Reaching a Decision to Apply

Workshop on Analysis of Alternatives and Socio-Economic Impacts in Applications for Authorisation

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Some Considerations for Deciding Whether to Apply for Authorisation

- **Do your business leaders and decision-makers understand the impact of authorisation, whether it is to continue use or to phase-out?**
- **What are your “potential” alternatives?**
- **Do you know the properties required to achieve the same technical function?**
- **What is your long-term business outlook if you continue to use the substance?**
- **If you “have” alternatives, can you phase out in 3 years, as a conservative estimate, from the time substance is placed on the Candidate List?**
- **What is your customer saying about SVHCs?**
- **Do your customers have alternatives available to them?**
- **What is your company’s R&D budget and long-term plan?**

Business and Economic Factors

Consideration	Remarks
Operate as usual and stop use by sunset date	• Feasible only for “non-strategic business”
Shut down manufacturing facility in the EU	• Loss of jobs locally • Disruption of supply to EU downstream users • Loss of innovation in the EU, especially if affected products are used in the areas of energy saving solutions, safety and protection of humans, etc.
Increase R&D to stop use of substance	• No guaranteed result • May not be possible if substance is used in majority of portfolio of products you sell → option, close business • Reality: during economic hardship, R&D resources may be reduced • Uncertainty of future market may be a disincentive to innovate
Ensure continued supply	• For formulators and articles producers, supplier has not confirmed they intend to apply for authorisation of your use • Allows for greater flexibility to choose between suppliers

Business and Economic Factors

Consideration	Remarks
Plans to reduce use of substance and its presence in products	• An option if no alternative substance or technology has been identified
Likelihood of obtaining authorisation	• Have communicated internally to business managers and decision makers on impact of authorisation and different options available • May have already identified available resources - both financial and expertise required - to prepare authorisation application • Possibility of joint application to share costs, but need to be wary of competition law issues • May already have information to show that health risks are adequately controlled or able to show little to no exposure throughout life-cycle of use of the substance.
Other uncertainties leading to decision to apply	• Cannot keep substituting if health concern criteria keep changing • Difference in RMO of alternatives with similar toxicity profile creates uncertainty in available alternatives and raises question of preference of one SVHC over another → "wait and see" approach

Alternatives: A major factor

Consideration	Remarks
Gather available information on potential alternative substances	• May already be known before decision to apply
Identify substance properties that are important for:	• Technical processing (e.g., does not destroy the raw material during formulation) • Function of the product (e.g., product sold downstream retains the same desired properties)
Special applications typically have a narrow range of alternatives	• May have similar toxicity profile to substance where substitution is sought
Alternatives do not always provide the same (or better) technical function	• Especially important for applications where safety is a primary concern (e.g., automobile and aerospace industries)
Alternatives may be available	• But may not always be able to phase-out before application deadline and/or sunset date
Alternate way of processing (“technical alternatives”)	• Takes years of R&D efforts with no guaranteed result

Alternatives: A major factor

Solvent	Property 1	Property 2	Property 3	Commercial availability	Toxicity
Substance A	Good	Good	Good	Good	CMR
Alternative 1	Good	Good	Bad	Good	CMR
Alternative 2	Bad	Good	Bad	Good	CMR
Alternative 3	Bad	Bad	Bad	Limited	Unknown
Alternative X	Maybe	Good	Good	Good	Unknown

For example, would require significant increased use of energy → greater environmental impact

- Does not provide desired result during processing
- End product does not have the same technical function

- Uncertainty in available supply
- Limited data available → potential concerns on substance properties

Toxicity not well studied, but based on similar chemical properties to Substance A, not unreasonable to conclude it is a CMR

Downstream User (Customer) Reactions

Consideration	Remarks
Don't want any SVHCs!	• Proactive communication by supplier on long-term plans and actual potential health risks versus perception (i.e., risk communication) • For some uses, amount of substance remaining further down the supply chain is very low, and there is no or little exposure and release to the environment
• Disruption of supply • No alternatives for the downstream user	• Some industry sectors have lengthy recertification and requalification process required by law (e.g., air worthiness, product safety, quality assurance programs) • Some products may have thousands of components → potentially perpetual process of recertification/requalification • Even for minor changes (e.g., reduction in SVHC content), may still need to go through lengthy process → increased cost of doing business and need to stay competitive • Alternative material needs to be evaluated against real-life simulations (e.g., change in brake components in cars, electrical transformers, aircraft engines) • No alternatives that provide the same technical functionality → Wants reassurance that supplier intends to apply for authorisation

Other Considerations

Consideration	Remarks
Multiple uses	• Which use(s) to apply for?
Joint application	• What if other potential applicants have different assessment of the situation?
Company's internal structure	• Need to ensure internal alignment → more time may be needed to gather information and come to an agreement on path-forward
Unique application	• Submit application separately to avoid having to share information on a "niche" use
Foreign manufacturer	• Whether to apply for authorisation on behalf of your EU customers
Balancing perception vs. actual risks	• May be difficult for some business decision-makers to understand regulatory actions taken for an application that has been in use for decades with stringent RMMs and no reported incidents
Estimated time-line	• Need to provide business decision-makers with estimated time-line and resources needed for preparing an authorisation application

Facts about Authorisation

- **In coming to a decision to apply, find that authorisation:**
  - **Is complex and resource intensive**
  - **Creates a lot of uncertainty about the future market which can impact innovation in the EU**
  - **Increases cost of doing business, potentially resulting in losing competitive edge against outside competitors**

- **Other RMOs may be more efficient in ensuring protection of human health and the environment**

TIME PERMITTING

Backup Slides of Example Cases

OTHERWISE,
THANK YOU FOR YOUR ATTENTION!

Example Company A

- **Substance A in use for 50+ years, known toxicity**

- **Available in-house information:**
  - **No known viable alternatives, other similar solvents all have similar toxicity profile**
  - **Final Product has strong socioeconomic benefits**
  - **No other competitor products perform with the same functionality**
- **Use**
  - **Solvent during processing and ends up as an impurity at residual level with no technical function**
  - **Impurity in article cannot be easily removed, but could be reduced**
  - **No consumer use of article**
  - **Occupational exposure well-controlled due to known CMR property**

- **Began market analysis to gage customer reaction when Substance A proposed for inclusion to the Candidate List. Customer concerns:**
  - **Product no longer available long term**
  - **What are the risks to human health or the environment?**
  - **“Don’t want to have any SVHC content!”**

- **Approval from business managers and decision-makers to set aside resources to apply for authorisation**

- **Decision to apply:**
  - **Immediately when substance placed on the Candidate List**
  - **Otherwise, option was to shut down the facility in the EU**

These examples are not reflective of all scenarios, but provided as examples only!

Example Company B

- Substance X used in niche market, known toxicity
- Majority of Company B's formulated products contain Substance X
- Not possible to phase-out:
  - No alternatives to provide same functionality for downstream users in niche market
  - Customer indicated desire to continue use of Substance X products, recognizing they may potentially be banned → no currently suitable alternatives that provide the same technical function required
  - Customer has long requalification process

Decision to apply:

- **Made even before Substance X was placed on the Candidate List**
- **Major reason: no alternative and majority of formulated products contain Substance X used in niche market**

These examples are not reflective of all scenarios, but provided as examples only!