How to apply for authorisation

An overview of the key elements:
application strategy, use applied for,
CSR, AoA and SEA

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Outline

- **The starting point**
- Application strategy
- Use applied for
- Chemical Safety Report
- Analysis of alternatives
- Socio-economic analysis

Starting point

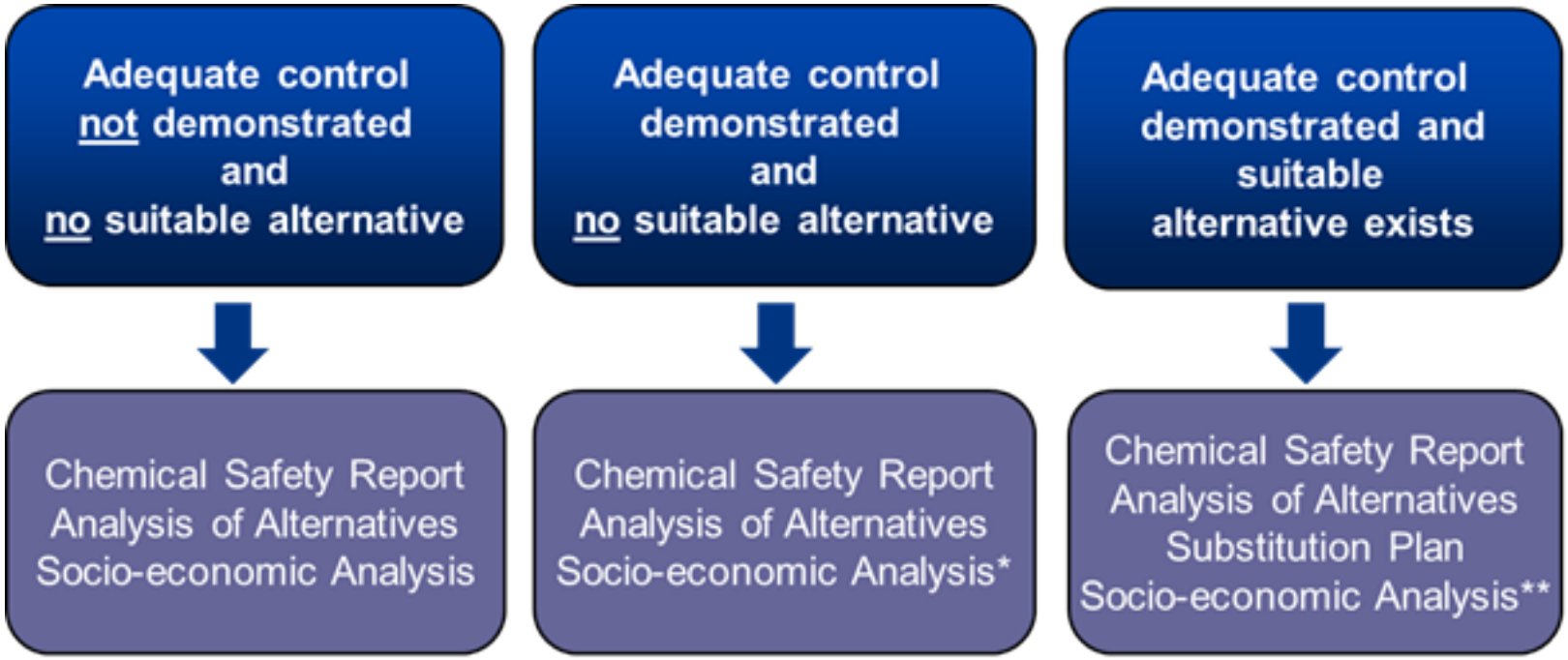
Adequate control route

- Threshold substances
- Applicants must show that the risk from using the substance is adequately controlled, i.e. that the exposure is below the derived no-effect level (DNEL) or the predicted no–effect concentrations (PNEC)

Socio-economic route

- Non-threshold substances AND threshold substance for which adequate control is not supported
- Applications must show that the socio-economic benefits of using the substance outweigh the risks and that there are no suitable alternative substances or technologies

Assessment Reports: possible packages



* highly recommended

** recommended

ECHA offers extensive support

- Guidance documents, Q&As, instructions and user manuals, available at: http://echa.europa.eu/applying-for-authorisation
- 'How to apply for authorisation' guide published in December 2016: https://echa.europa.eu/documents/10162/13637/apply_for_authorisation_en.pdf
- Publishes information on how RAC and SEAC treat applications (e.g. length of review period, economic feasibility, confidentiality), as well as RAC's Reference DNELs/dose-response relationships: https://echa.europa.eu/applying-for-authorisation/evaluating-applications
- Partners' service for applicants: https://echa.europa.eu/applying-for-authorisation/partners-service-for-applicants
- Pre-submission information sessions considered very useful
- Specific help to small and medium sized companies: http://echa.europa.eu/support/small-and-medium-sized-enterprises-smes
- Seminars, webinars, workshops & one-to-one sessions: https://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation/afa

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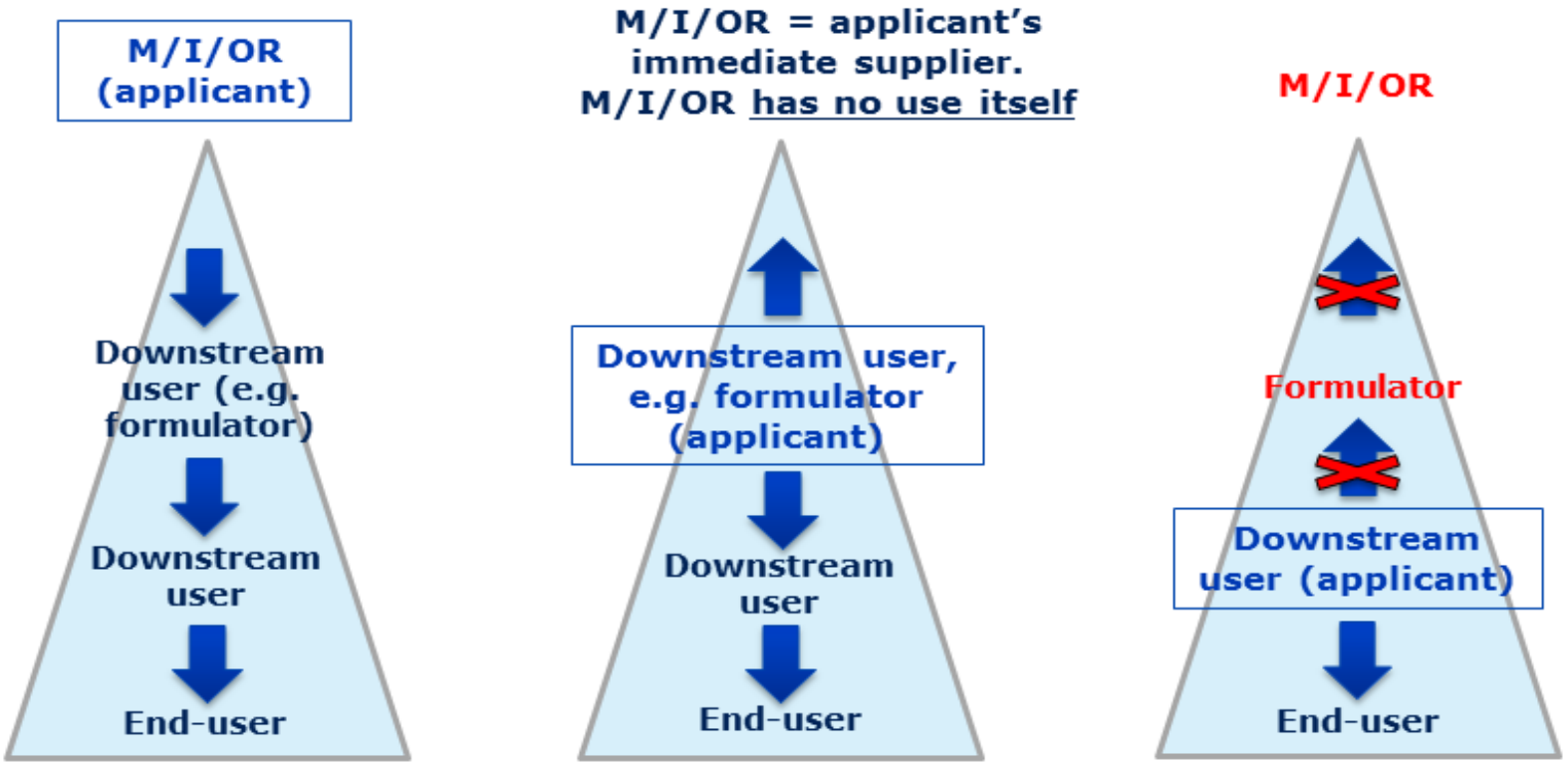
Consider how to apply



M/I: manufacturer/importer of the substance
Arrows: possible authorisation coverage
Rectangles: position of applicant in the supply chain

Scale of an application

Applicants	Uses and sites
Single downstream user: One or more own uses on own site(s)	Typically simple scope with specific data (e.g. on exposure, suitability of alternatives, markets, profits etc.)
Multiple downstream users: single or multiple own uses on multiple (named) sites	Larger, more complex downstream applications – representativeness of OC, RMM and exposure data comes into play
Upstream actors: single or multiple uses on multiple (sometimes un-named) sites covering part of a supply chain	Large upstream applications, where representative 'standards' on OC, RMM and exposure data are proposed

Consider the scope and number of uses

- Defining the scope of an authorisation application should be an iterative process.

Uses with a narrow scope

+ Uncomplicated exposure scenarios

+ Definitive assessment of the suitability of alternatives

+ Clear justification that benefits outweigh risks (socioeconomic route only) for the requested review period; potentially leading to greater potential for a longer review period and more certanty that an authorisation will be granted

- Application costs may be greater

Uses with a broad scope

+ Application costs may be lower

- More complex and/or greater number of exposure scenarios

- Challenging to prove the absence of suitable alternatives

- Justification for authorisation or review period could be affected by uncertianties; potentially leading to a short review period or even a refused authorisation

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Use applied for

- **Defining the uses applied for is critical**
- Uses define the scope of your application and are therefore the core of your application and the basis for any authorisation granted.
- Individual uses must be defined clearly and described in detail to minimise the uncertainties that may affect how your application is evaluated. Give the context of your use (within your process, your business, the market and society).
- Uncertainties in relation to the scope of the use may lead to a shortening of the review period for the whole use or potentially to not granting an authorisation.

Use description

A use description contains the following elements:

1. The **name** of the use applied for
   - Should ideally include: the function of the substance, the end-product(s) and the market sector
2. A description of the use in relation to **exposure scenarios**
   - Should describe operational conditions and risk management measures, the underlying process and the specific tasks leading to exposure of workers, consumers and the environment
3. A description of the use in relation to an **analysis of alternatives**
   - Should include a clear set of technical criteria/specifications/functional requirements for the AXIV substance and for the end-product(s)
   - Don’t apply for uses where you know there are suitable alternatives. If there are “sub-uses” where suitable alternatives exist, identify them and state, that they are not included in your application.

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Chemical Safety Report (CSR)

- The CSR describes the use/**exposure scenarios** of the substance and the **risks** to human health and/or the environment arising from its intrinsic properties specified in Annex XIV.
- The CSR only needs to address the risks posed by the hazard properties of the substance that are listed on Annex XIV. Other properties may be relevant for the AoA.
- Instead of submitting a complete CSR, ECHA recommends that where RAC reference DNEL or dose-response relationships are used by an applicant, **only Sections 9 and 10**, i.e. the exposure scenarios and the risk characterization, are included in an application for authorisation.

Exposure Scenario

- An exposure scenario is the set of operational conditions (**OCs**) and risk management measures (**RMMs**) that, together, describe the use of an Annex XIV substance and the measures taken to control exposures of humans and the environment.
- The exposure scenario is sub-divided into environmental, worker and consumer contributing scenarios.
- Several worker contributing scenarios (**WCS**) can be used to distinguish between the exposure potential of different tasks within a single multi-step industrial process (e.g. sampling, material transfer, unloading of end-products from racks or jigs) or to distinguish between different groups of workers (e.g. process vs maintenance workers).

Risk characterisation

- Calculation of **RCRs** or excess **risks** should be undertaken for **all relevant** endpoints, tasks, routes of exposure and populations (including article service life and consumer uses of mixtures).

- Where applicable, risk characterisation for workers should
  - be undertaken based on aggregated and shift-long exposures across different tasks and
  - incorporate all relevant routes of exposure e.g. inhalation and dermal.

- Adequate control route: sensitivity analysis may be prudent where RCR values approach 1.

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Analysis of Alternatives (AoA)

In the AoA, the applicant identifies alternative substances or technologies and analyses their:

- Technical feasibility
  - Should be judged based on whether or not (or to what extent) the alternative fulfils or replaces the function of the Annex XIV substance
- Economic feasibility
  - Changes in the costs and revenues of those actors currently using the Annex XIV substance - if they adopted the alternative
- Availability
  - An alternative can generally be regarded as available, when it is reasonably accessible before the sunset date and available in the required quantity to allow implementation
- Risk reduction potential
  - A suitable alternative must result in a reduced overall risk to human health and the environment compared with the use of the Annex XIV substance

Analysis of Alternatives (AoA)

- Applicants should also outline their **substitution** planning activities:
  - Past, current and future activities related to the identification of possible alternatives
  - The estimated time that would be required for testing any identified alternative candidates and the time needed for any relevant certification, qualification or regulatory approval
  - R&D capacities and time optimisation (e.g. whether parallel activities or testing are possible or not)
- This information is taken into account in setting the **length of review period**.
- A substitution plan is required in an application where adequate control is shown and alternatives are considered to be suitable. The plan details the timetable for replacement of the Annex XIV substance in the use applied for.

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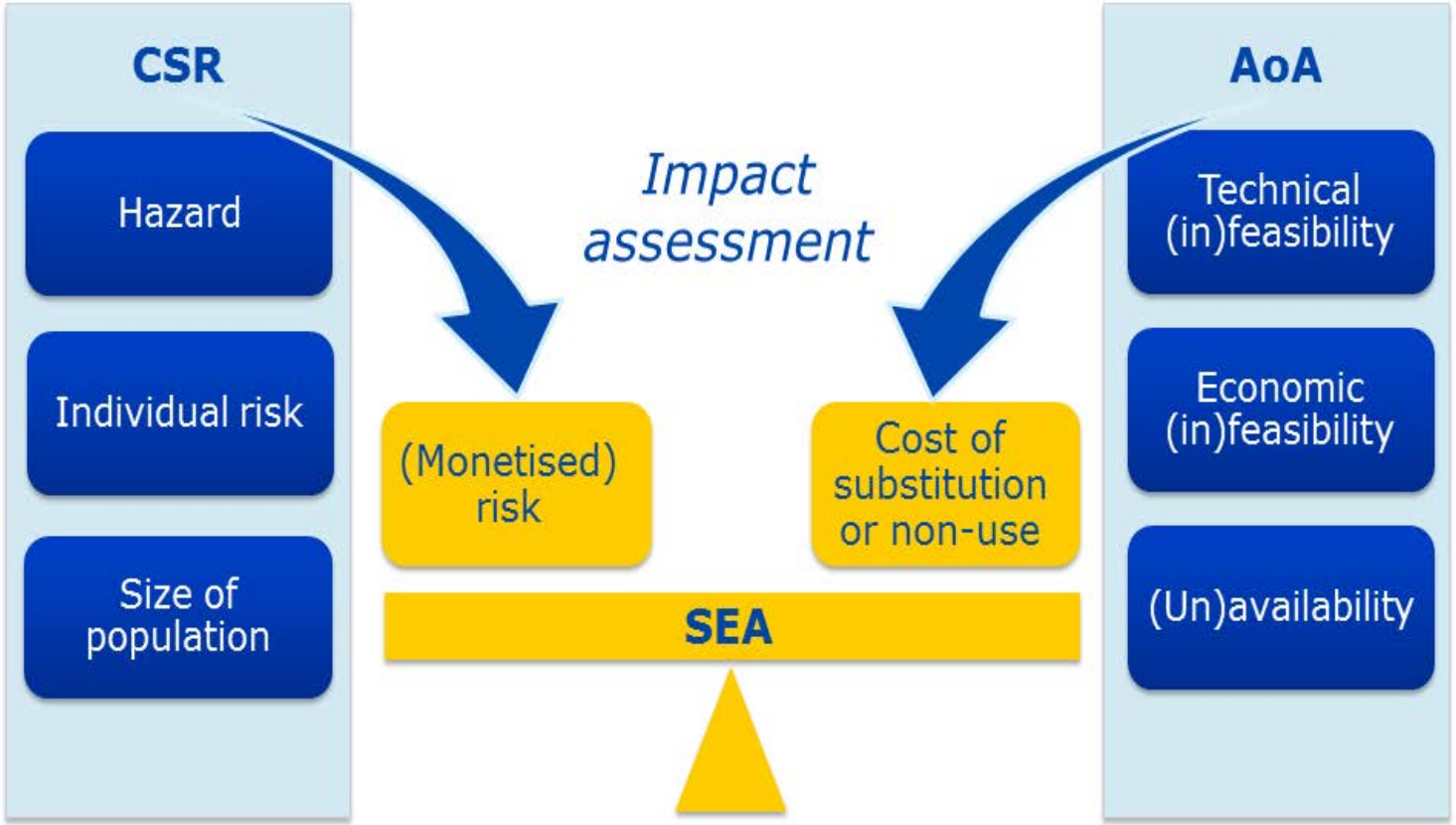
Socio-economic Analysis (SEA)

- The SEA describes what would happen if the applicant or other actors in its supply chain were no longer able to use the substance (“non-use scenario”), and what the impacts to the applicants and other affected actors would be.
- The aim is to conclude whether the socio-economic benefits of the applicant’s continued use of the substance outweigh the risks to human health and the environment.
- Socio-economic benefits are considered in a broad sense to include impacts on applicants, suppliers, consumers, competitors, market functioning, etc.
- Applicants should not only consider the impacts on them, but explain the anticipated reaction of the market to changes in the product/service affected in terms of quality, performance, price, availability and value added to society.

Links between CSR, AoA and SEA



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