

Description of uses for authorisation / Broad Information on Uses

Seminar on applications for
authorisation

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Outline

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

Terminology and definitions

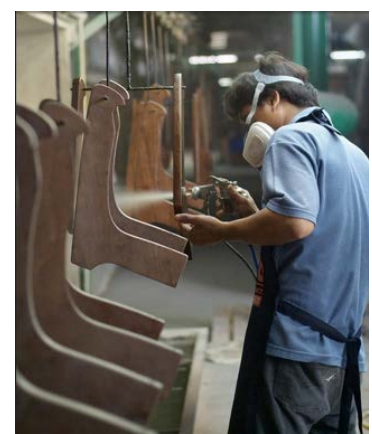


- **Identified use** *[Art 3(26)]*
 - Developed by registrants in the registration dossiers

- **Use applied for** *[Art 60(9)(c)]*
 - Developed by applicants in the authorisation dossiers
 - Use for which the authorisation is (not) granted

- **Broad Information on Uses (BIU)** *[Art 64(2)]*
 - Developed by ECHA after an application has been submitted
 - Covers the “uses applied for” of Annex XIV substance
 - Published on ECHA’s web-site to receive comments on alternatives during a public consultation

- 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;”*



Exemptions – Supply chain considerations



- **Exempted uses:**

- Scientific **Research & Development** < 1 tonne per year and per legal entity, under controlled conditions (analytical activities included)
- 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 feeding stuffs, food contact material, biocides and pesticides, fuels)
- Authorisation process cannot cover risks related to:
 - **Manufacturing** processes
 - **Imported articles** containing Annex XIV substances
- Further clarifications on-going on the exact scope of other legislations, manufacture and ancillary uses

Supply chain considerations (1/2)

- Manufacturers, importers, downstream users, and only representatives can apply and hold authorisations
 - for their own uses
 - for uses down their supply chains
- A downstream user can use a substance without applying or holding an authorisation provided that:
 - i. he notifies ECHA [Art 66]
 - ii. and he uses the substance in accordance with the conditions of an authorisation granted to an actor up his supply chain [Art 56(2)]

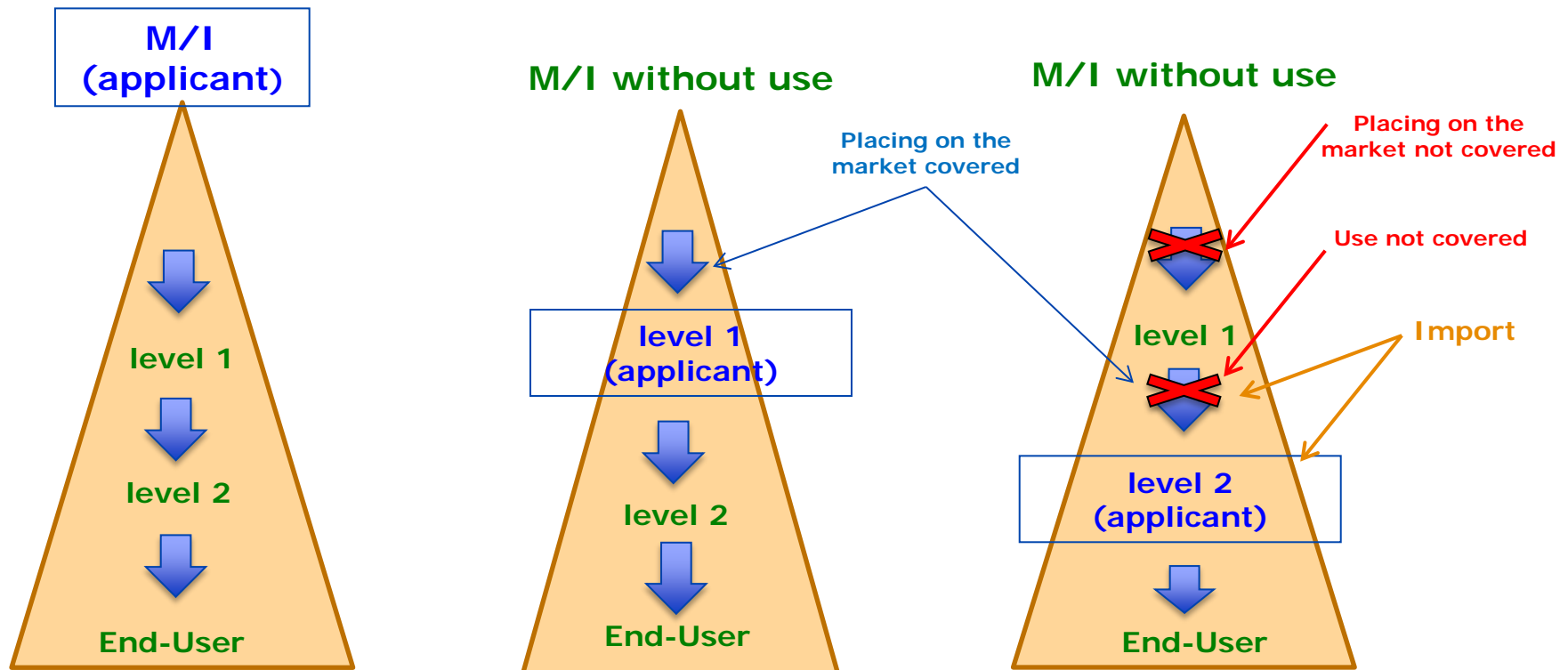
Supply chain considerations (2/2)

Use coverage: top-down but not bottom-up

→ No upward coverage of uses

→ Upward coverage of the 'placing on the market' only one level-up

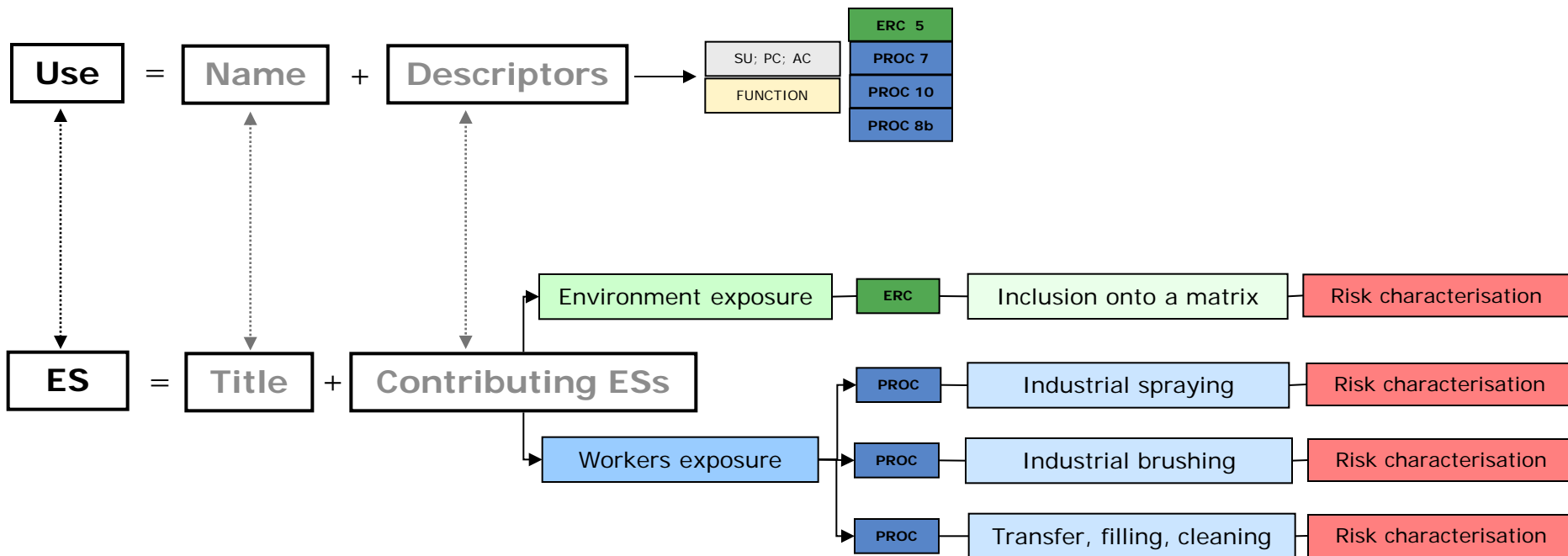
→ potential supply chain disruptions



Main principles for the development of a “use applied for”



- “Identified use” in the context of registration
 - Safe use: exposure/risk dimension (control, minimisation)
 - Link with the exposure scenarios and contributing scenarios



- Use vs exposure scenario:

- General Rule:



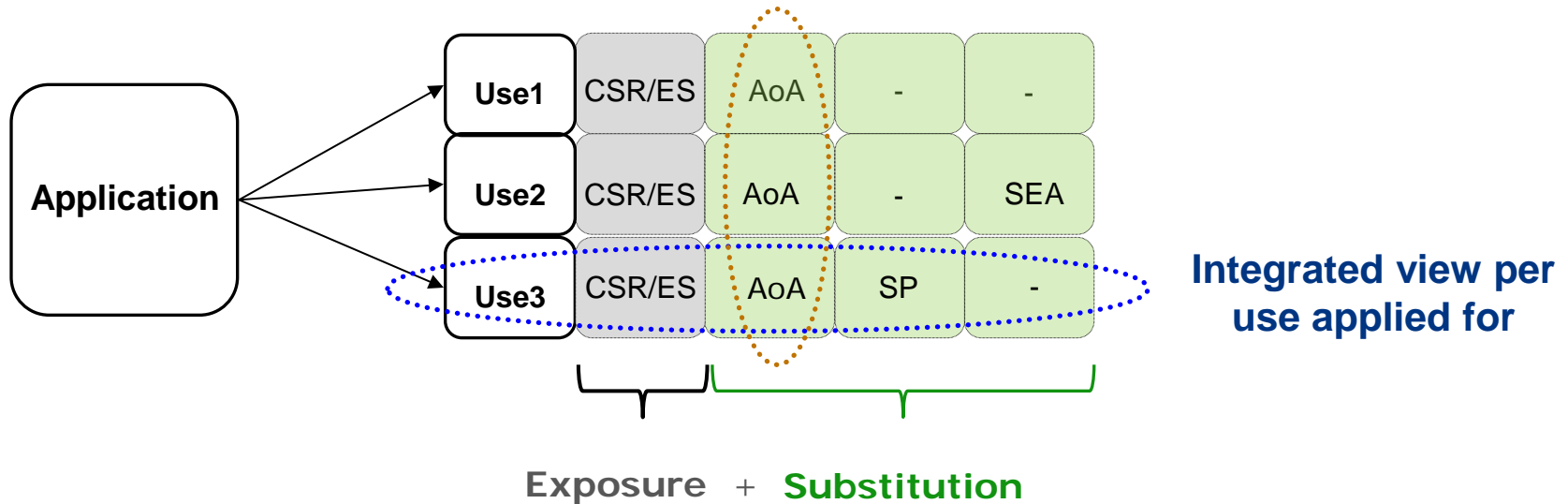
- one use → one exposure scenario (ES)
 - not recommended to group different life-cycle stages within the same use

- Example: Formulation

- Formulation = ancillary use to the end-use e.g. within an integrated technical process at a defined workplace
 - → One use and one exposure scenario. The main use is the end-use. One ES can cover all activities/tasks related to both the ancillary use and the end-use
 - Formulation = production of mixtures by formulators who supply different legal entities (e.g. end-users) for further uses
 - → Two uses and two exposure scenarios. Formulation by formulators + end-use by end-users

- “Use applied for” in the context of Authorisation
 - Exposure/risk dimension: (CSR/ES adequate control – risks minimisation) and
 - Substitution dimension: function, Analysis of Alternative (AoA, Substitution Plan (SP), Socio Economic Analysis (SEA)

Assessment Reports structured by use



Description of “use applied for” is characterised by:

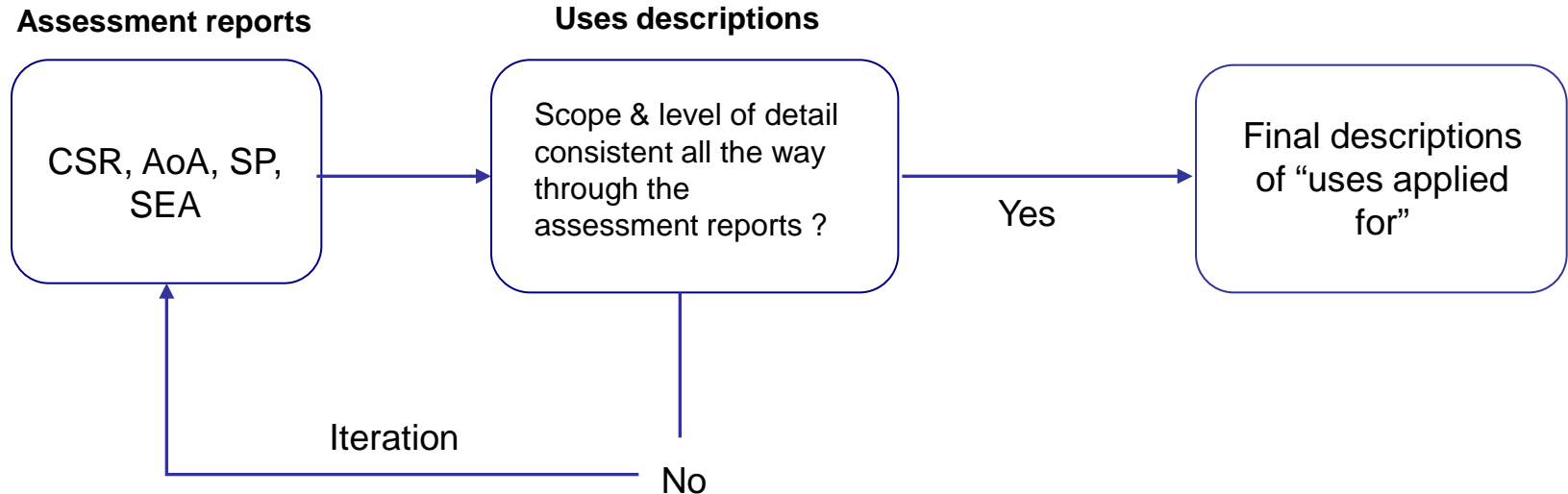
- Its level of detail: precision of information in the CSR/AoA/SEA to describe:
 - workers’ tasks, operational conditions, risks management measures
 - the analysis of the function provided by the AXIV substance
 - → Recommended to provide a sufficient level of detail so that all stakeholders can understand how the substance is used
- Its scope: a use can in theory cover a large number of:
 - technical processes, end-products/articles occurring in many
 - market sectors, legal entities/supply chains
 - → ‘Generic’ use vs ‘specific’ use: recommended to maintain the scope at a reasonable level of broadness (uncertainty on the representativeness of exposure levels and/or suitability of alternatives...)



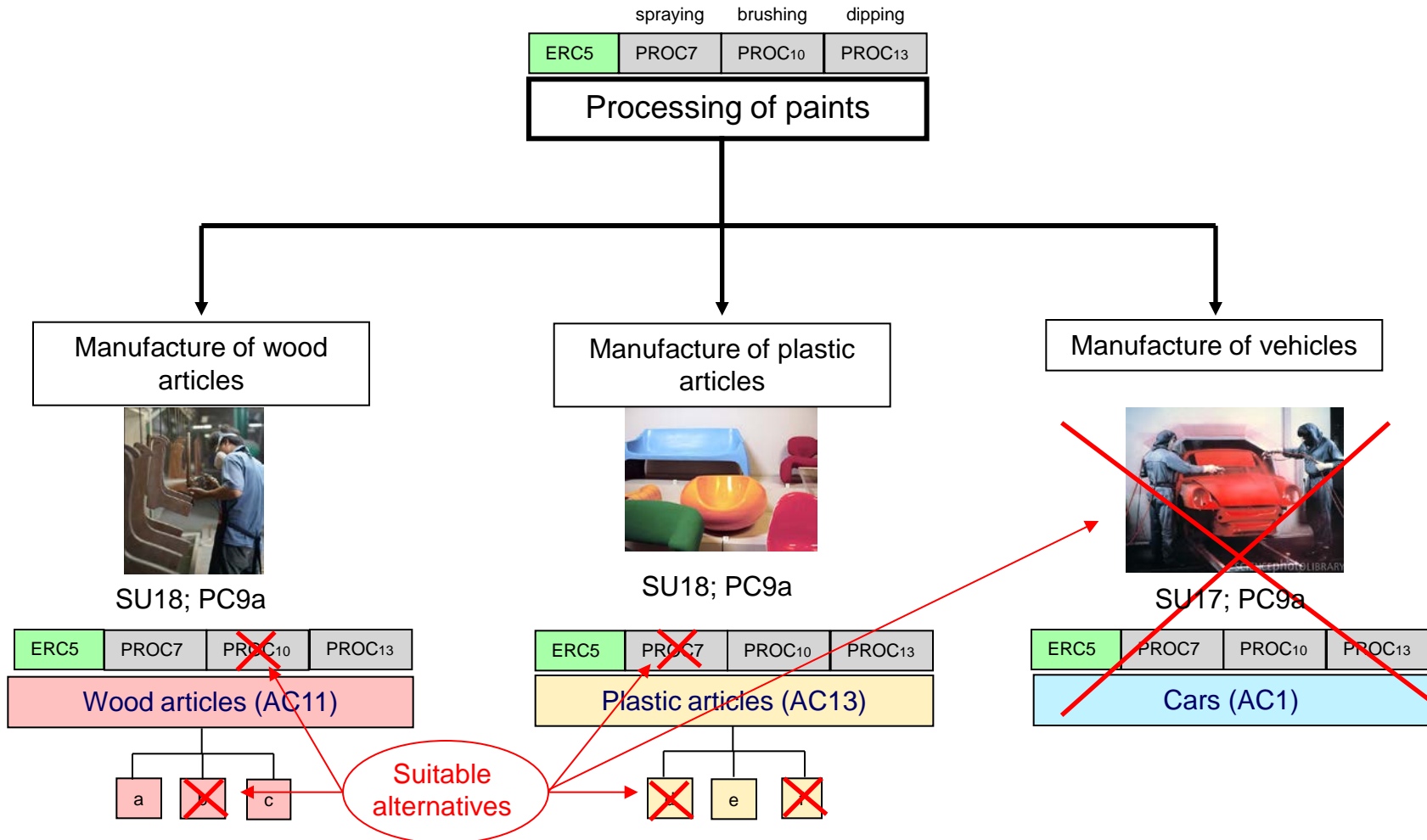
- Approach taken during registration...
 - CSA performed at the highest level of the supply chain
 - Wide coverage from the top to the bottom
 - Impractical to prepare a large number of detailed/specific uses descriptions
 - More advantageous to group uses in a smaller number of generic ESs
- ... is a good basis for the development of “uses applied for”...
- but initial scopes of registered “identified uses” can/should be refined in order to
 - focus on uses in specific market sectors, supply chains, processes or types of articles where e.g. there are no suitable alternatives
 - provide more precise information, improve the quality of the dossier
- Initial emissions and risk characterisations may also need to be refined

“Use scoping”: an iterative process

- Development of a use description 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 applied for



- The “same” use can take place in different market sectors



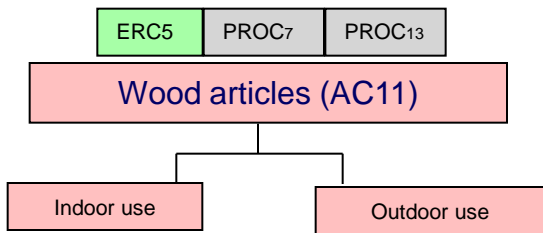
Example (2/2)

Use1

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

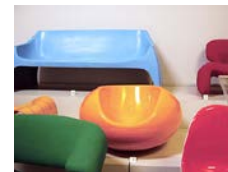


SU18; PC9a

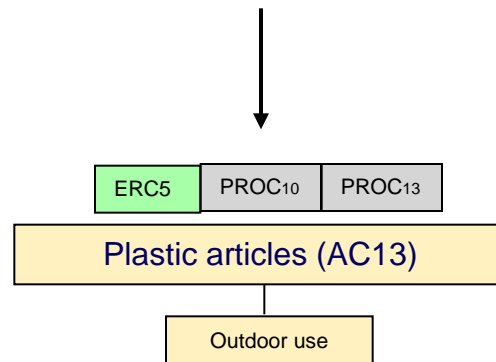


Use2

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



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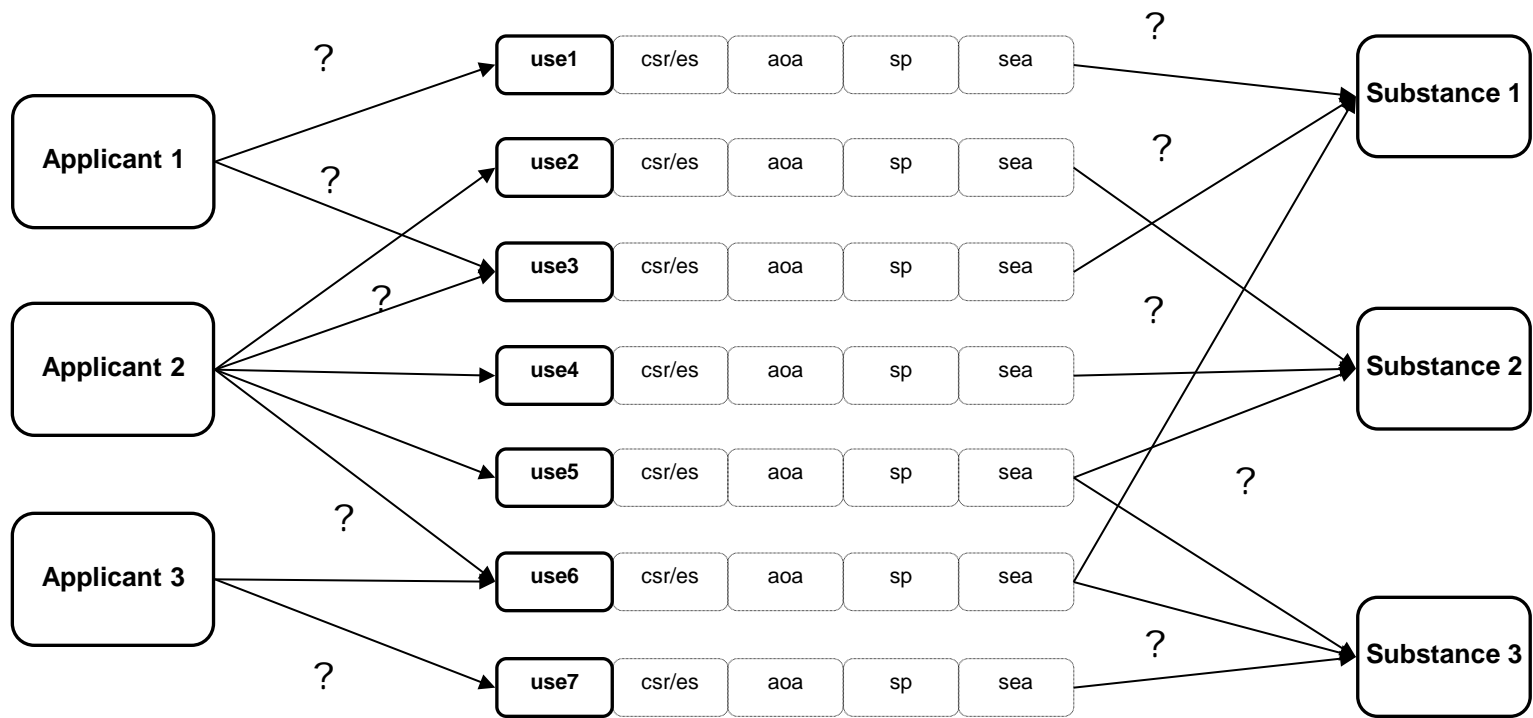


Uses in joint applications



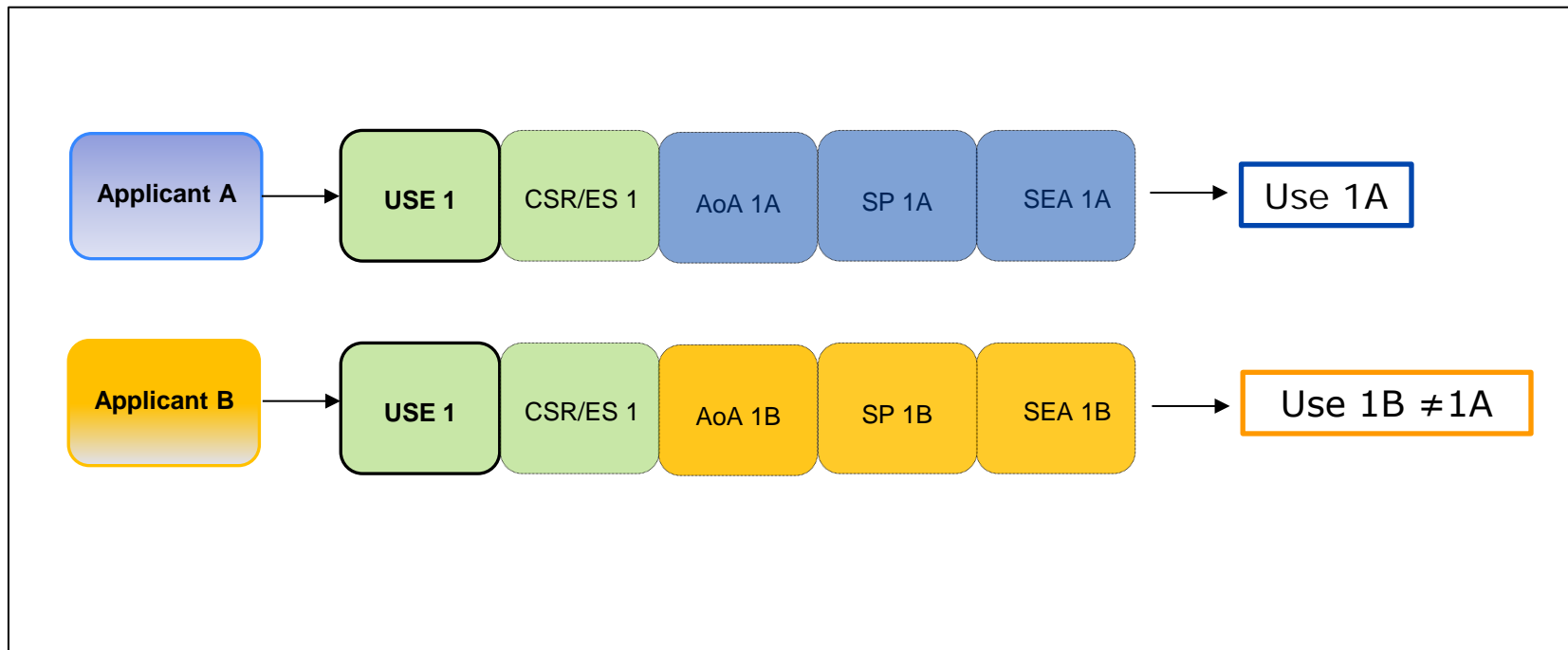
- Joint AfAs: all combinations of applicants' types and uses are in theory possible
 - One group of M/Is covering all uses of their whole market
 - One group of DUs (e.g. formulators) covering their own uses
 - One group of actors (M/I → formulator → end-user) covering their own supply chain
 - ...
- Pros and cons in the AfA guidance Appendix 2
- Main drivers:
 - Scoping i.e. generic vs specific uses, AoA and SEA
 - Communication: confidentiality and/or competition law issues between co-applicants
 - Clarity of the whole package

Complex applications (several applicants, substances, uses)



Several applicants – several uses

Ensure clarity all the way through the assessment reports



Uses in joint applications (4/4)

Fee comparison joint vs single applications: 3 applicants ; 1 substance; 3 uses

Case 1: all applicants apply for all uses

	Use 1	Use 2	Use 3
App 1	X	X	X
App 2	X	X	X
App 3	X	X	X

3 uses per applicant

Fee (€)	Total	Per applicant	Reduction
3 single AfAs	223 860	74 620	
1 joint AfA	154 570	51 523	30.9 %

Case 2: Hybrid situation

	Use 1	Use 2	Use 3
App 1		X	X
App 2	X		X
App 3	X	X	

2 uses per applicant

Fee (€)	Total	Per applicant	Reduction
3 single AfAs	191 880	63 960	
1 joint AfA	154 570	51 523	19.4 %

Case 3: each applicant applies for his own use

	Use 1	Use 2	Use 3
App 1	X		
App 2		X	
App 3			X

1 use per applicant

Fee (€)	Total	Per applicant	Reduction
3 single AfAs	159 900	53 300	
1 joint AfA	154 570	51 523	3.3 %

Broad Information on Uses




- **Definition and purpose of the BIU**

- Concept developed in consultation with NGOs and Industry
- Set of public information related to the use of Annex XIV substance (conditions of use, functional requirements) and the suitability of alternatives for that use
- To provide information on the uses of the Annex XIV substance to gather relevant and meaningful information on alternatives during a public consultation
- To ensure that all available information on alternatives is taken into account in the decision for granting an authorisation

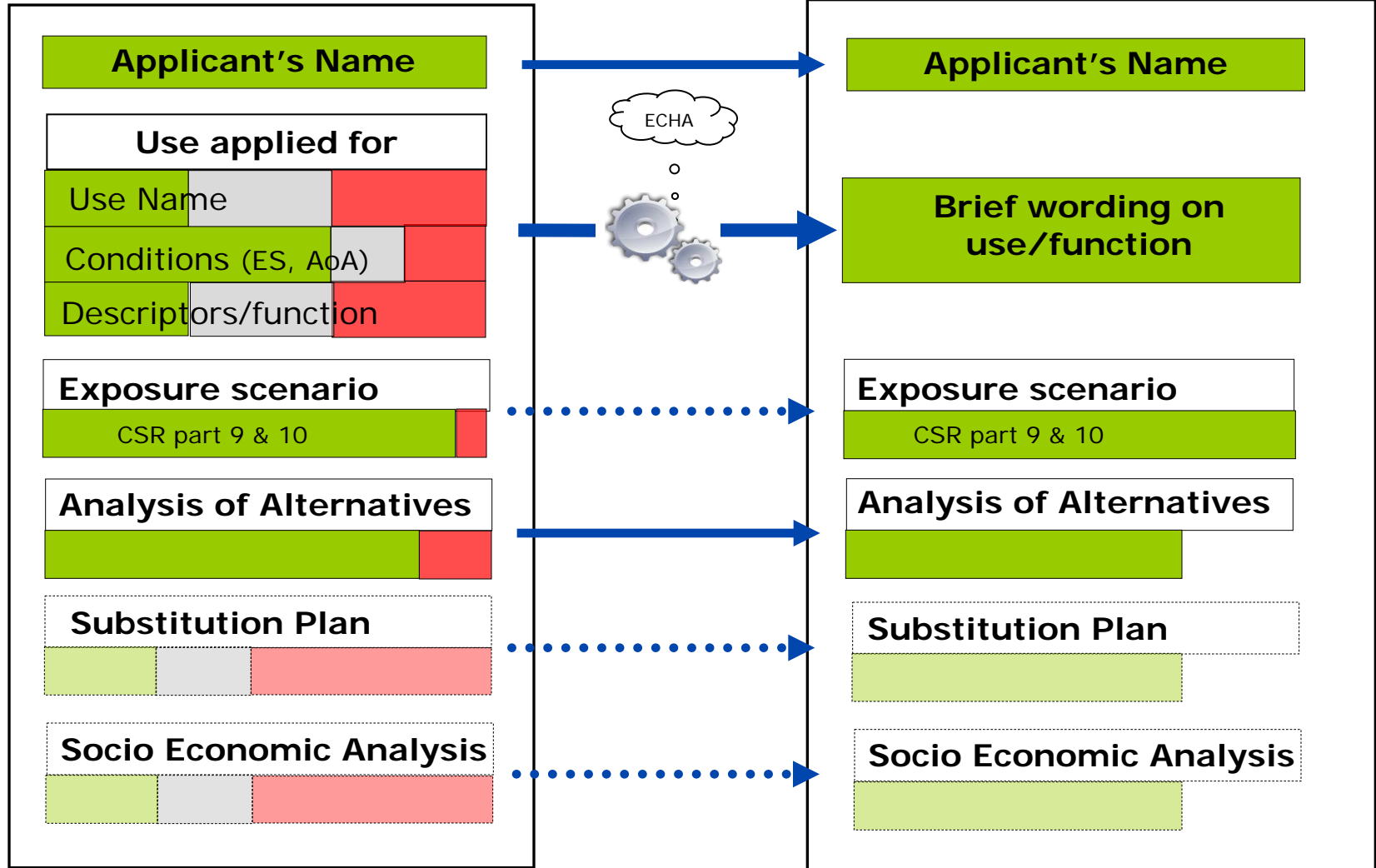
→ Trade-off between meaningfulness/level of detail and confidentiality

ECHA publishes...

- Name of the applicant
- “Brief wording” of the BIU including (use name, use conditions, function, use descriptors)
- Public version of the Exposure Scenarios (to be soon extended to CSR part 9 and 10)
- Public version of the Analysis of Alternatives
- Public summary of the Substitution Plan (to be soon extended to the full public version)
- Public summary of the Socio-economic Analysis (to be soon extended to the full public version)
-  AoA/SP/SEA templates to be updated soon (‘blinking-out’ approach, review period, tonnages)

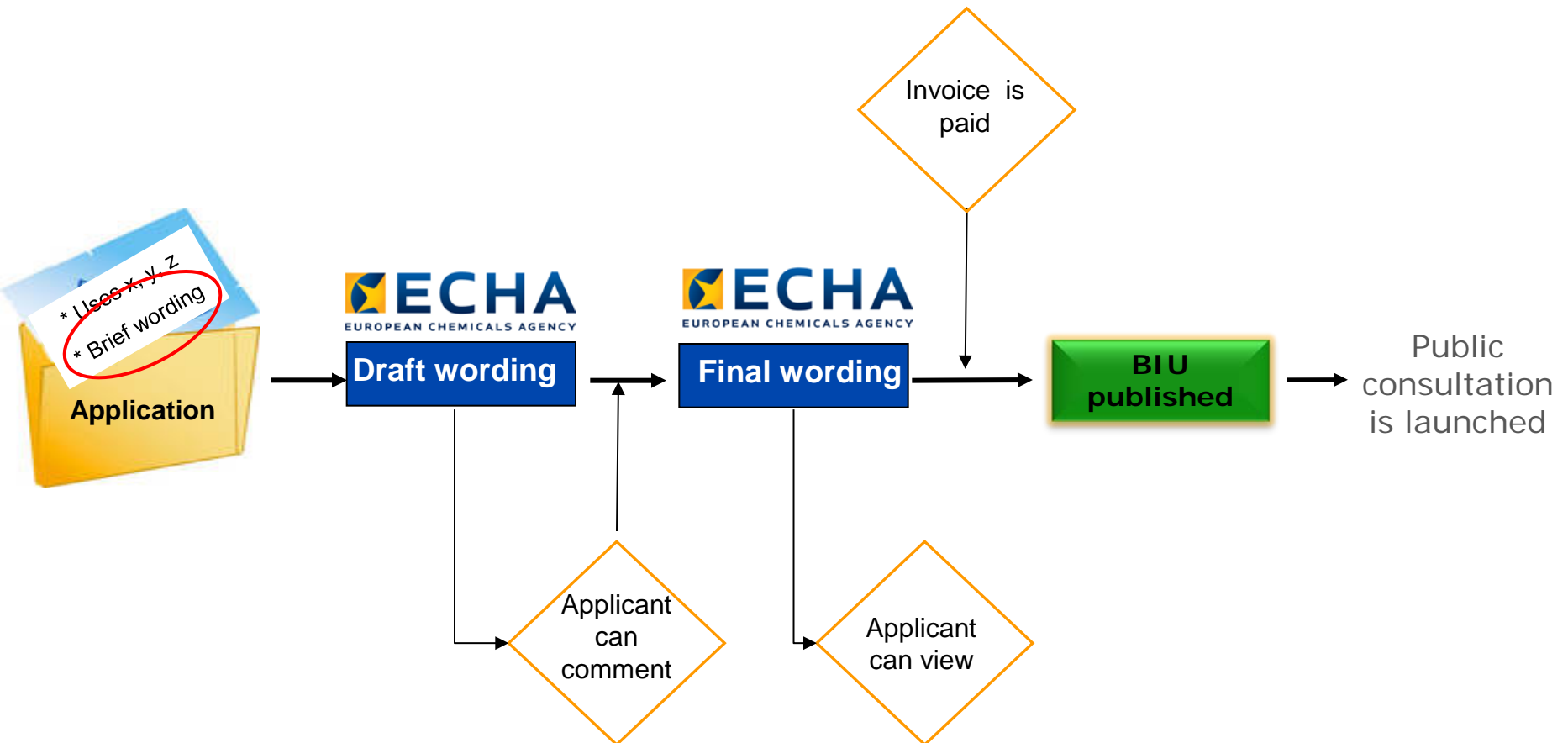
Application

Publication

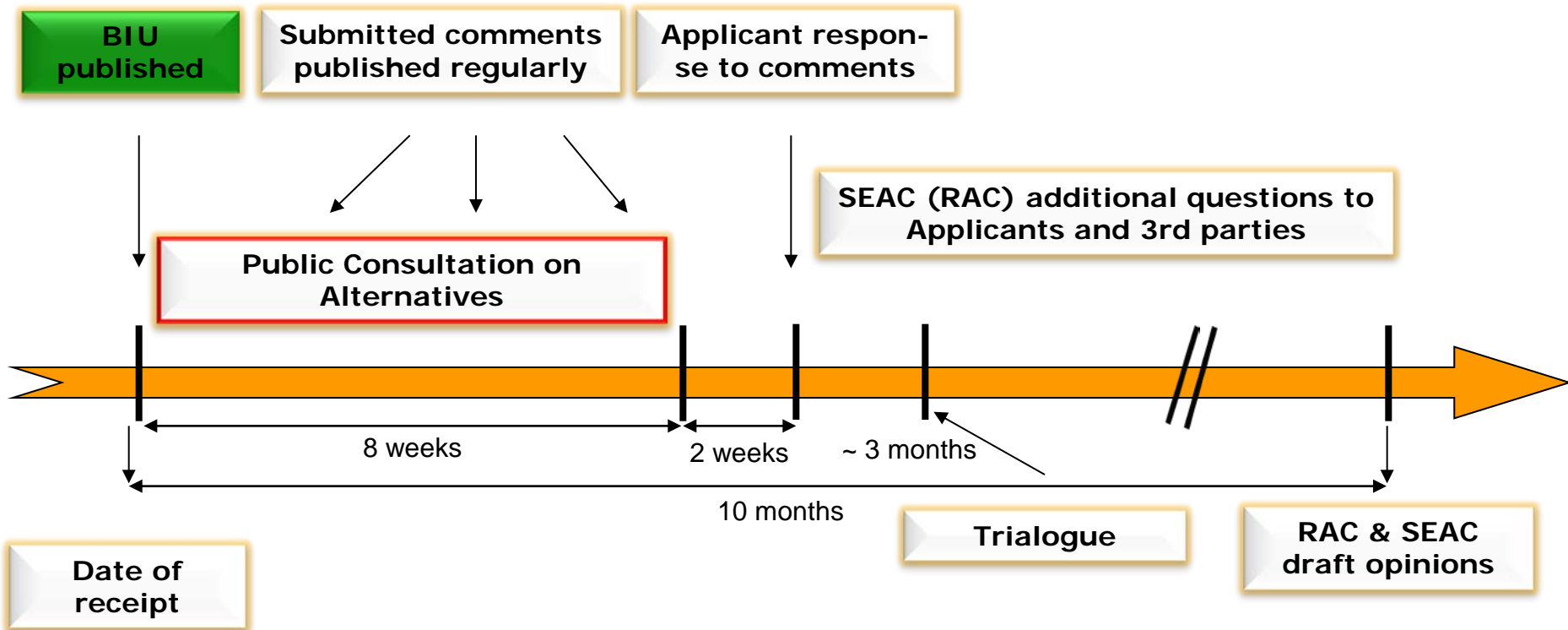


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- ECHA will determine on the basis of the proposal provided by the applicant (voluntary basis), a non-confidential "**brief wording**" describing the use(s) applied for



Process overview



Key messages



- **Development of use descriptions...**

- use whenever appropriate the use descriptor system with additional, sequential and detailed narrative description of tasks
- describe properly the function provided by Annex XIV substance
- scoping is a key: refine original (generic) scope via an iterative process considering also the scope of AoA and SEA

- **Broad Information on Uses / Public consultation**

- be as transparent as possible
- provide anonymized but still meaningful information (e.g. with ranges)
- provide robust reasons why you need to keep some information confidential
- one round of consultation with applicant
- a focused, meaningful and transparent BIU will ensure a meaningful and targeted information during the public consultation

Thank You!

