

EU Chemicals Strategy for Sustainability

Essential uses

JBCE,
2 March 2022
[REDACTED]
DG GROW

#ChemicalsStrategy

#EUGreenDeal



European
Commission

Planned Actions under REACH Revision

- Chemicals Strategy for Sustainability/REACH revision:
 - Extend current use of **generic (hazard-based) bans** of most harmful chemicals, except for essential uses.
 - A use is essential only if (Montreal Protocol):
 - it is **necessary for the health, safety** or
 - is **critical for the functioning of society** (encompassing cultural and intellectual aspects); and
 - **no available** technically and economically feasible **alternatives** that are acceptable from the standpoint of environment and health;
 - **Reform authorisation and restriction processes**, which are too heavy to deal with current and future workload

Why apply essential use criteria?

- **Current criteria** for REACH authorisation:

- Adequate control of risks
- Socio-economic analysis to demonstrate that benefits outweigh risks

- **Adequate control**

⇒ *To be further analysed whether some form of "safe use" derogation should remain (outside the essential use framework)*

- **Socio-economic analysis:**

- In principle covering most relevant factors, but:
 - Lengthy process and many non-quantifiable aspects
 - Cannot deal with societal preferences
 - Sometimes misses the relevant questions

⇒ *Replace by essential use concept*

Processes to assess derogations and authorisations

- **Current process:**
 - First **scientific/technical assessment** by ECHA
 - Subsequently **decision by the Commission** on the basis of ECHA opinions
 - **Why change the process for assessment of essentiality?**
 - Current process **takes a long time** – unnecessary for clearly essential and clearly non-essential uses
 - **Essentiality criteria** include both scientific/technical elements and societal preferences
 - It does not make sense to put questions on societal preferences to a scientific/technical body
 - It does not make sense to put scientific/technical questions to a general decision making body
- ⇒ ***Need to combine general and scientific assessments/putting the right questions to the right bodies***

Examples: Chrome plated lipstick cases

- **Current approach:**

- Part of a big authorisation request :
 - Application to ECHA submitted in 2015
 - ECHA Opinion given in 2016
 - **Still no decision, *inter alia*** because there is **lack of acceptance** on utilisations such as chrome plated lipstick cases
- Scientific/technical assessment can identify whether the alternative works with the **same quality**
- It cannot address the question whether society is ready to **accept any risks** for workers, and whether we could not live with other types of lipstick cases

⇒ ***Apply essential use criteria to include question of societal preferences to allow faster and more relevant decisions***

Examples: Authorisation for OPE/NPE

- Used in **medical products** (vaccines, IVD kits) as a cleaning agent:
 - **Alternatives** are in principle available but require approval by European Medicines Agency
 - **Current approach:**
 - +/- 70 individual authorisation applications:
 - **Takes years** and occupies a large number of agents and officials in ECHA, Commission and Member States
 - Addresses **many standard issues** but **not necessarily** the key question how as many alternative products can get **EMA approval** as fast as possible
 - Is it efficient to spend so much time/resources on this issue?
- ⇒ **Reform the authorisation/restriction process** – generally applicable derogations
- ⇒ **Apply essential use criteria** to allow faster, more flexible and relevant decisions

Examples: Cobalt in car batteries

- Currently no plans to restrict cobalt in batteries
 - Nevertheless, good example to illustrate choices:
 - Electrical cars are high priority for society
 - Alternatives under development
 - What are the relevant questions to be answered?
 - Scientific/technical assessment of availability of alternatives?
 - Criticality for society?
 - What about providing the necessary investment security?
- ⇒ *Essential use concept and revised processes could help to pose the right questions to the right levels*

Proposed process to apply the essential use concept in REACH

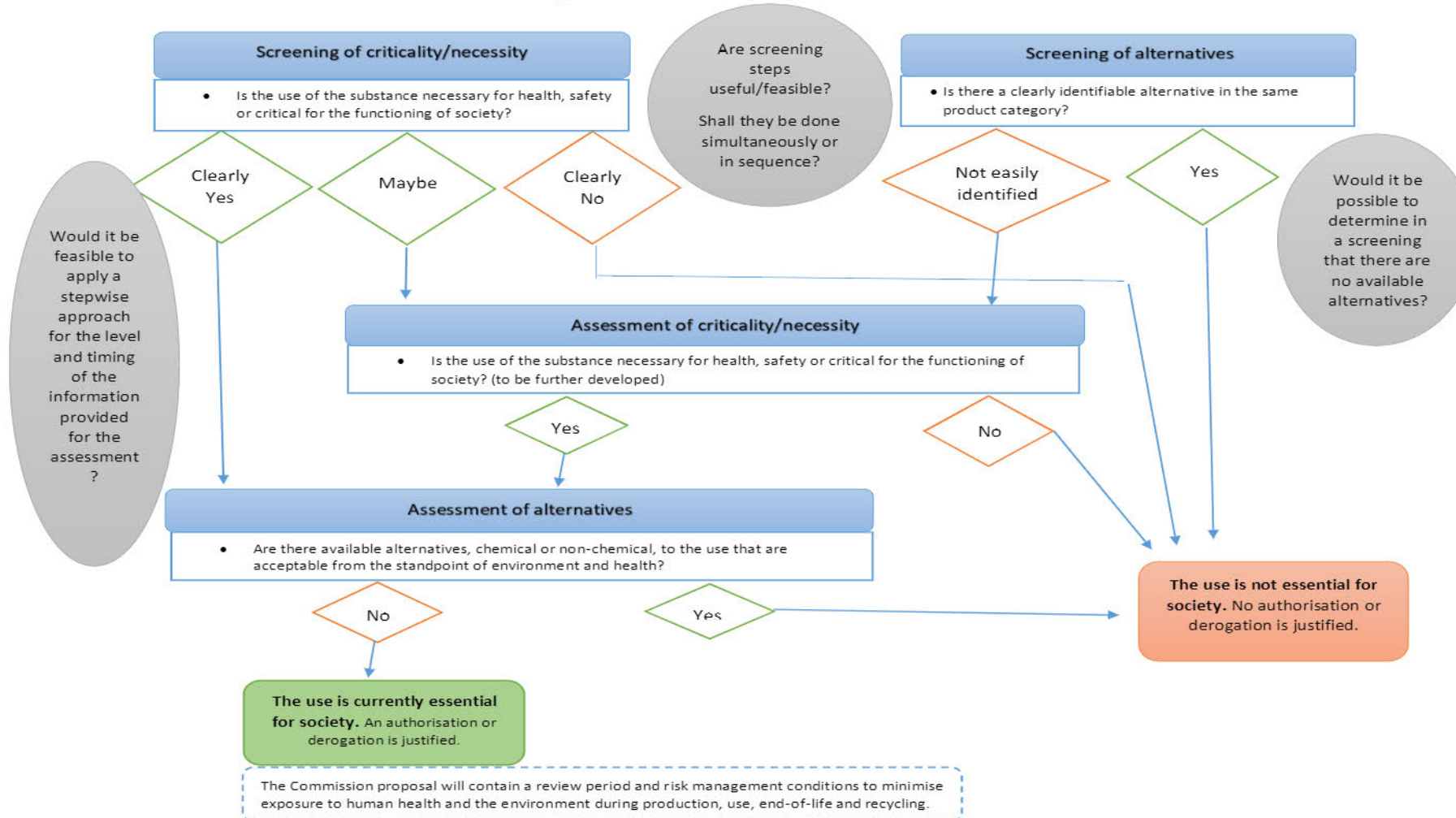
- **Step one:**
 - Initial screening of **alternatives**, identifying if:
 - there is a **clearly identifiable alternative** in the same product category, or
 - **not so clear-cut** (remaining cases); to be discussed whether at this stage it would be possible to identify whether there is **clearly no alternative**
 - Initial screening of **criticality/necessity**, identifying those cases where a use is:
 - **clearly critical/clearly necessary**, or
 - **clearly non-critical/unnecessary**, or
 - **not so clear-cut** (remaining cases)

➤ *Where no further scientific/technical assessment is needed, **decisions on the derogation or authorisation could already be taken at this stage (Step 3).***
- **Step two:** where needed, further **scientific/technical assessment** (if appropriate after adjustment of information requirements at the screening stage)
- **Step three:** **decision** on the derogation or authorisation.



Proposed process to apply the essential use concept in REACH

Flowchart - Options for assessment of essential uses in REACH



Thank you

EU Chemicals Strategy for Sustainability

© European Union 2021



Unless otherwise noted the reuse of this presentation is authorised under the [CC BY 4.0](https://creativecommons.org/licenses/by/4.0/) license. For any use or reproduction of elements that are not owned by the EU, permission may need to be sought directly from the respective right holders