Authorisation - update

REACH IMPLEMENTATION WORKSHOP XII

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Sheraton Brussels Airport Hotel

cefic

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The Cefic Authorisation/Restriction Platform

- Working group of the Cefic Programme Product Stewardship
- >30 members from companies, Sector groups, national associations, Cefic.
- Goal:
  - Facilitate the implementation of REACH on authorisation/restriction by Cefic Members
  - Develop practical tools, guidance and opinions on implementation
  - Communicate to the members via workshops, via Cefic website
  - Promote common work processes and tools across the industry

Industry for industry

- share information, share experience of the “pioneer “ companies.
- authorisation is case by case, development of generic precedents needs watching
- industry input essential for discussion of actual and potential “design improvements” in processes and interpretations
- beyond the mechanics (application, process, decision making) for all stakeholders there are critical lessons to learn about business impact and economic consequences
- methodology, decision factors, and outlook of authorization, are still uncertain, it is very important for industry to inject realism into the process

Contents

Authorisation -

- Some questions and answers
- ECHA: grounds for granting an authorisation
- Some questions still open

YES/NO QUESTIONS

1. Can you use the adequate control route to apply for authorisation of a non-threshold substance?
2. Can you submit an application for authorisation for a group of substances?
3. If part of an application is rejected, is the whole application rejected?
4. For applications for authorisation, is there 18 months between submission and sunset dates?
5. Is there 21 months between submission and sunset dates?
6. Can the applicant meet with the rapporteurs during the opinion forming process?
7. Does ECHA decide on the application for authorisation?

YES/NO QUESTIONS (cont)

Is the price tag of the early Applications for Authorisation

8. <500 k€
9. ....between 500 k€ and a million €?
10. ....> a million €?
11. Is the economic feasibility of possible alternatives considered from the point of view of the supply chain?
12. Do you need to consider articles in your Application for Authorisation?
13. Can you submit in a language other than English?

The answers

Question 1

1. Can you use the adequate control route to apply for authorisation of a non-threshold substance?

NO

For substances where there is no agreed-upon no concern level (i.e., threshold), the only way to obtain an authorisation is to demonstrate the benefits to society outweigh the risks to human health or the environment ***on the basis of socio-economic factors.***

Questions 2 and 3

2. Can you submit an application for authorisation for a group of substances?

YES

on the basis of similarity of physicochemical, toxicological and ecotoxicological properties, or where these follow a regular pattern as a result of structural similarity (Annex XI 1.5).

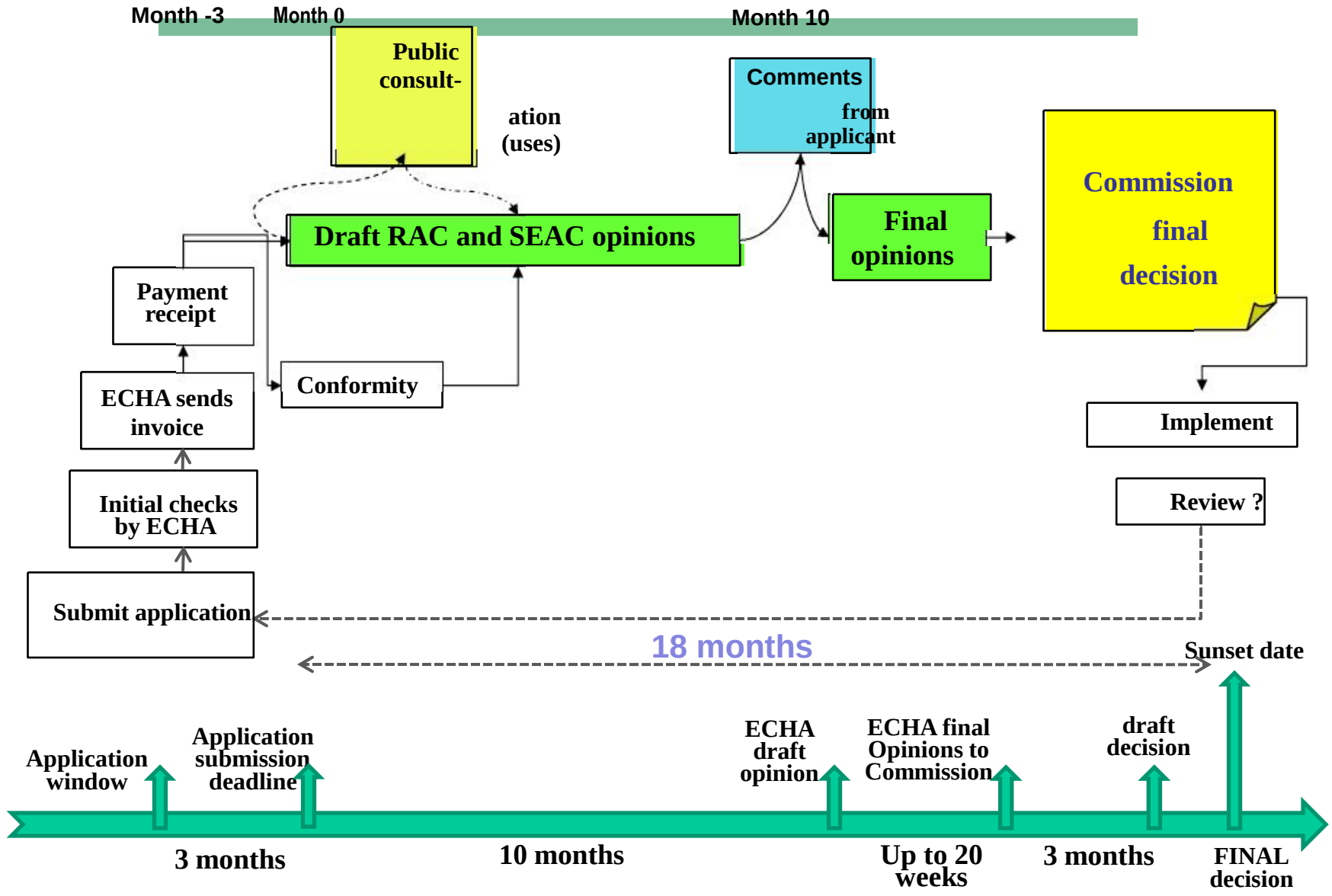
3. If part of an application is rejected, is the whole application rejected?

NO

Questions 4 and 5

4. For applications for authorisation, is there 18 months between submission and sunset dates?
5. Is there 21 months between submission and sunset dates?

Authorisation timelines



Questions 6 & 7

6. Can the applicant meet with the rapporteurs during the opinion forming process?

YES

7. Does ECHA decide on the application for authorisation?

NO

Questions 9, 10 & 11

Is the price tag of the early Applications for Authorisation

8. <500 k€
9. ....between 500 k€ and a million €?
10. ....> a million €?

Questions 11 & 12

11. Is the economic feasibility of possible alternatives considered from the point of view of the supply chain?

NO - *the assessment of economic feasibility focuses on the economic viability of the possible alternative for the applicant; SEA addresses the wider social and economic benefits ....*

12. Do you need to consider articles in your Application for Authorisation?

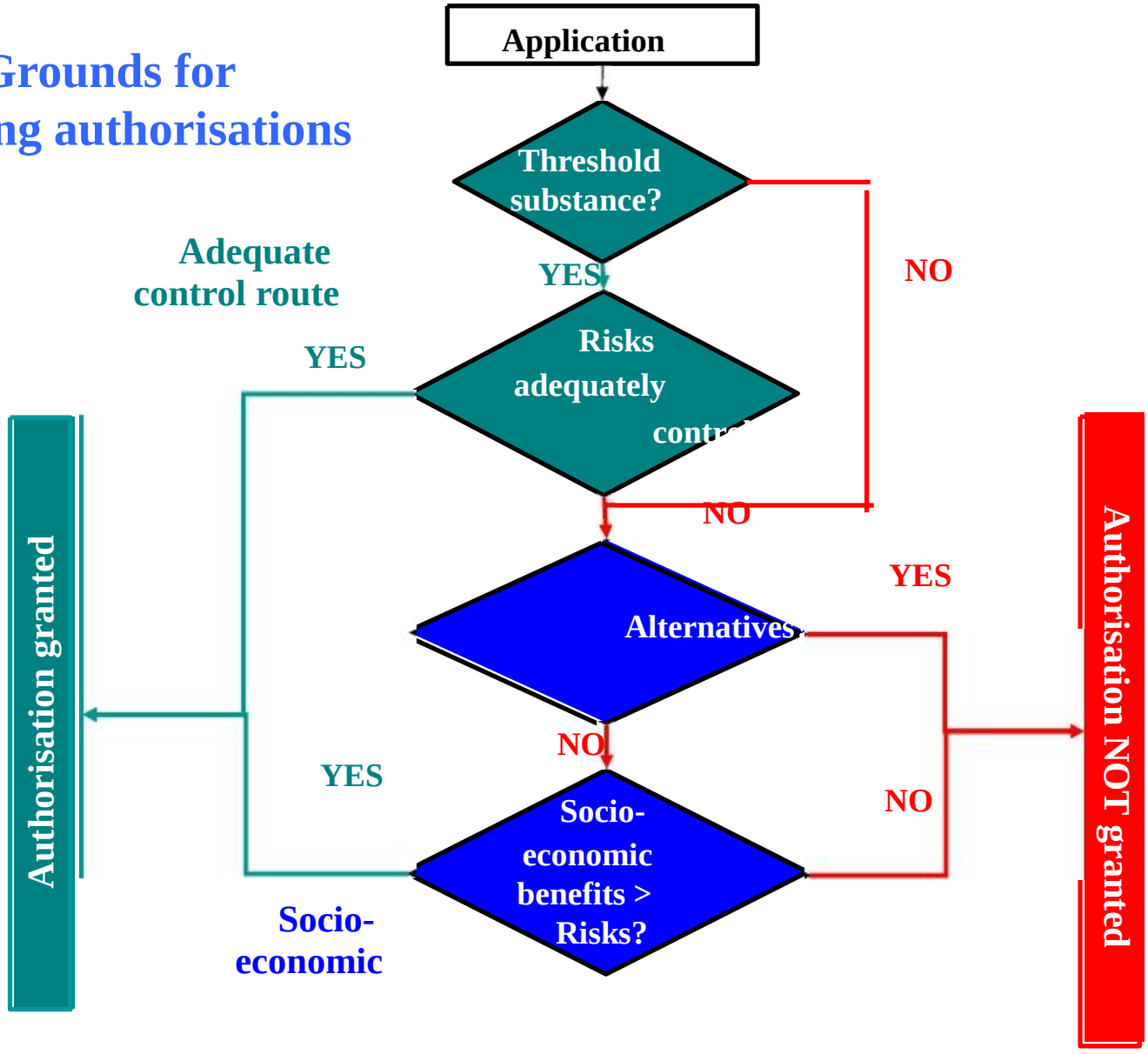
YES - the use(s) for which authorisation is sought, covering the use(s) of the in articles, where this is relevant.
The service life of articles containing the substance may also need to be considered.

Questions 13 & 14

13 Can you submit in a language other than English?

YES, but ...

Grounds for granting authorisations



Unanswered questions

1 Exemptions according to Art 2(3) of REACH – an example

- Does it mean that one Member State may allow exemption for all EU countries?
- What the „interests of defence“ really means

Unanswered questions

2 Annex XIV substance as an impurity

According to current knowledge, impurities are not subject to authorization

BUT..

Germany submitted Annex XV dossier for 4-nonylphenol, branched and linear which includes substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, covering also UVCB- and well-defined substances which include any of the individual isomers or a combination thereof

Concentration of isomers not mentioned in Annex XV dossier, 1% according to CLP?

Threshold and non-threshold substances

DNEL vs. DMEL value

DNEL:

Safe exposure level for threshold substances

Clearly calculated number

DMEL:

Exposure level considered to be of „very low concern“ for non-threshold substances

politically acceptable limit; not the same in EU MS

Risk level could be 10^{-3}, 10^{-4} but also 10^{-6}

Thank you