Union authorisation in practice

Biocides Stakeholders' Day

1 September 2016

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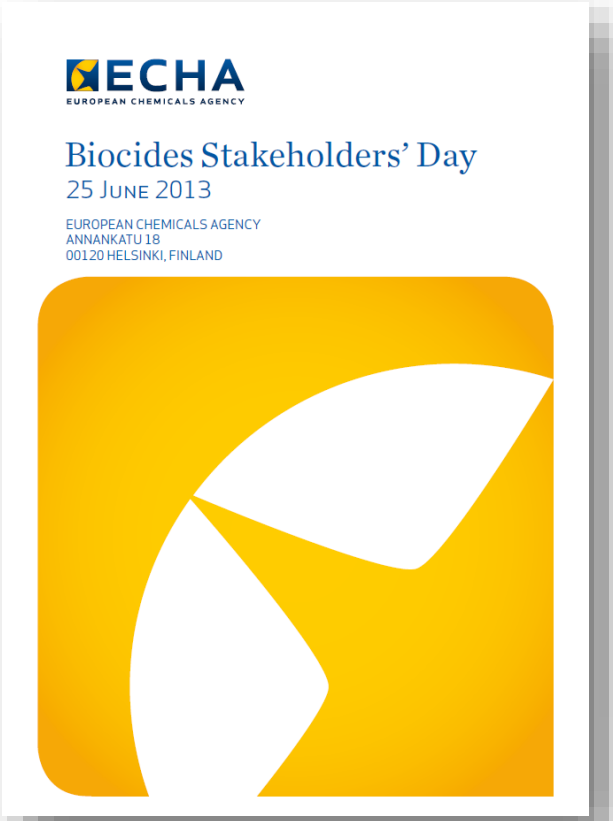
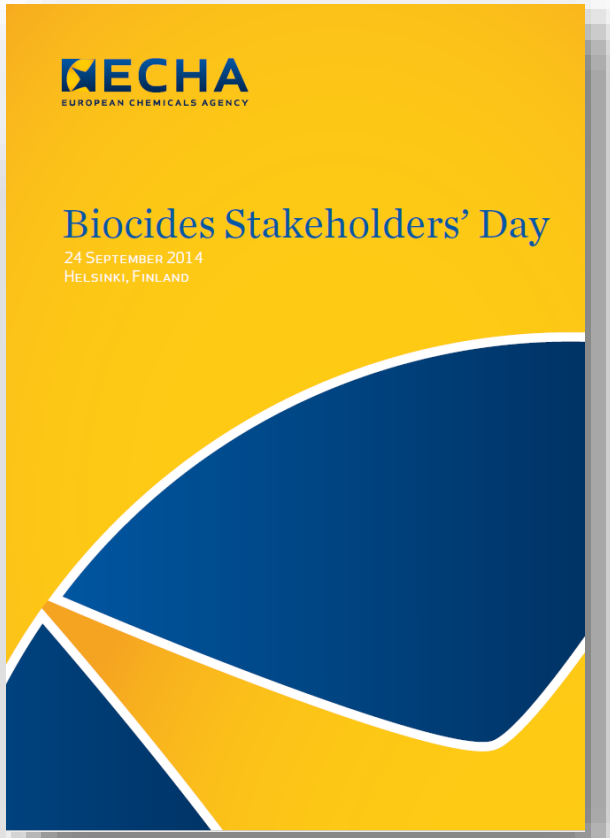
EUROPEAN CHEMICALS AGENCY

2013



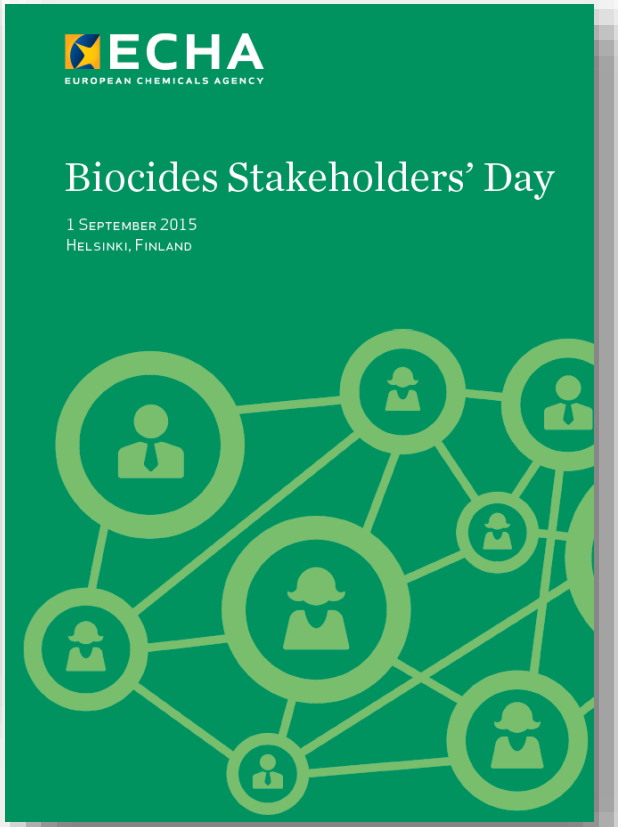
Union authorisation of biocidal products

2014



Union authorisation: analysis of benefits and risks

2015



Union authorisation: how ECHA is helping

Overview

1. Introduction and current status
2. Experience so far and practical tips
3. Outlook and deadlines
4. Conclusions

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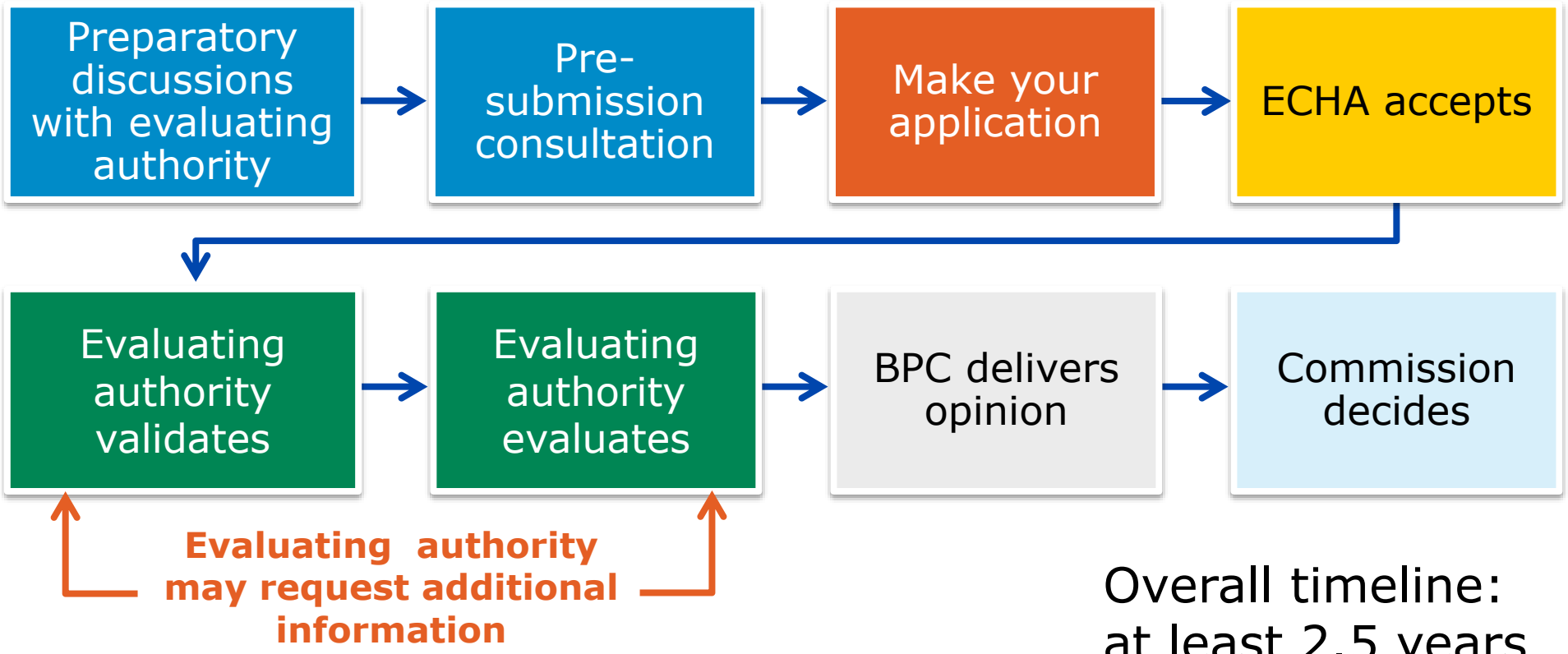
Union authorisation – how it goes



Overall timeline:
at least 2.5 years

Union authorisation – a plus for you

Single authorisation for entire EU market

- Direct access to EU/EEA market
- Same rights and obligations
- Positive impact on product availability
- Similar conditions of use → policy disagreements solved in advance

Centralised process coordinated by ECHA

- Harmonised procedures
- Fixed deadlines
- Help for you
- Cooperation with Commission and competent authorities

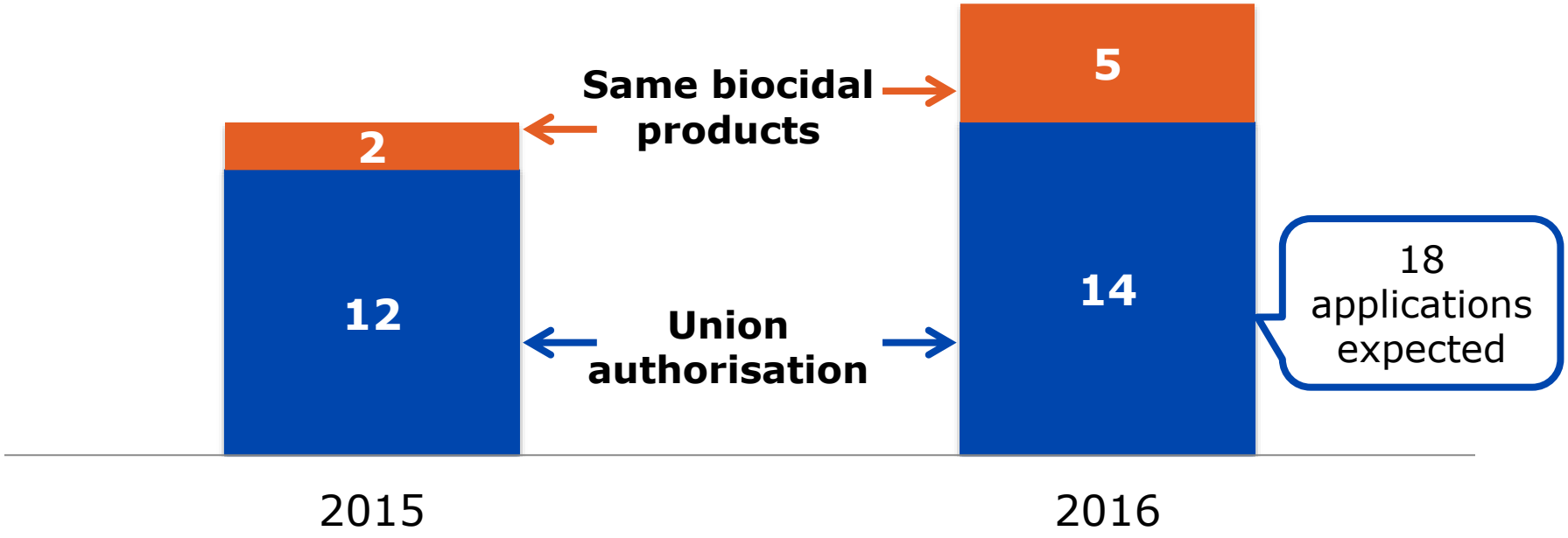
Union authorisation – how you see it

- ☹ High cost
- ☹ Not all product types eligible
- ☹ Uncertainties about the process

- ☺ Simplification
- ☺ Less administrative burden
- ☺ Biocidal product family concept

A.I.S.E./Cefic EBPF survey: *BPR Impact on biocidal products and innovation* (2015)

Union authorisation – your applications



- Mainly biocidal product families
- Disinfectants, insecticides and preservatives

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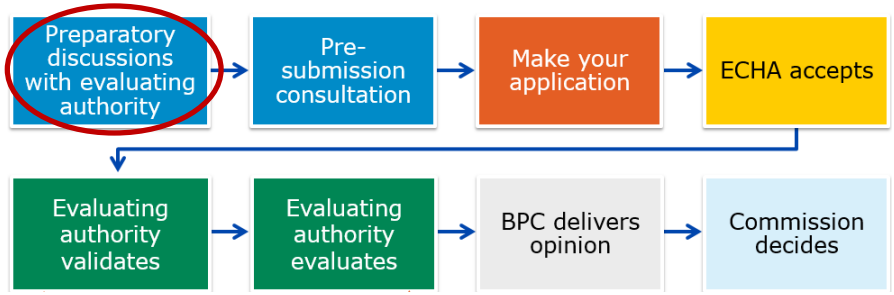
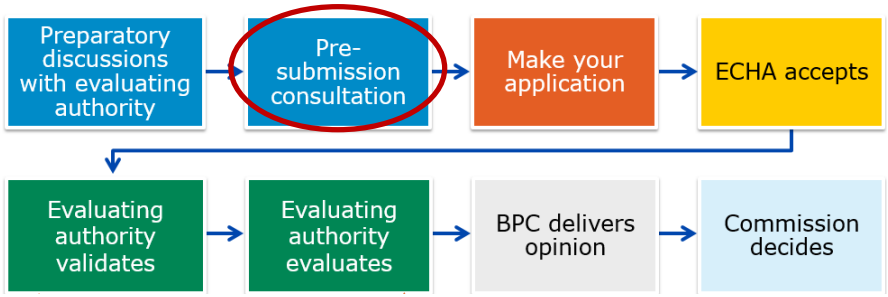


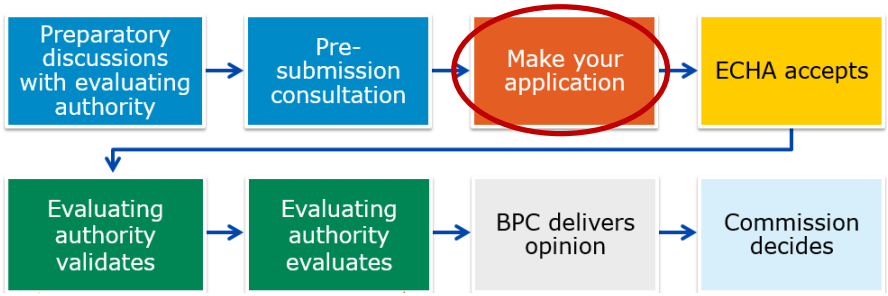
Preparatory discussions

- Decide on your evaluating competent authority
- Discuss technical or methodological questions
- Request for a pre-submission meeting with ECHA if needed
- Have your SME status verified by ECHA



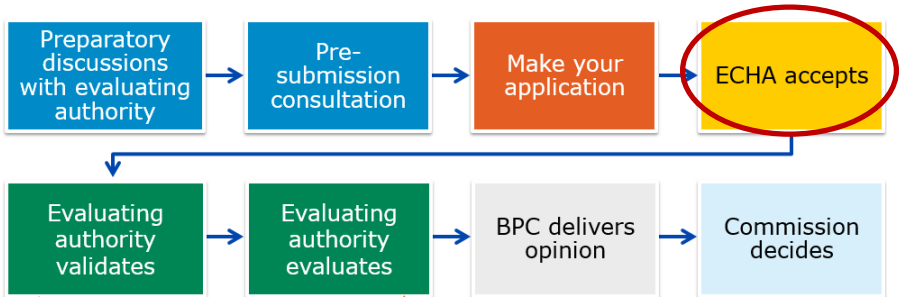
Pre-submission consultation

- Strongly recommended
- Good indication on whether the product is eligible
- Feedback useful to:
  - Decide if Union authorisation is the right strategy
  - Prepare your application



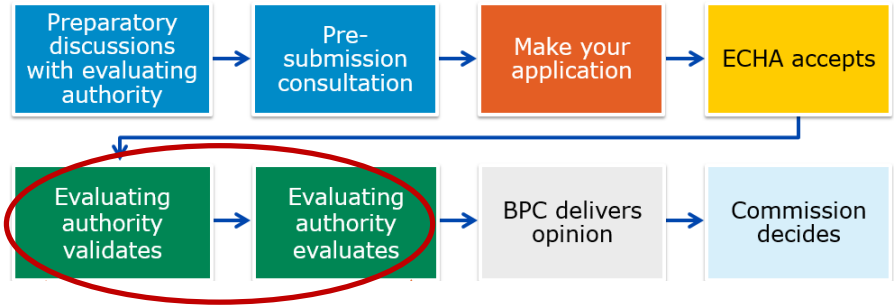
Application

- Consult the biocides submission manuals
- Create an ECHA account
- Upload the necessary documentation, including:
  - Agreement of the evaluating competent authority
  - Outcome of pre-submission or self-assessment of similar conditions of use
- Contact ECHA Helpdesk in case of issues
- Apply well before the deadline



ECHA acceptance

- Monitor the status of your submission in R4BP 3
  - Check the message inbox and task items
- Pay attention to the deadlines
  - Resubmission of information
  - Reply requested for a specific topic
  - Payment of the ECHA fee
- Contact ECHA for enquiries on your application



Validation and evaluation

- Monitor your case and pay attention to deadlines
  - Requests for additional information
  - Payment of the invoice sent by evaluating competent authority during validation
- Discuss with your evaluating competent authority if additional information requested
- Contact ECHA dossier manager if necessary

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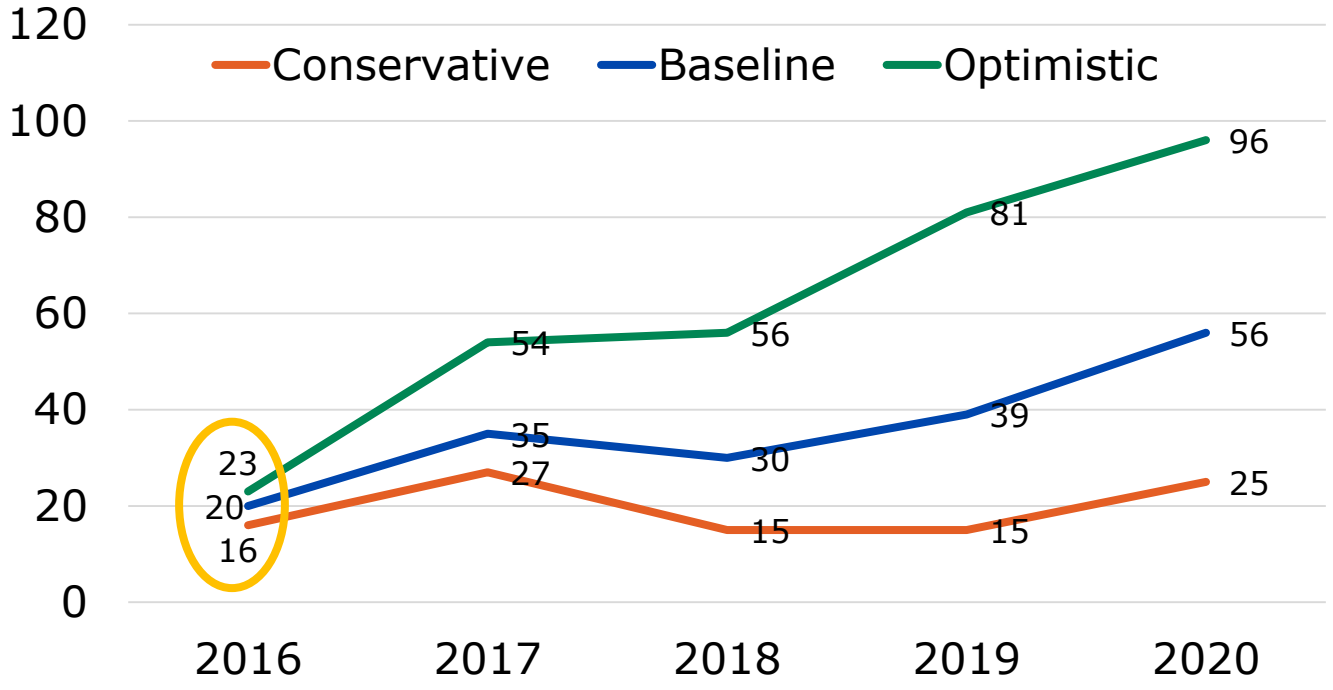
Industry view on evaluation of biocides market

- A.I.S.E./Cefic EBPF survey: *BPR Impact on biocidal products and innovation* (2015)
- Intention to choose Union authorisation for almost **50%** of the products
- Majority of the products grouped into families

Union authorisation estimates 2016-2020



Data from Commision *Background study for the assessment of the appropriateness and impact of the existing fee model for the Biocidal Products Regulation and its possible revision,* Final report, 15 April 2016

Same biocidal product possibilities

- Start from individual member of a biocidal product family
- National authorisation(s) from a “master” Union authorisation

Winning combination

Union authorisation + Biocidal product family + Same biocidal product

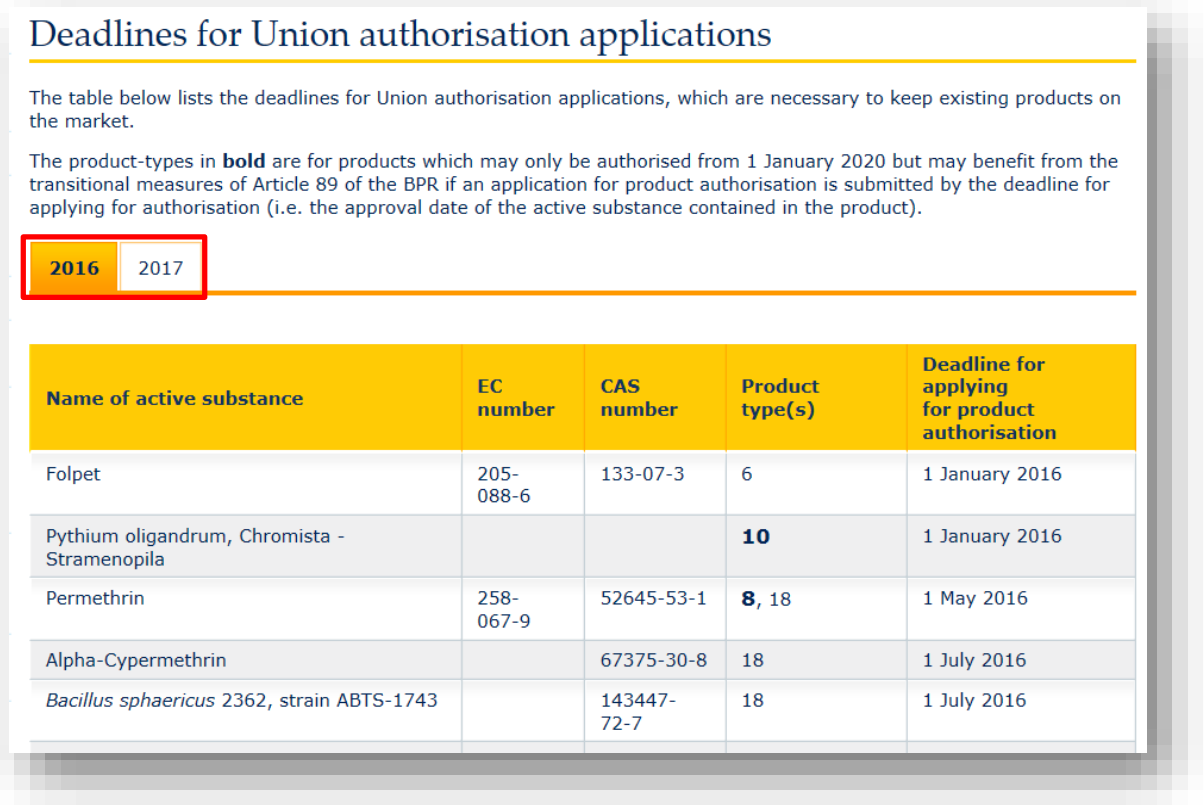
Flexibility

- Product portfolio management
- Marketing strategy

Simplification

- Centralised management
- Reduced administrative costs

Upcoming deadlines for applications



Deadlines for Union authorisation applications

The table below lists the deadlines for Union authorisation applications, which are necessary to keep existing products on the market.

The product-types in **bold** are for products which may only be authorised from 1 January 2020 but may benefit from the transitional measures of Article 89 of the BPR if an application for product authorisation is submitted by the deadline for applying for authorisation (i.e. the approval date of the active substance contained in the product).

2016 2017

Name of active substance	EC number	CAS number	Product type(s)	Deadline for applying for product authorisation
Folpet	205-088-6	133-07-3	6	1 January 2016
Pythium oligandrum, Chromista - Stramenopila			**10**	1 January 2016
Permethrin	258-067-9	52645-53-1	**8**, 18	1 May 2016
Alpha-Cypermethrin		67375-30-8	18	1 July 2016
Bacillus sphaericus 2362, strain ABTS-1743		143447-72-7	18	1 July 2016

ECHA website > Regulations > Biocides > Union authorisation > Deadlines

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Conclusions

- Benefits for you
  - Direct access to EU market
  - More marketing flexibility
  - Less administrative burden
  - Harmonisation across EU
- Things are improving all the time
  - We share information
  - Process more and more streamlined and reliable

We are here to help

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