

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
 - Mentioned in Annex VI section 3.5
- **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** [Art 64(2)]
 - Developed by ECHA after an application has been submitted
 - Covers the “uses applied for”
 - 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** (< 1T, under controlled conditions)
 - 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:
 - **Manufacturing** processes
 - **Imported articles** containing the Annex XIV substance
- Further clarifications needed on the exact scope of SRD, other legislations, manufacture

Supply chain considerations (1/2)

- Manufacturers, importers, downstream users 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. 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)

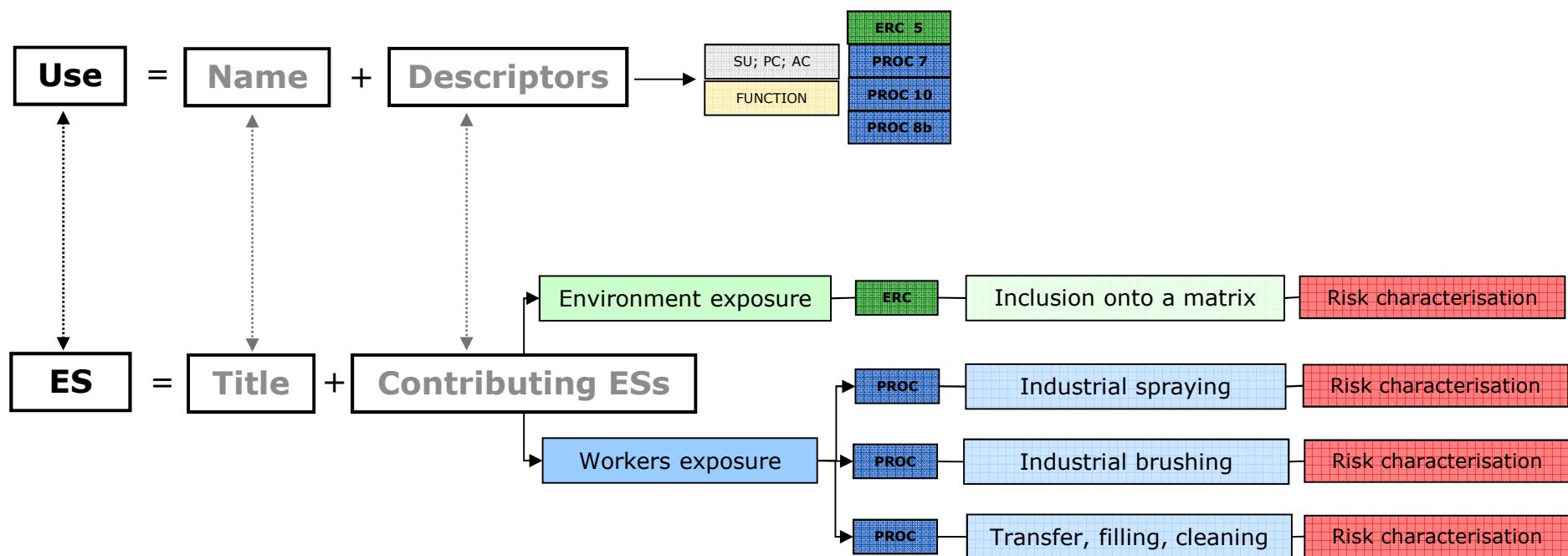
- A company can supply the substance to his immediate downstream user for a use, provided that this immediate DU holds an authorisation for that use [*Art 56(1)(e)*]
- In other words, a downstream user holding an authorisation
 - can cover the placing on the market for his use(s) only one level up his supply chain
 - cannot cover use(s) up his supply chain
- Uses' coverage: "top-down" not "bottom-up"
- Potential supply disruptions if missing links in the chain

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



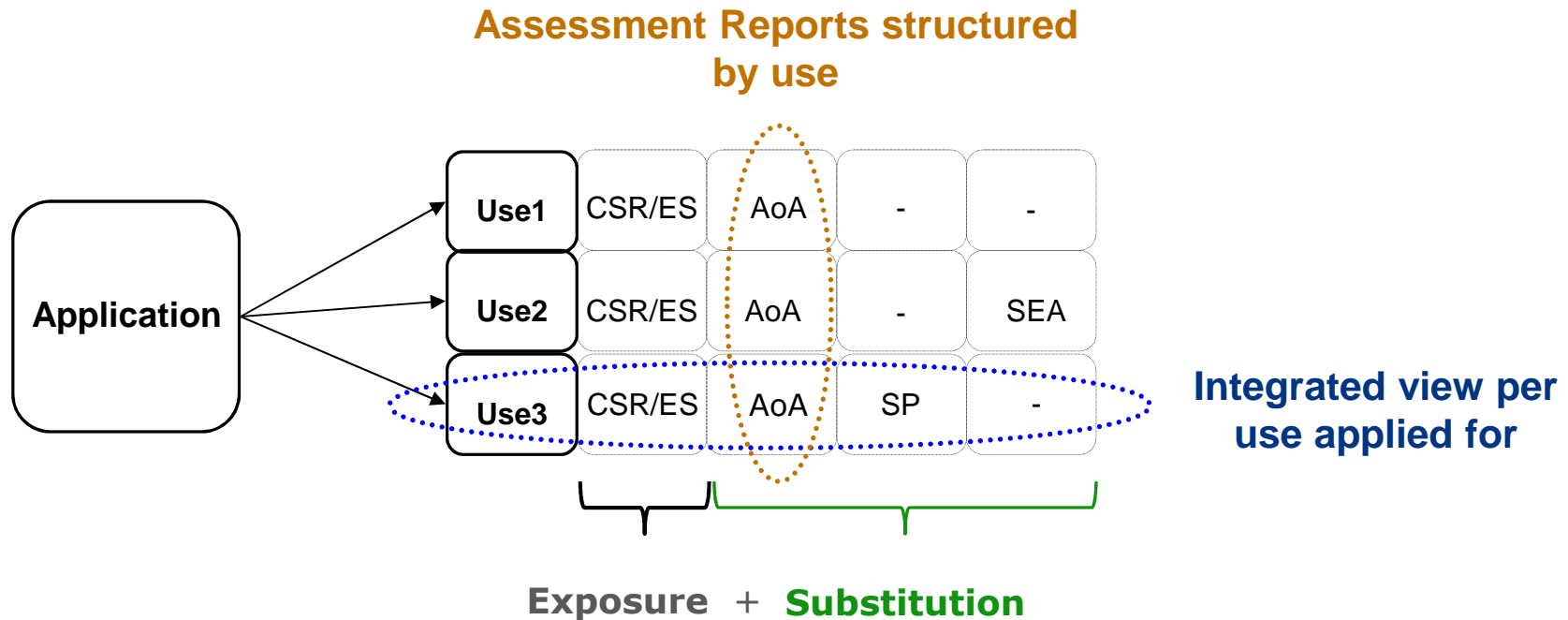
“Use applied for” development (1/4)

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



“Use applied for” development (2/4)

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



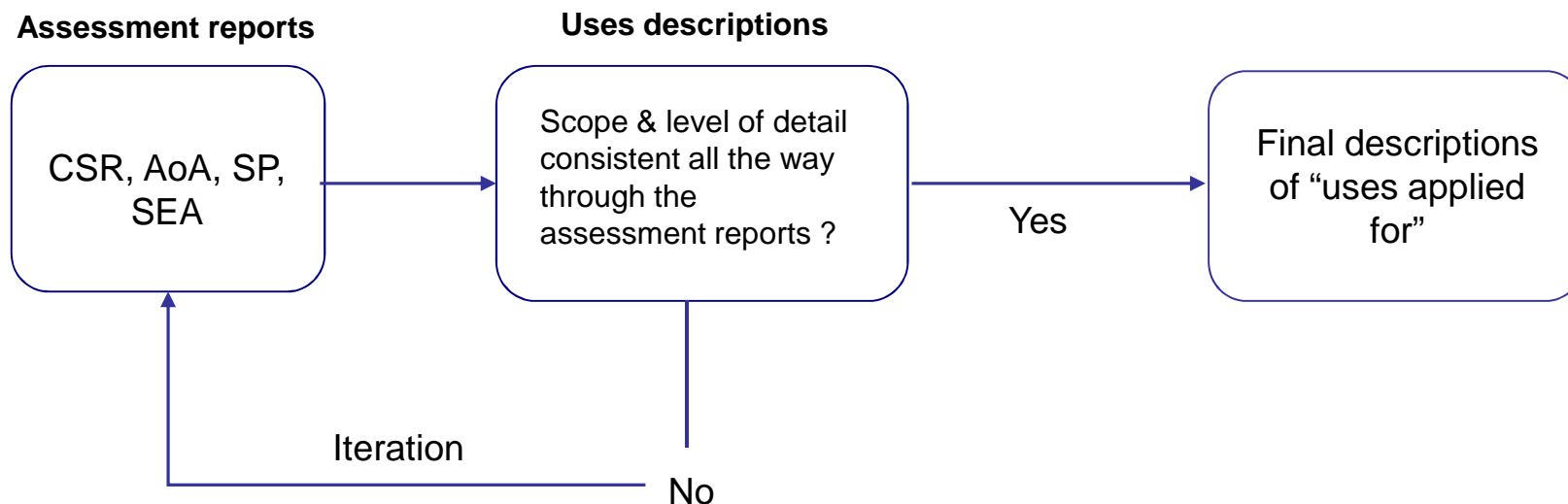
Description of “use applied for” is characterised by

- 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)

- 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 be refined to build clear cases
 - to focus on uses in specific market sectors, supply chains, processes or types of articles where there are no suitable alternatives
 - to withdraw or apply for niche uses, new uses
 - to provide more precise information, improve the quality of the dossier
 - consequently emissions and risk characterisations may need to be refined too

“Use applied for” Tier approach

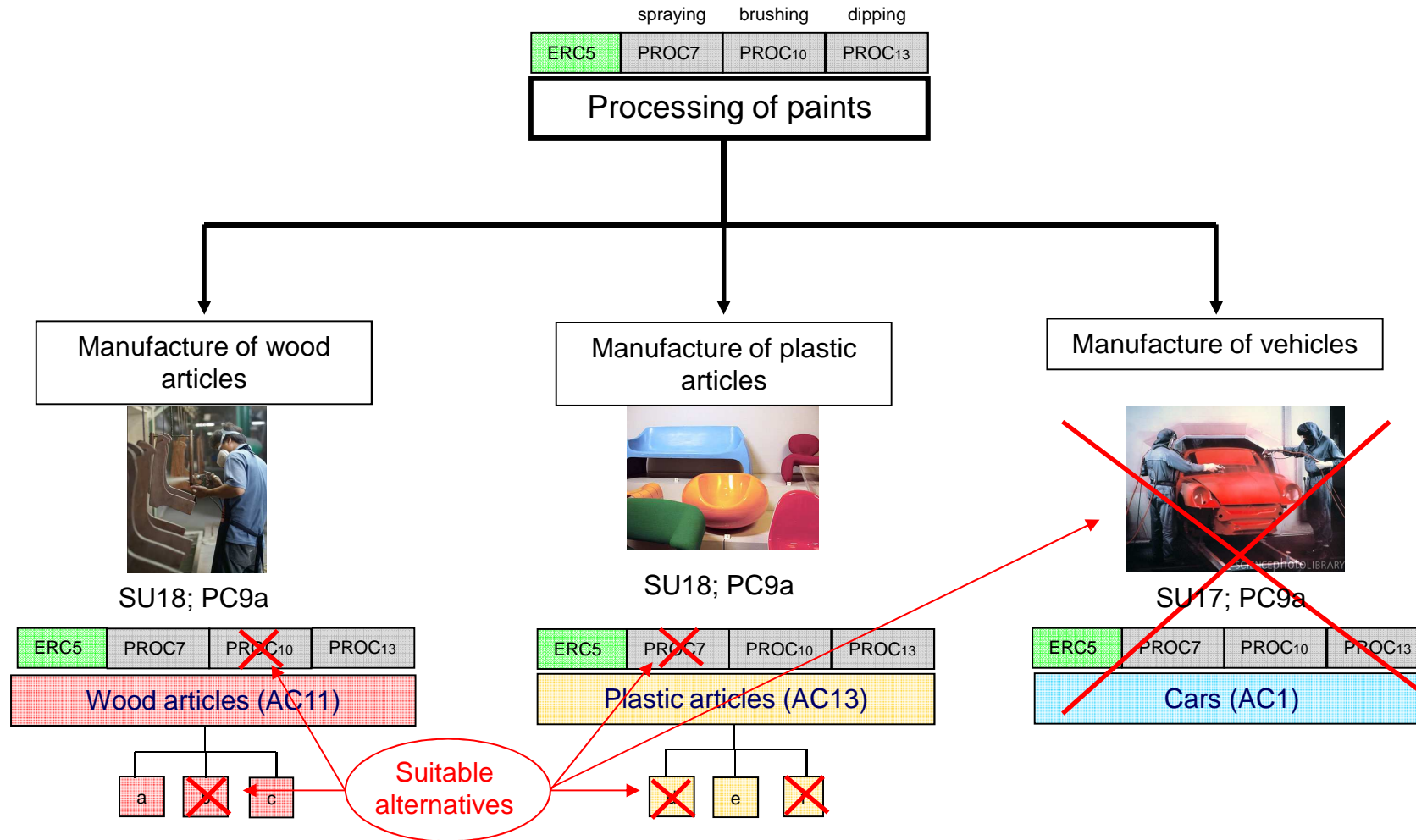
- Development of a use description is an iterative process to be finalised after the work on the CSR, AoA, SEA has been carried out



- 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



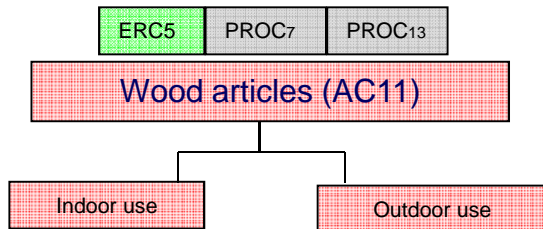
Example (2/2)

Use1

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



SU18; PC9a

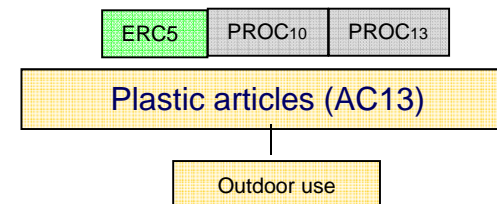


Use2

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



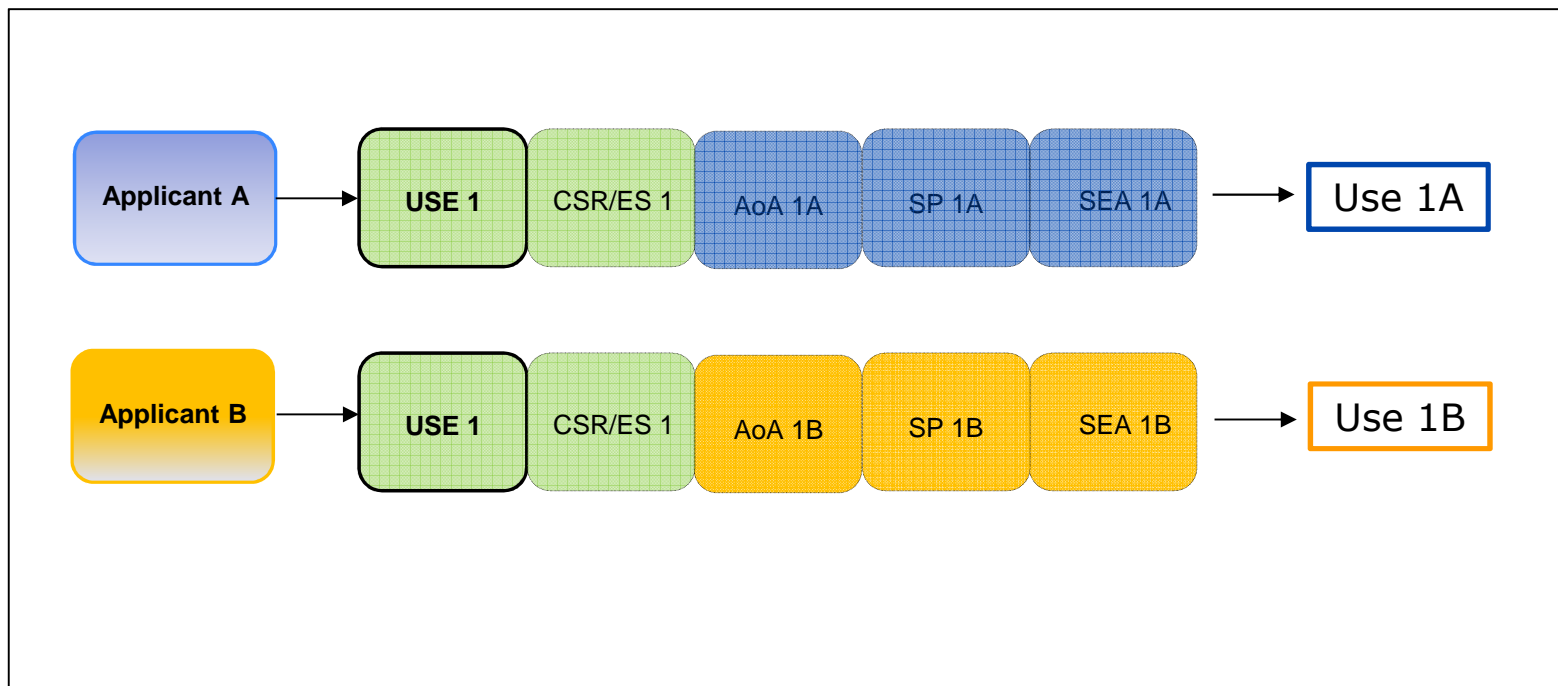
SU18; PC9a



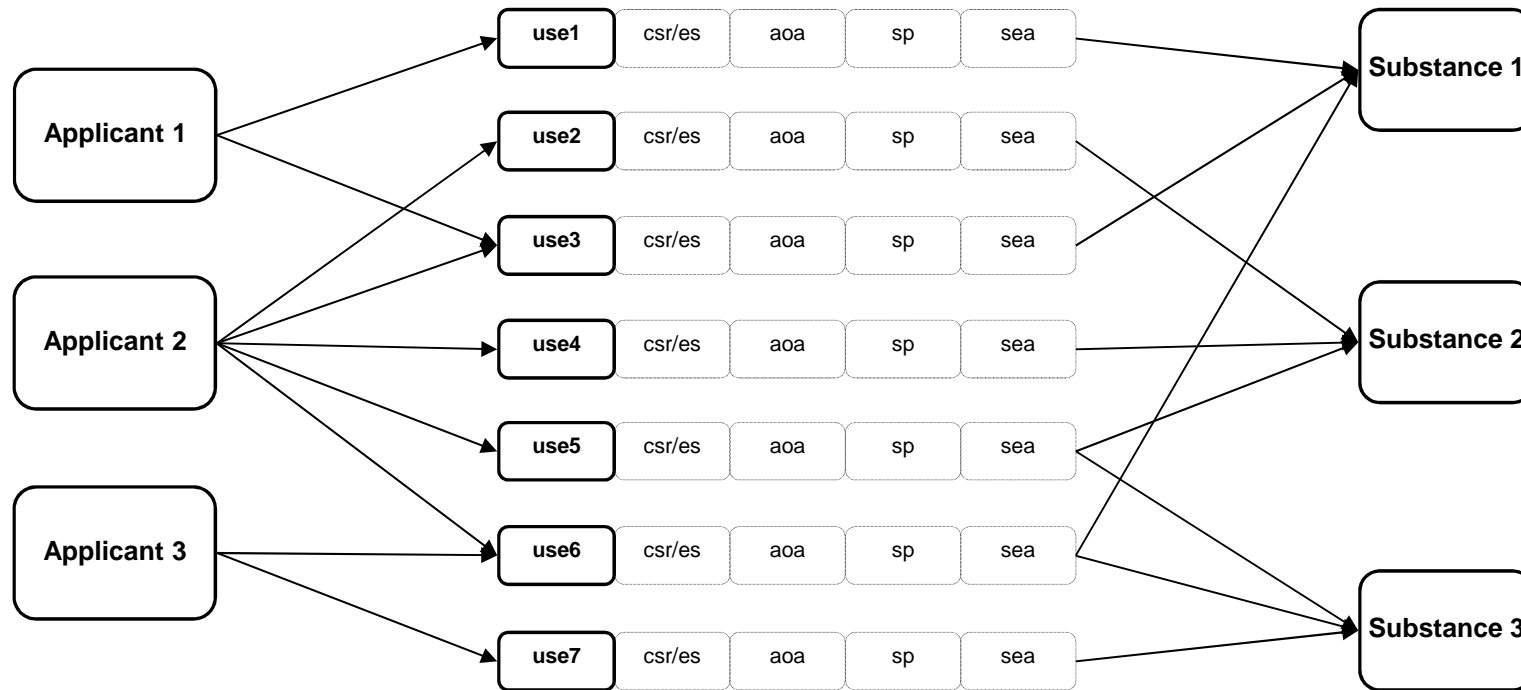
Uses in joint applications



Several applicants – several uses



Complex applications (several applicants, substances, uses)



Complex applications

Scenario 4: all uses shared by all applicants

	Use 1	Use 2	Use 3	Use 4
App 1	X	X	X	X
App 2	X	X	X	X
App 3	X	X	X	X

Scenario 2: not all uses are shared

	Use 1	Use 2	Use 3	Use 4
App 1	X		X	
App 2			X	X
App 3	X	X		X

Scenario 3: all uses shared – not by all applicants

	Use 1	Use 2	Use 3	Use 4
App 1		X	X	X
App 2	X	X	X	
App 3	X	X	X	X

Scenario 1: none of the uses is shared

	Use 1	Use 2	Use 3	Use 4
App 1	X		X	
App 2		X		
App 3				X

Broad Information on Uses



- **Why?**

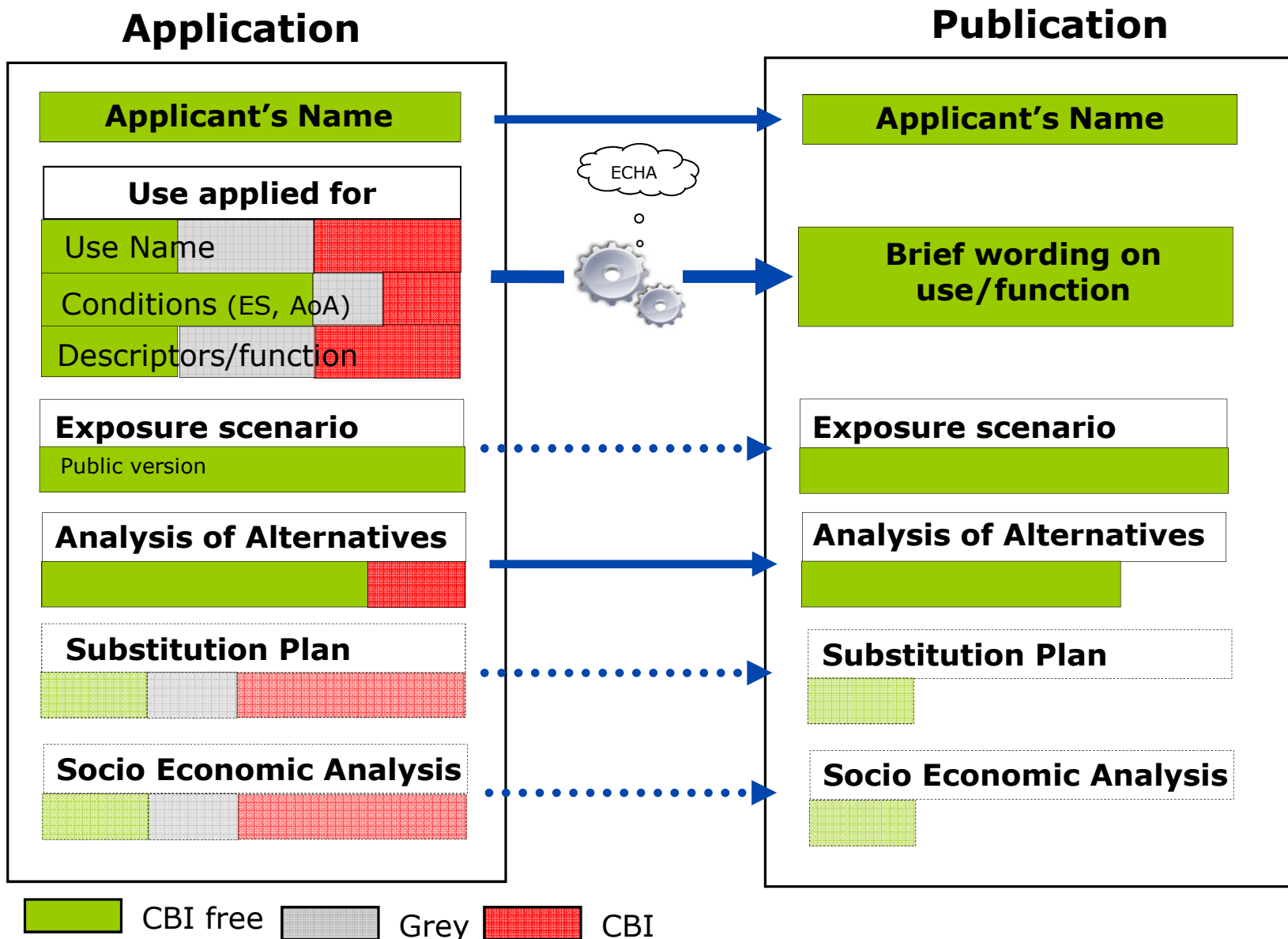
- To provide information on the uses of the Annex XIV substance to gather relevant and meaningful information on alternatives during a public consultation
- All available information on alternatives is taken into account in the decision for granting an authorisation

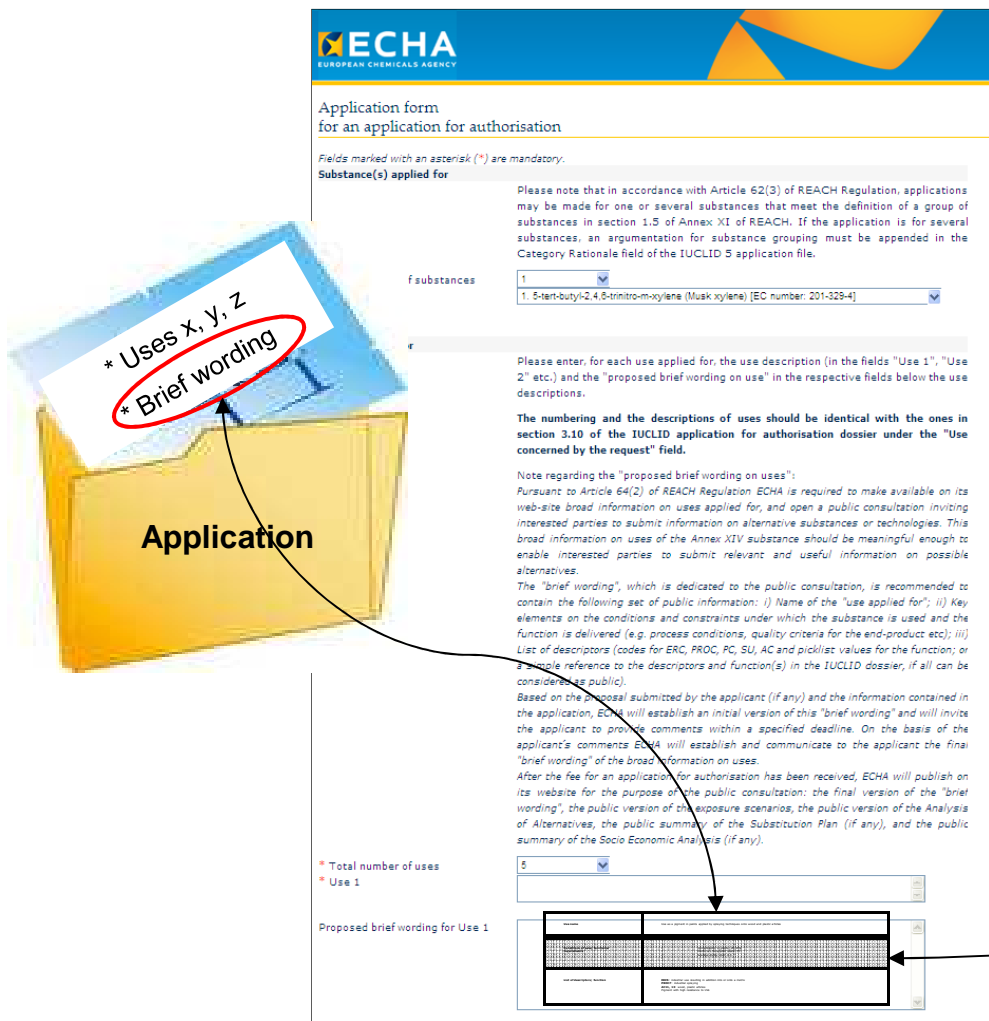
- **What?**

- 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
- Trade-off between meaningfulness/level of detail and confidentiality
- Exact content developed in consultation with NGOs and Industry

ECHA intends to publish...

- Name of the applicant
- “Brief wording” of the BIU 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 summary of the Substitution Plan
- Public summary of the Socio-economic Analysis





*** Uses X, Y, Z**
*** Brief wording**

Application

ECHA
EUROPEAN CHEMICALS AGENCY

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.

f substances

1

1: 5-tert-butyl-2,4,6-trinitro-m-xylene (Musk xylylene) [EC number: 201-328-4]

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).

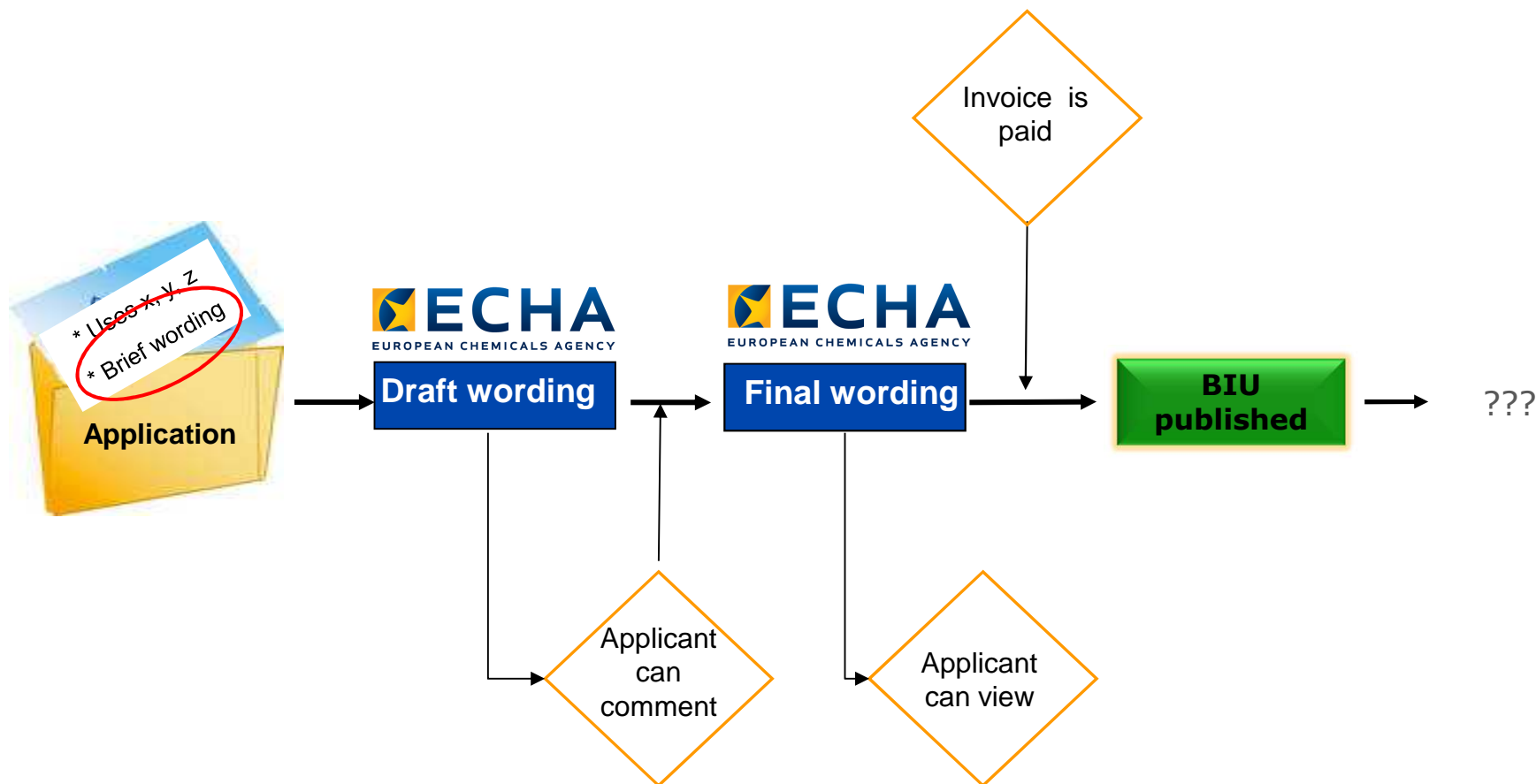
Total number of uses: 5

Use 1

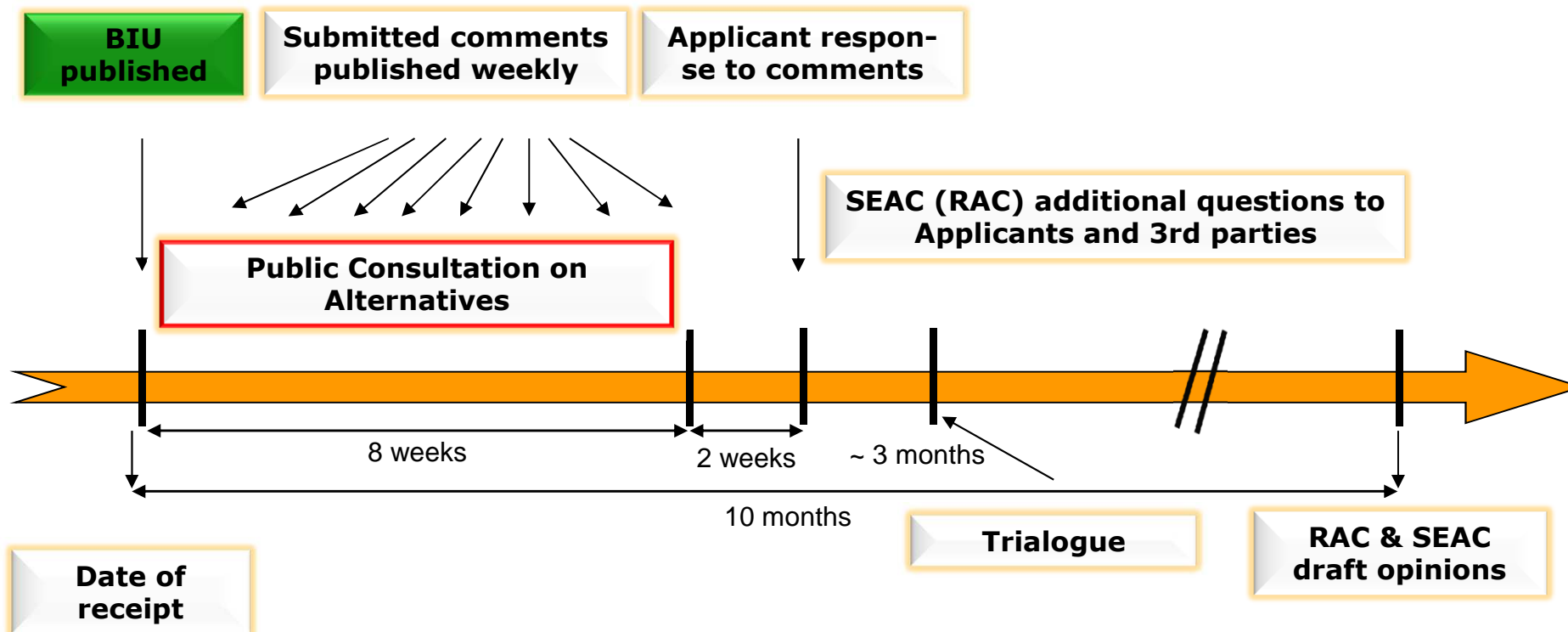
Proposed brief wording for Use 1

Use name	Use as a pigment in paints applied by spraying techniques onto wood and plastic articles
Conditions of uses; functional requirements	<ul style="list-style-type: none"> Substance concentration in paints: 20-30% Paints can be applied below 5°C Average drying time: 8 h ...
List of descriptors; function	<p>ERC5: industrial use resulting in addition into or onto a matrix</p> <p>PROC7: industrial spraying</p> <p>AC11, 13: wood, plastic articles</p> <p>Pigment with high resistance to UVs</p>

- 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
 - describe properly the function provided by Annex XIV substance
 - refine original (generic) descriptions of uses
 - develop the scope of uses, AoA, SEA via an iterative process
 - http://echa.europa.eu/documents/10162/13566/uses_description_in_auth_context_en.pdf
- Broad Information on Uses / Public consultation
 - On round of consultation with applicant on the brief wording
 - BIU with the right scope and level of detail to get meaningful and targeted information during the public consultation
 - http://echa.europa.eu/documents/10162/13555/public_information_afa_en.pdf

Thank You!