Lessons learnt from applications for authorisation

Ninth Stakeholders' Day

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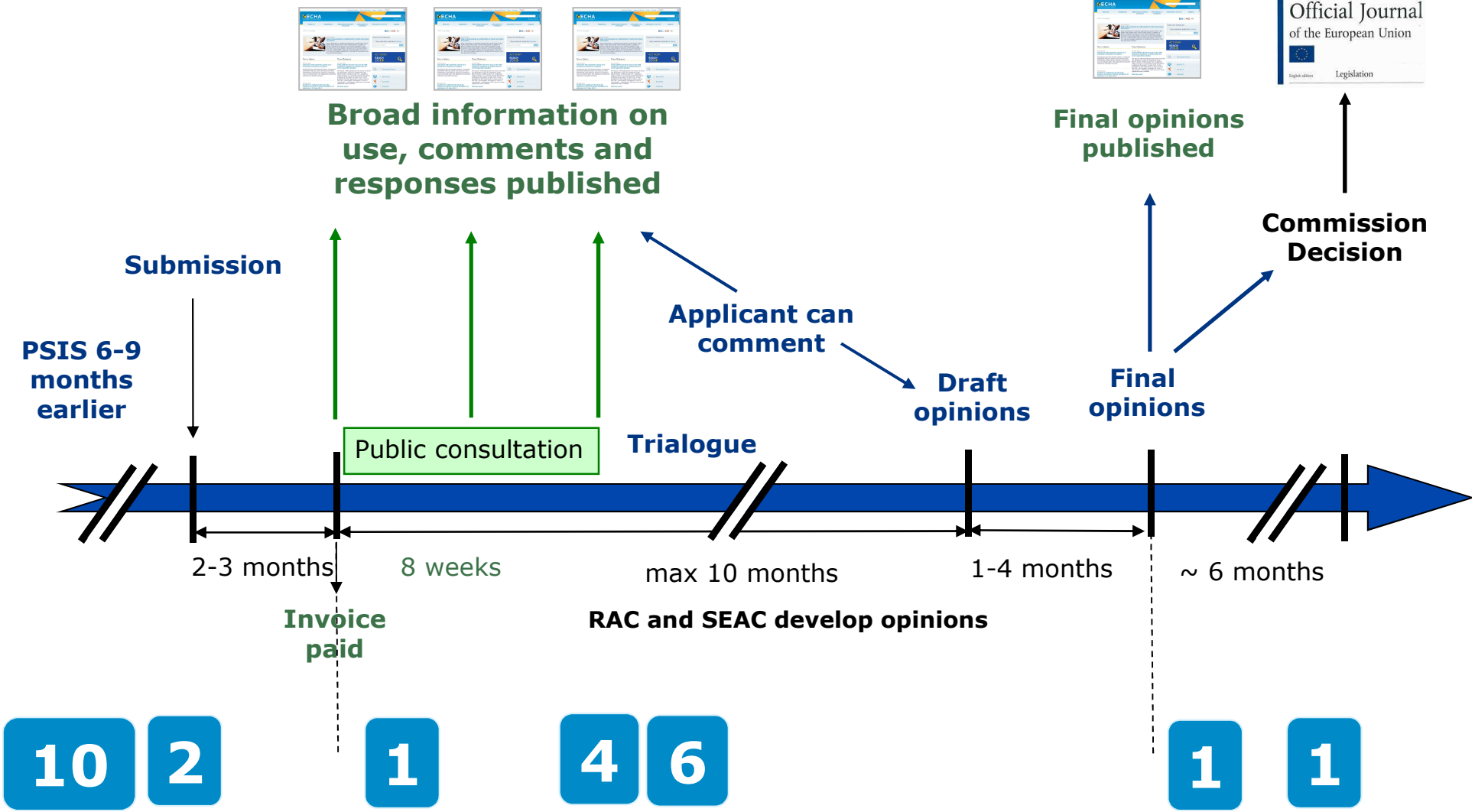
Matti Vainio
European Chemicals Agency

Outline

- Some key messages about authorisation
- Role of downstream users: application strategies
- ECHA's support activities
- Take home

13 applications in the pipeline



Some key messages about authorisation

Applying is normal business

- Applying is a normal business decision
  - Just like getting any other permit from an authority e.g. for operating a plant, or for security or other reasons
- There is no stigma to apply
- Need to substitute and keep the EU competitive
  - Substitution can sometimes take decades
- Own your application
  - Know your strengths – clarify where external advisers add value
  - If you have a strong case, show this by applying early
- Focus on your and your customers' core business
  - Reduces confusion and your application costs

Substitution

- REACH encourages industry to substitute SVHCs
  - Public consultation on alternatives highlights this
  - R&D activities for substitution to be included in the Analysis of Alternatives
- No particular timeline envisaged
  - Proper justification in the Analysis of Alternatives is key to demonstrate that technically and economically feasible alternatives are not available
  - SEA template changed to include the possibility for the applicant to justify the length of the review period
  - Length: short (e.g. four years), seven years, 12 years…
    - Counted from the sunset date

Communication is key

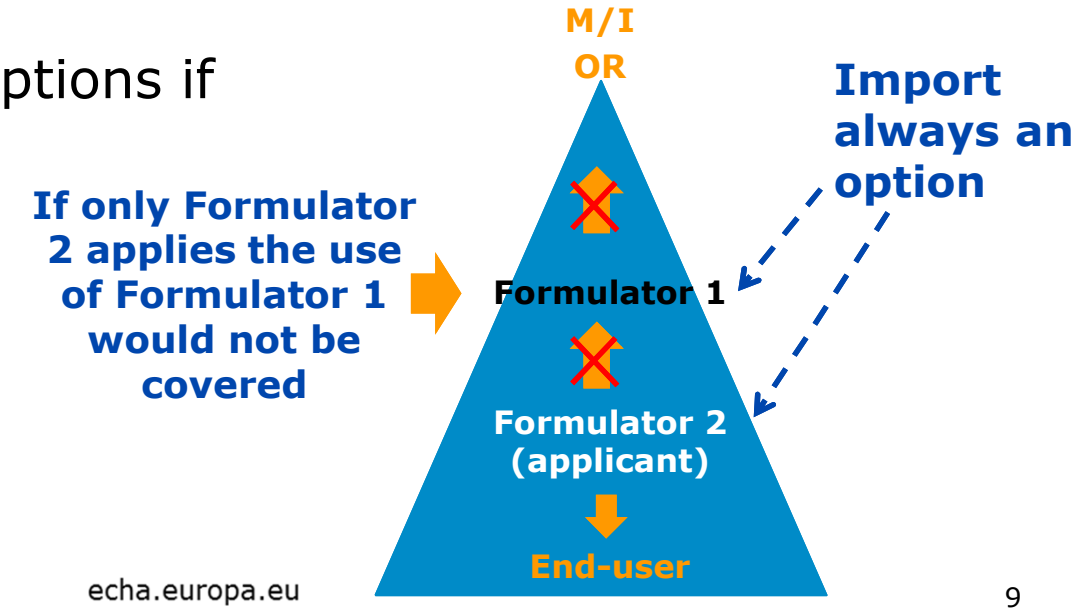
- Proper communication in the supply chain is extremely important when preparing an application

- Involvement of downstream users - including article manufacturers - is crucial to address the interests of all
  - Acceptability of alternatives often customer driven
  - Economic impact of non-authorisation can be greatest downstream

Role of downstream users:
Application strategies

Understand the supply chain

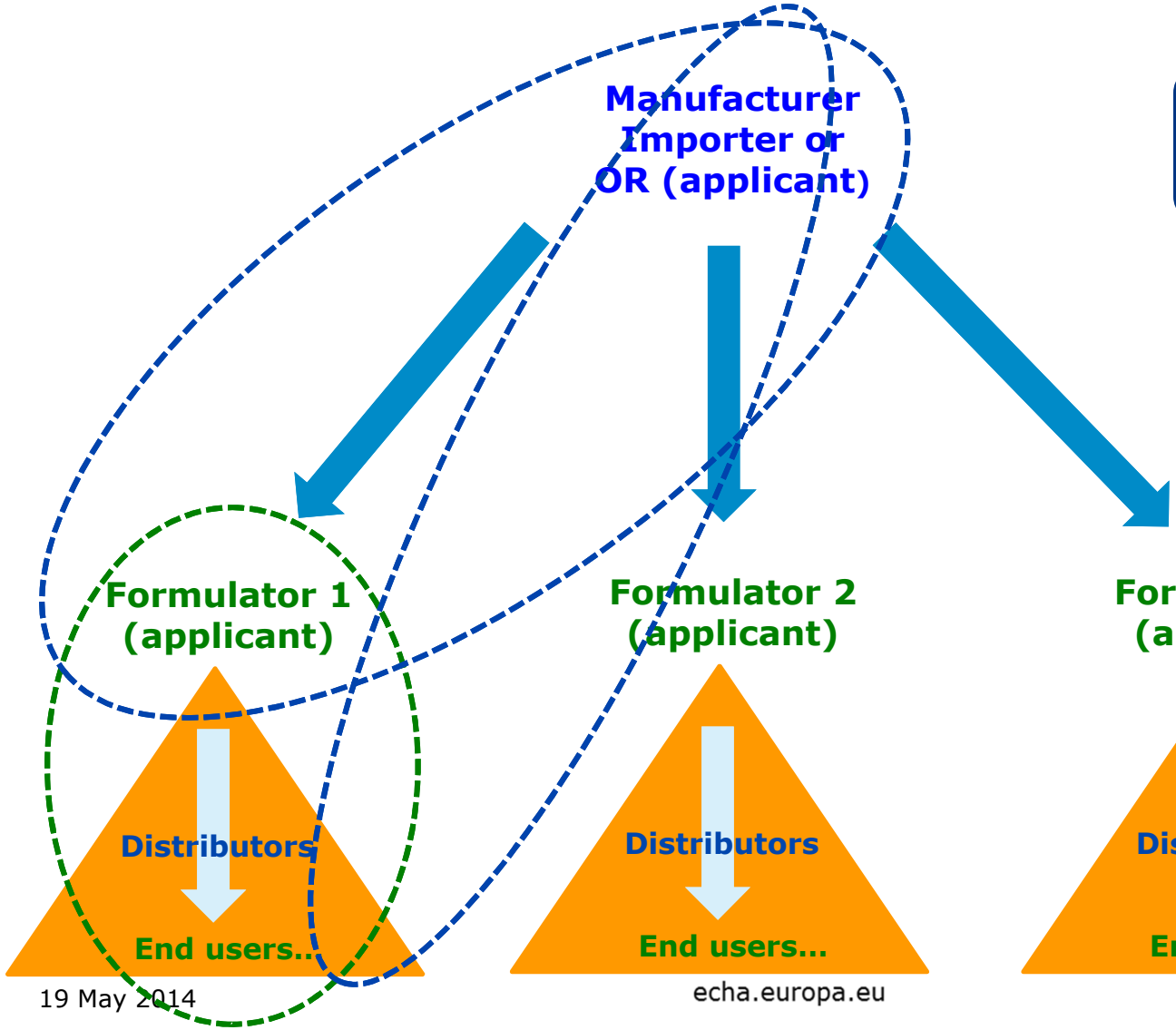
- REACH: manufacturer/importer (M/I) or only representative (OR) can cover the whole supply chain
  - Use descriptions need to be representative for the whole supply chain
- Downstream user (formulator or end user) can cover only their own use and the uses below
- Communicate and share effort in the supply chain
- Potential supply disruptions if missing links



Possible application strategies

- End users applying for their own specific uses
- Manufacturer, importer or only representative applying for many (hundreds?) of downstream users
- ”Double” application
  - Some downstream users have applied separately for the same use as their supplier
  - Ensures 100% certainty of supply (through imports) in all events
- Would a ”two-tiered” approach work?
  - Manufacturer applies for the use of its customers (formulators)
  - Formulators apply for the use of their clients (end users)

Would a two-tiered approach work?



Create confidence about the availability of the substance

Apply for the uses of direct customers (formulator)

Possibly add uses of some end users

Fill the gaps and cover end users

Apply for own use (fill gaps) and for the use of direct customers (end users)

ECHA’s support activities

Extensive support to applicants

- Guidance documents, user manuals and templates
- Over 80 Questions and Answers; Helpdesk assists
- Pre-submission information sessions
- Seminars, webinars and workshops
- Specific help to small and medium-sized companies
  - If you use RAC's reference DNELs or dose-response function, just use it (no additional data needed)
- How RAC and SEAC treat applications, e.g.
  - What is made publicly available?
  - Length of the review period
- All available on ECHA's website

✓ Suggest improvements to us

It works

- 'Wurstfabrik' works:
  - Two opinions in four months each
  - Two-four opinions expected in June
  - First decision expected in June
- Specific issues addressed, for instance
  - *Results of dedicated work with aviation industry (April)*
- Applicants's feedback:
  - *It works, but applying took a lot of time and effort*
- ECHA preparing for increased number of applications
  - Aim: fit-for-purpose applications without unnecessary application cost
  - Streamlined opinion making procedures in RAC and SEAC
  - Updated website, new submission tool (REACH-IT)
  - Application formats changed to increase efficiency and transparency
  - New "Partners' service" to be launched

Take home

Take home

1. Start early
2. Communication is the key
3. Own your application process: it is a business decision
4. First experiences reassuring: it works
5. Simplified applications:
   - No hazard data if reference DNEL or dose-response used
   - Streamlined opinion making process in RAC and SEAC
6. Learn from concrete examples of applications
   - Check ECHA's website now
7. Participate in ECHA's (free) workshops, request PSIS
8. Updated applications formats and Partners' service
9. Contribute to the public consultations on alternatives
10. Ask, suggest, we listen and act

Thank you

matti.vainio@echa.europa.eu

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