because of possible CMR and PBT properties
  - Political willingness for action

- Your substances are difficult to assess:
  - Complex and variable chemistry and properties
  - The database needs to be expanded and any use of (new) science needs to be discussed and used once agreed

- This work is also relevant in the future:
  - Although virgin fossil sourcing for fuels has an end,
    - some substitutes will have the same/similar challenges
    - current chemistry will continue to be used in other applications and
    - other uses might be developed
  - Data, information and knowledge now generated, can also be applied for generations to come

Need for collaboration

An open and constructive approach between industry and authorities is the most responsible way forward

Thank you!

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