# Description of uses for authorisation / Broad Information on Uses

ECHA's seminar on Applications for Authorisation

2 October 2012

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# Content

- Definitions and terminology
- Exemptions – Supply chain considerations
- Principles for the development of a “use applied for”
- Broad Information on Uses (BIU)

# Definitions and terminology

# Definitions and terminology (1/2)

- Article 3 (24): *"Use: means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation;"*

# Definitions and terminology (2/2)

- **Identified use** [Article 3(26)]
  - Developed by registrants in the registration dossiers
  - Mentioned in Annex VI section 3.5

- **Use applied for** [Article 60(9)(c)]
  - Developed by applicants in the authorisation dossiers
  - Use for which the authorisation is granted

- **Broad information on uses** [Article 64(2)]
  - Developed by ECHA after an application has been submitted
  - Covers the "uses applied for"
  - Published on ECHA's web-site for public consultation on alternatives
  - Aim = receive from third parties meaningful information on alternatives
  - RAC/SEAC consider the received information in their opinions

# Exemptions – Supply chain considerations

# Exemptions

- Some general exemptions:
  - scientific Research & Development
  - all intermediates
  - substances for which management of risks for human health and/or environment are already covered by other relevant Community legislation (medicinal products, cosmetic products, food and feed, food contact material, biocides and pesticides, fuels)
  - …
- Authorisation process cannot cover risks related to:
  - manufacturing processes
  - imported articles containing the substance

# Supply chain considerations

- **Article 66**
  - DU don't necessarily need to apply but…
  - shall notify ECHA if using a substance in accordance with **Art 56(2)** i.e.
  - in accordance with the conditions of an authorisation granted to an actor up his supply chain for that use
  - No obligation for applicants to "declare" DUs in their applications

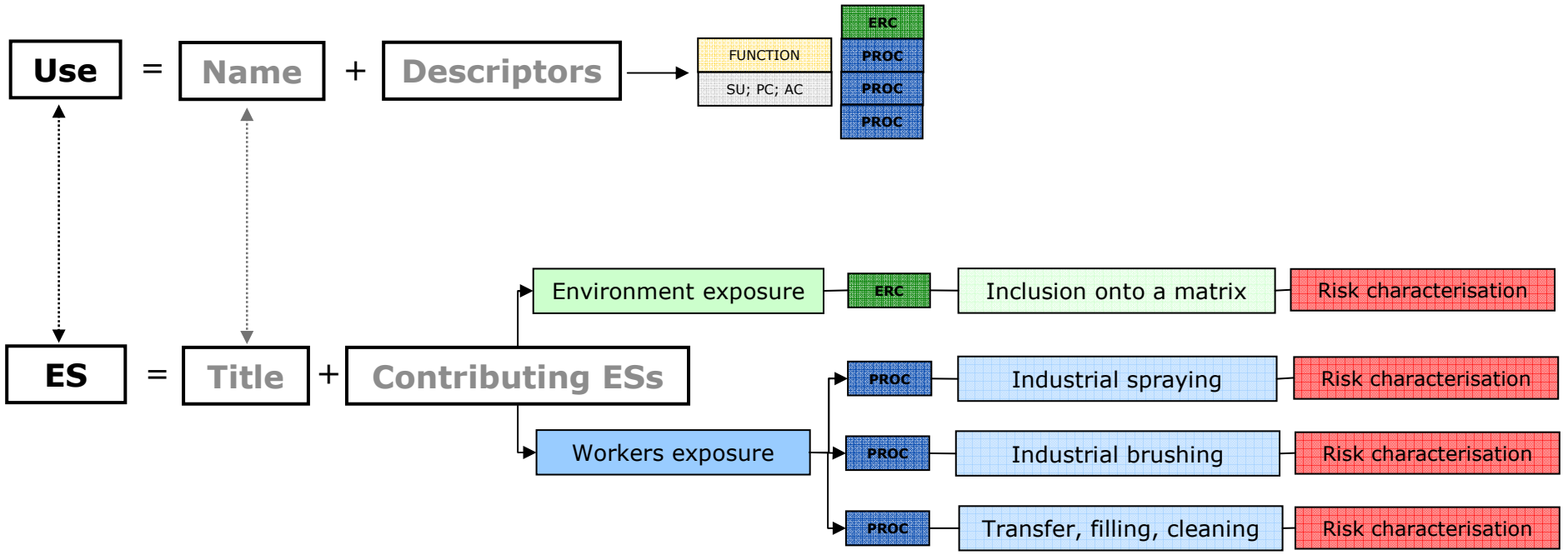
- **Article 56(1)(e)**
  - in practice EU manufacturers or importers who only place the substance on the market are exempted from authorisation provided that:
  - the immediate downstream user they provide the substance with has an authorisation for his own use

- To avoid supply disruption someone has to apply (REACH does not seem to allow a DU to cover a use up his supply chain)

# Main principles for the development of a "use applied for"

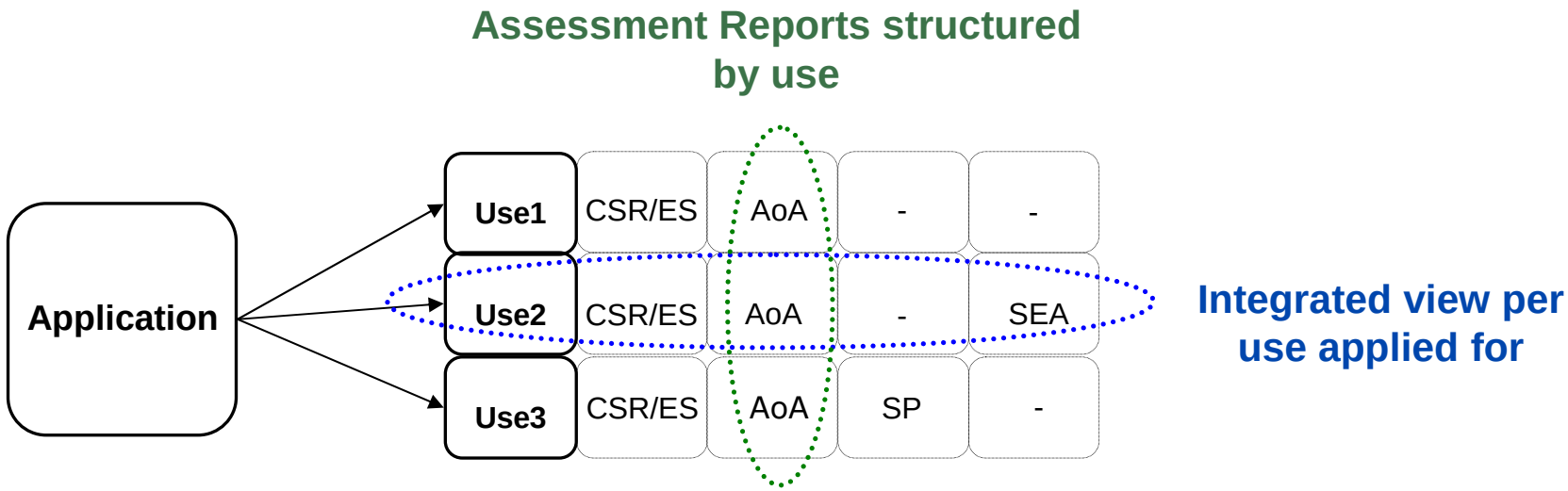
# "Use applied for" development (1/4)

- Constituents of a "use"
  - a name, and a set of descriptors, function,
  - a link to an exposure scenario in the CSR covering this use and demonstrating safe use or minimisation of risks



# "Use applied for" development (2/4)

- ECHA recommends to structure the assessments reports by use



# "Use applied for" development (3/4)

Description of "use applied for" is characterised by

- Its scope: market sectors, supply chains, processes, end-products, articles, life-cycle stages

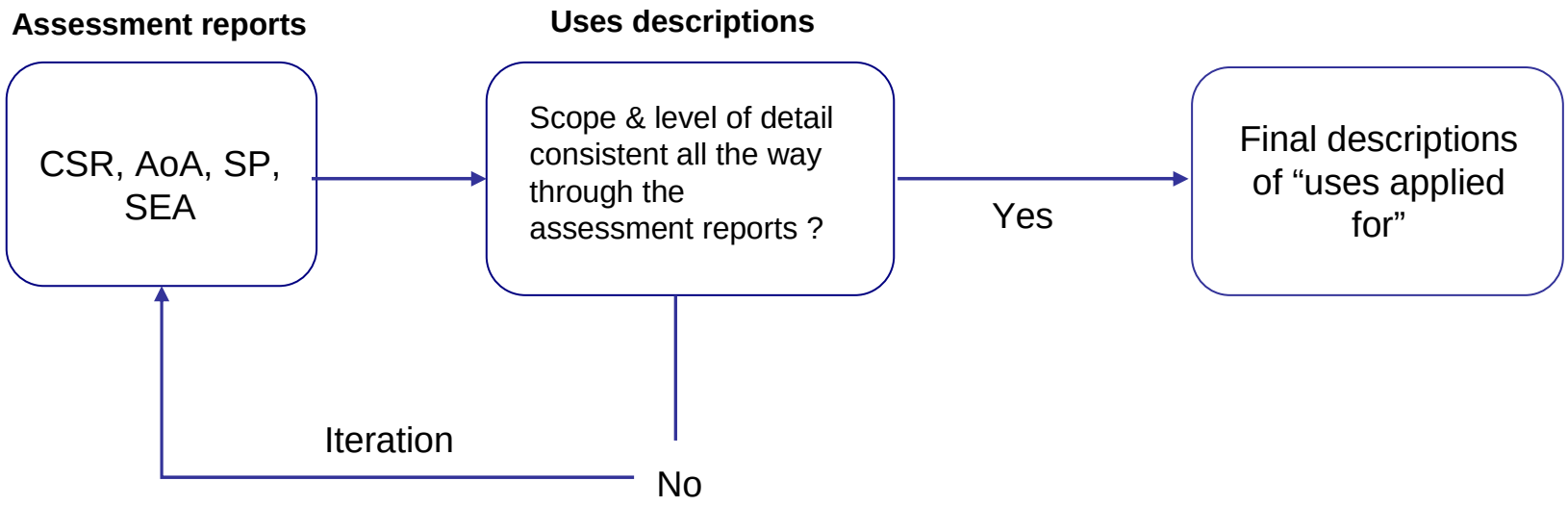
- Its level of detail: precision of information contained in the name of the use, the exposure scenarios (title, descriptions of tasks, OCs & RMMs), the assessment reports (AoA, SP, SEA)

# "Use applied for" development (4/4)

- Approach taken during registration…
  - CSA performed at the highest level of the supply chain
    - Wide coverage from the top to the bottom
    - Impractical to prepare a large number of detailed/specific uses descriptions
    - More advantageous to group uses in a smaller number of generic ESs
- … is a good basis for the development of "uses applied for"…
- but "identified uses" in registration dossiers can be refined if
  - applicants don't need to apply for all registered identified uses
  - applicant wants to start a new use
  - suitable alternatives are available but only in some market sectors, supply chains, processes, or articles
  - overall emissions and risk characterisations are impacted
  - applicant wishes to provide more precise information/improve the quality

# "Use applied for" Tier approach

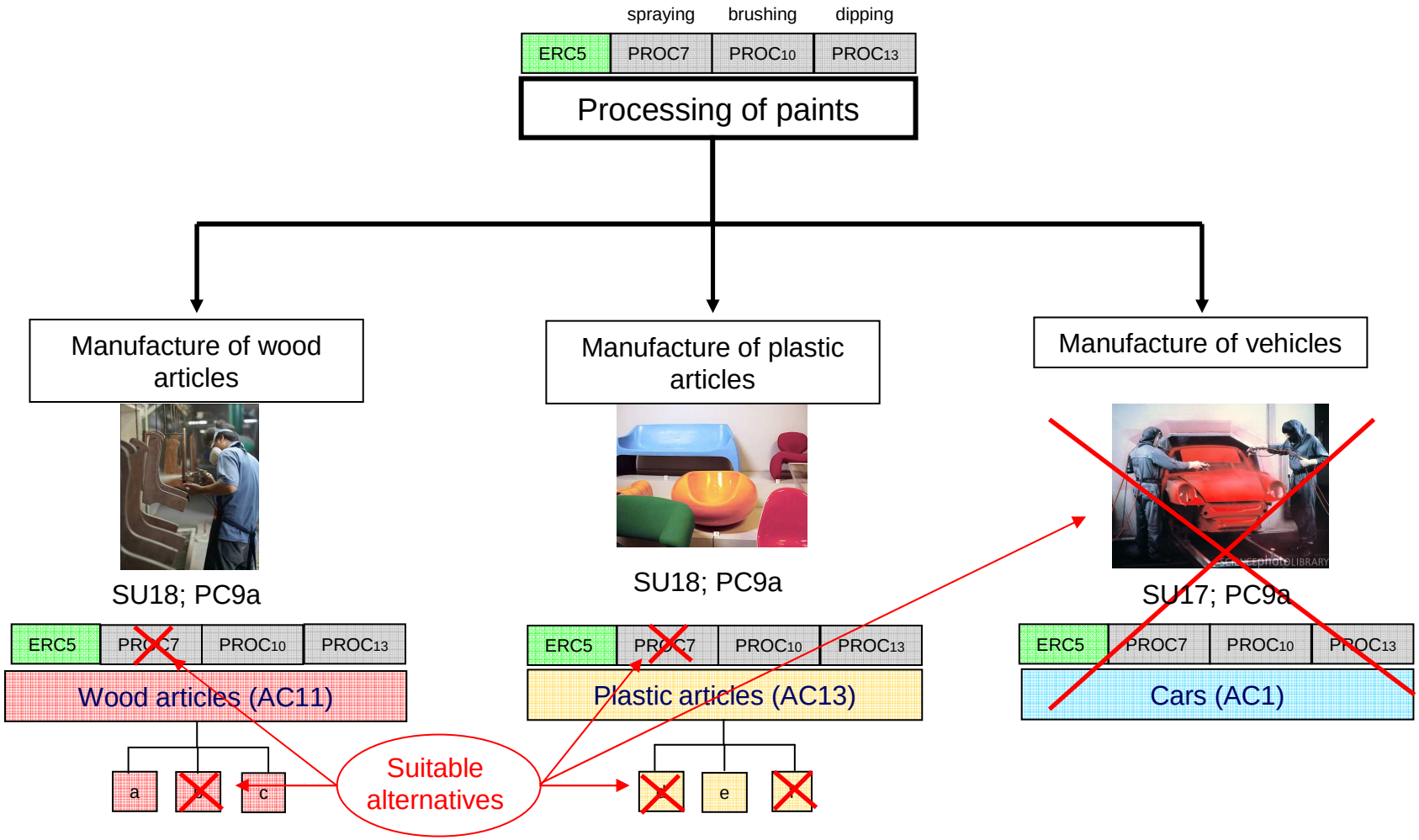
- Development of a use description is an iterative process to be finalised after the work on the CSR, AoA, SEA has been carried out




- Work on AoA and SEA important for the initiation of the iterative process for the derivation of the final scope of the use(s)

# Example (1/2)

- One use may take place under different conditions in different market sectors



# Example (2/2)

Use1

Use of paints to be applied by HPLV spraying, brushing and dipping onto wood articles

SU18; PC9a

ERC5 | PROC10 | PROC13

Wood articles (AC11)

Indoor use | Outdoor use

Use2

Use of paints to be applied by brushing and dipping onto plastic articles

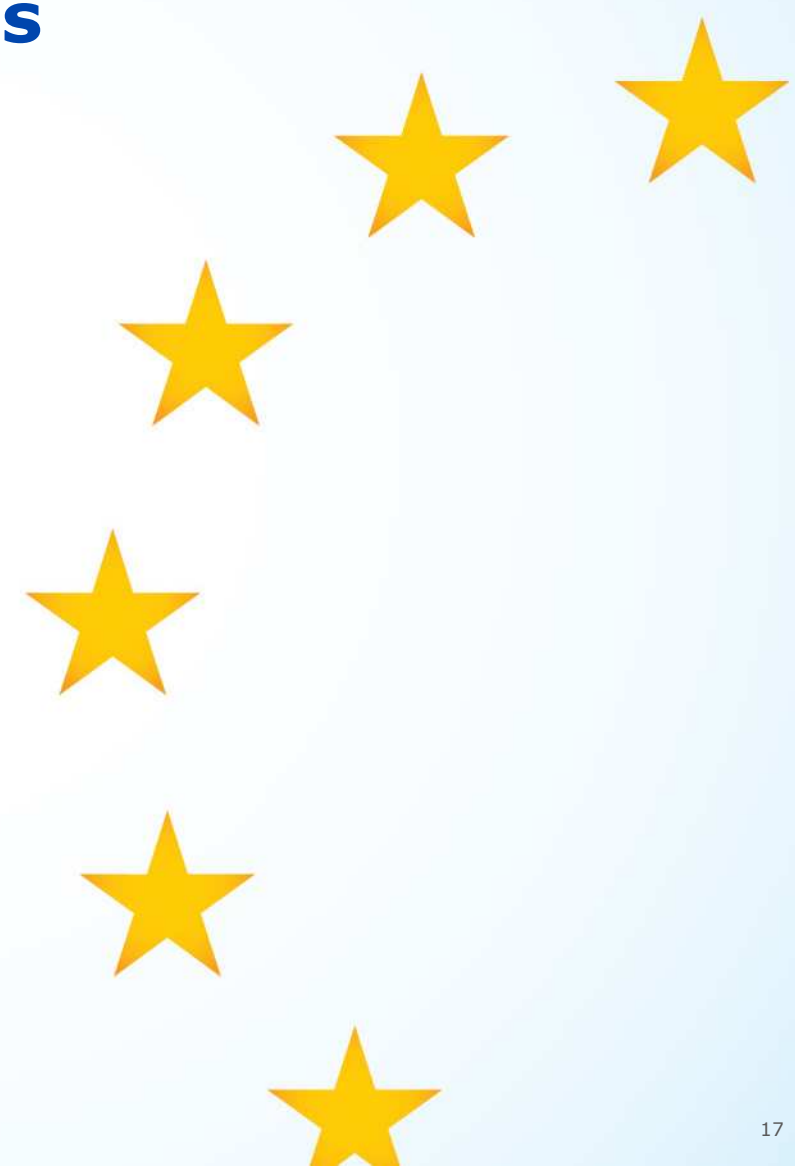
SU18; PC9a

ERC5 | PROC10 | PROC13

Plastic articles (AC13)

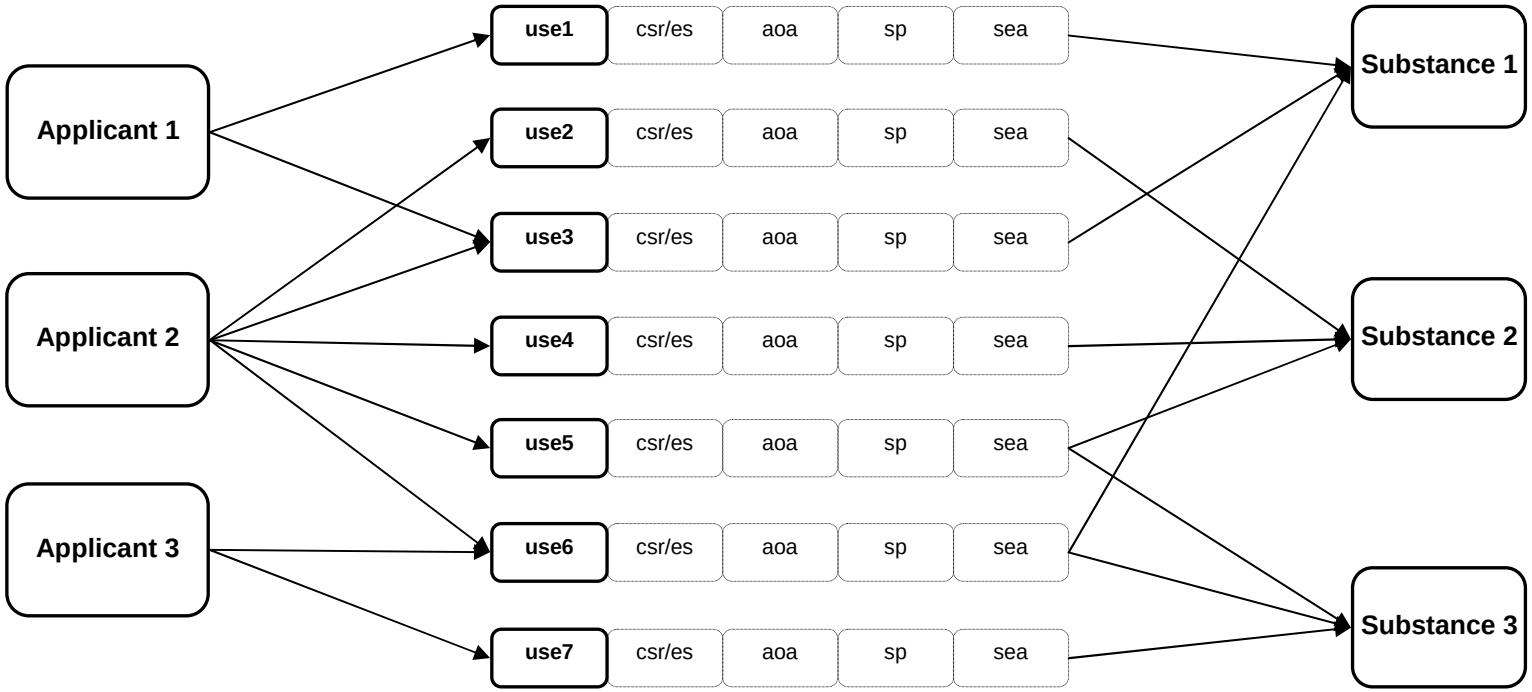
Outdoor use

# Uses in joint applications



# Uses in joint applications

## Complex applications



# Uses in joint applications

## Complex applications

**Scenario 4: all uses shared by all applicants**

| | Use 1 | Use 2 | Use 3 | Use 4 |
|---|---|---|---|---|
| **Person 1** | X | X | X | X |
| **Person 2** | X | X | X | X |
| **Person 3** | X | X | X | X |

**Scenario 2: not all uses are shared**

| | Use 1 | Use 2 | Use 3 | Use 4 |
|---|---|---|---|---|
| **Person 1** | X | | X | |
| **Person 2** | | | X | X |
| **Person 3** | X | X | | X |

**Scenario 3: all uses shared – not by all applicants**

| | Use 1 | Use 2 | Use 3 | Use 4 |
|---|---|---|---|---|
| **Person 1** | | X | X | X |
| **Person 2** | X | X | X | |
| **Person 3** | X | X | X | X |

**Scenario 1: none of the uses is shared**

| | Use 1 | Use 2 | Use 3 | Use 4 |
|---|---|---|---|---|
| **Person 1** | X | | X | |
| **Person 2** | | X | | |
| **Person 3** | | | | X |

# Broad Information on Uses

# Broad Information on Uses (1/5)

- **Why?**
  - To provide information on the uses of the Annex XIV substance for the sake of the public consultation on alternatives
  - Enable third-parties to provide useful information for the Committees when evaluating assessments made by applicants on alternatives

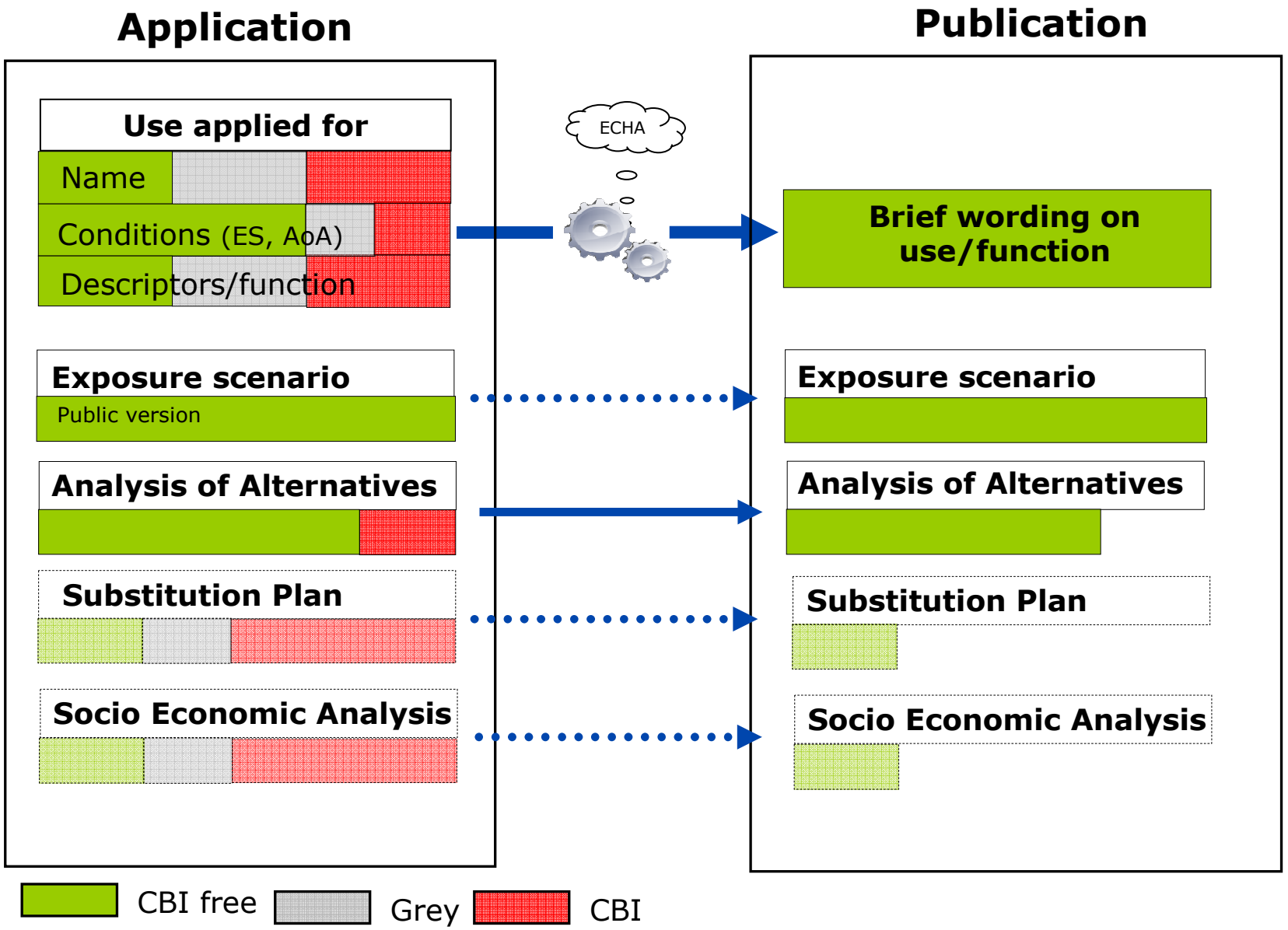
- **What?**
  - Set of public information related to the "use applied for" Annex XIV substance
  - Disclose key information related to the use (conditions, function) and to the AoA, SP, SEA
  - Trade-off between meaningfulness/level of detail and confidentiality
  - Exact content developed in consultation with NGOs and Industry and communicated at the last Stakeholders day

# BIU / Public consultation (2/5)

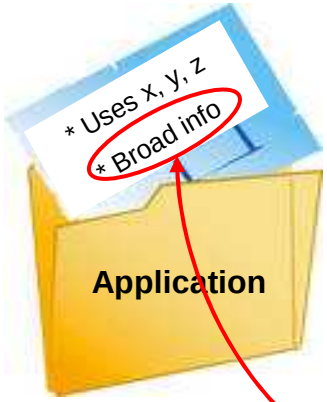
ECHA intends to publish…

- Name of the applicant
- "Brief wording" of the Broad Information on Use including
  - Name of the use
  - Conditions of use (exposure, functional requirements)
  - List of use descriptors (codes, function)
- Public version of the Exposure Scenario
- Public version of the Analysis of Alternatives
- Public version of the Substitution Plan
- Public version of the Socio-economic Analysis

# BIU / Public consultation (3/5)



# Broad Information on Uses (4/5)

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Application form
for an application for authorisation

*Fields marked with an asterisk (*) are mandatory.*

**Substance(s) applied for**

Please note that in accordance with Article 62(3) of REACH Regulation, applications may be made for one or several substances that meet the definition of a group of substances in section 1.5 of Annex XI of REACH. If the application is for several substances, an argumentation for substance grouping must be appended in the Category Rationale field of the IUCLID 5 application file.

* Total number of substances: 1

* Substance 1: 1. 5-tert-butyl-2,4,6-trinitro-m-xylene (Musk xylene) [EC number: 201-329-4]

**Use(s) applied for**

Please enter, for each use applied for, the use description (in the fields "Use 1", "Use 2" etc.) and the "proposed brief wording on use" in the respective fields below the use descriptions.

**The numbering and the descriptions of uses should be identical with the ones in section 3.10 of the IUCLID application for authorisation dossier under the "Use concerned by the request" field.**

Note regarding the "proposed brief wording on uses":
*Pursuant to Article 64(2) of REACH Regulation ECHA is required to make available on its web-site broad information on uses applied for, and open a public consultation inviting interested parties to submit information on alternative substances or technologies. This broad information on uses of the Annex XIV substance should be meaningful enough to enable interested parties to submit relevant and useful information on possible alternatives.*
*The "brief wording", which is dedicated to the public consultation, is recommended to contain the following set of public information: i) Name of the "use applied for"; ii) Key elements on the conditions and constraints under which the substance is used and the function is delivered (e.g. process conditions, quality criteria for the end-product etc); iii) List of descriptors (codes for ERC, PROC, PC, SU, AC and picklist values for the function; or a simple reference to the descriptors and function(s) in the IUCLID dossier, if all can be considered as public).*
*Based on the proposal submitted by the applicant (if any) and the information contained in the application, ECHA will establish an initial version of this "brief wording" and will invite the applicant to provide comments within a specified deadline. On the basis of the applicant's comments ECHA will establish and communicate to the applicant the final "brief wording" of the broad information on uses.*
*After the fee for an application for authorisation has been received, ECHA will publish on its website for the purpose of the public consultation: the final version of the "brief wording", the public version of the exposure scenarios, the public version of the Analysis of Alternatives, the public summary of the Substitution Plan (if any), and the public summary of the Socio Economic Analysis (if any).*

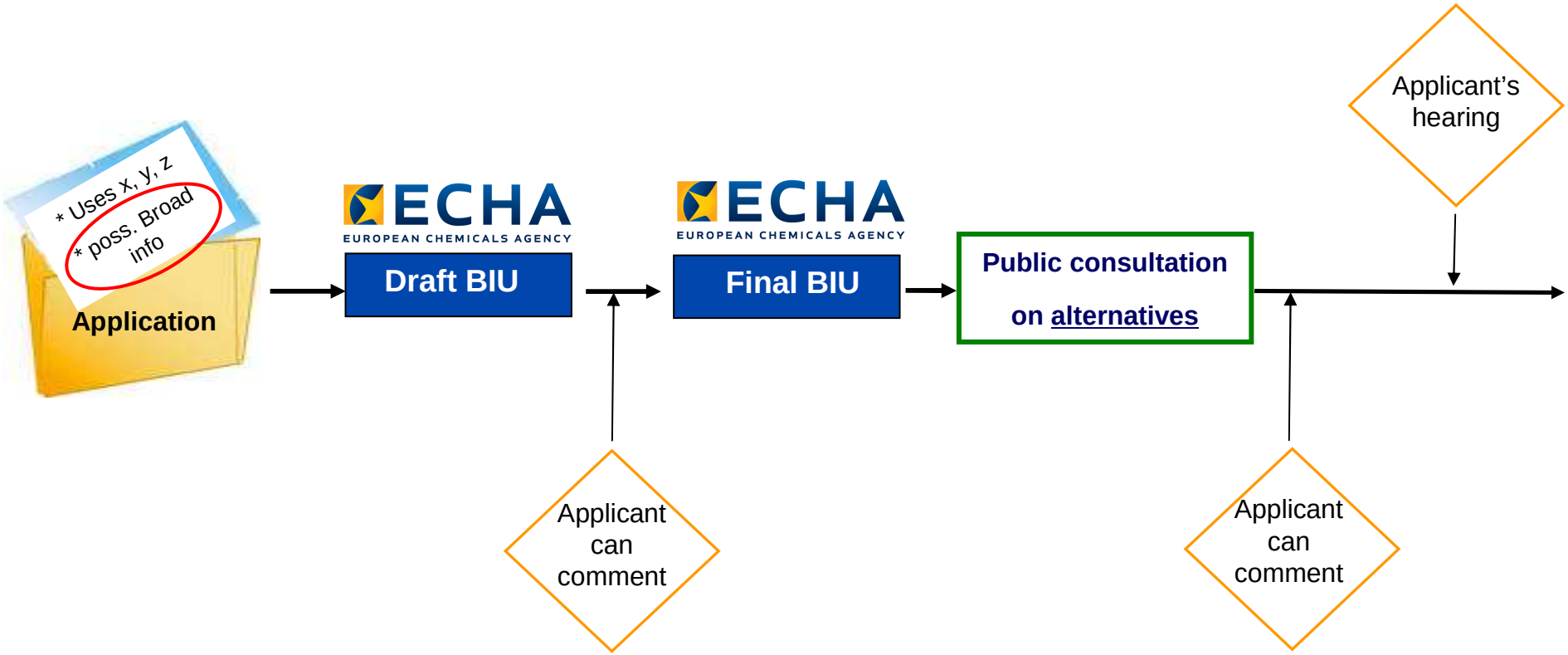
* Total number of uses: 5

* Use 1:

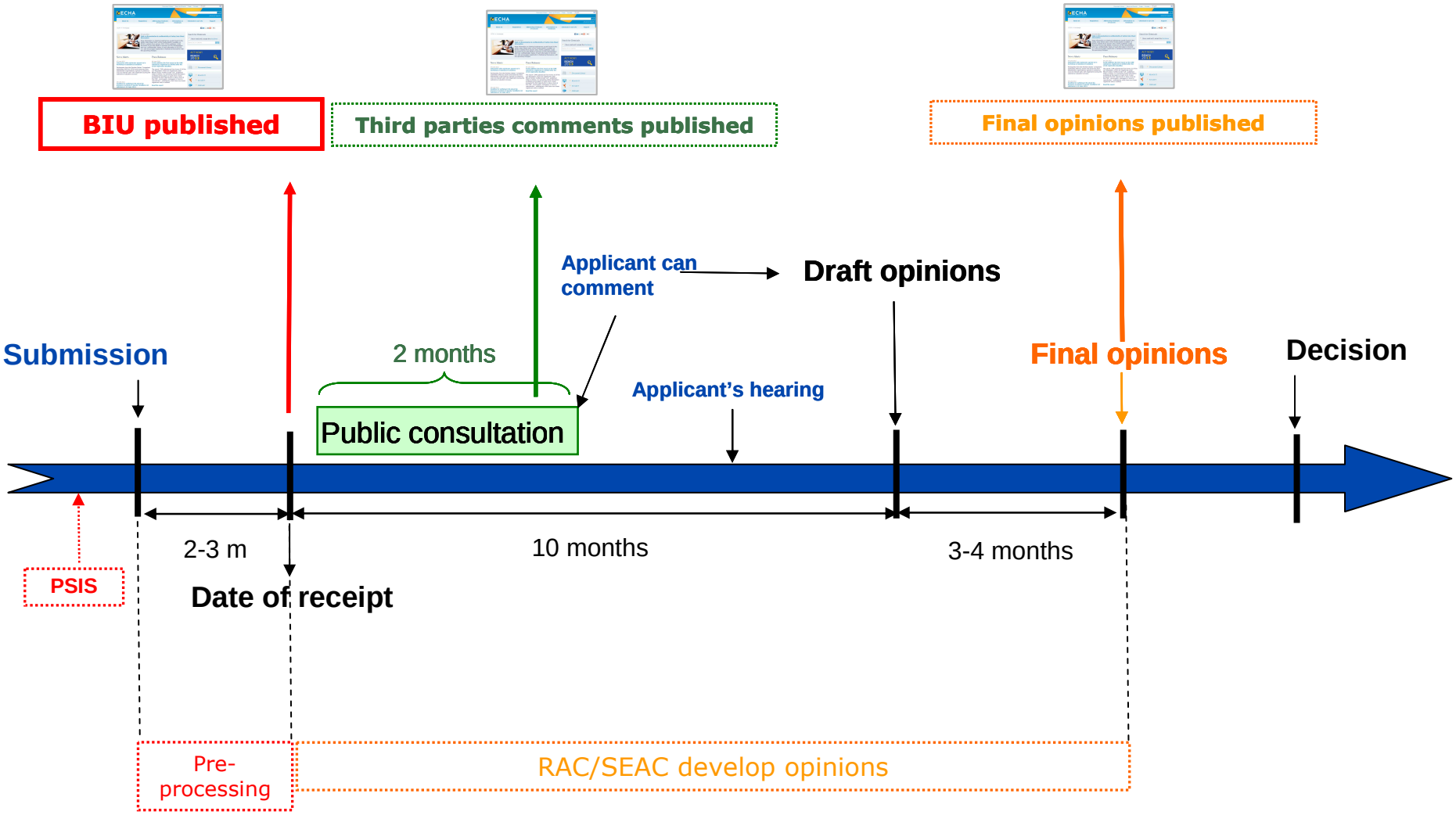
Proposed brief wording for Use 1:

# Broad Information on Uses (5/5)

- ECHA will determine on the basis of a proposal by the applicant (voluntary basis), a non-confidential "brief wording" describing the use(s) applied for



# Overview of publication of information in the AfA process



# Key messages

# Key messages

- Development of use descriptions…
  - use whenever appropriate the use descriptor system
  - describe properly the function
  - refine original (generic) descriptions of uses
  - develop the scope of uses, AoA, SEA via an iterative process

- Broad Information on Uses / Public consultation
  - BIU content developed in consultation with NGOs and Industry
  - BIU to be meaningful for public consultation
  - comments received by third-parties will be made public
  - applicants can respond to comments received
  - ECHA is developing further instructions/formats for applicants to develop their proposal and for third parties to submit their comments

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# Thank You!