Union authorisation: how ECHA is helping

Biocides Stakeholders' Day

1 September 2015

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Overview

1. Union authorisation process
2. ECHA role and support
3. Format and recommendations
4. Conclusions

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Union authorisation process (1/3)

- Granted by the European Commission and valid on the entire Union market
- Single biocidal products or product families
  - approved active substance(s)
  - similar conditions of use across EU (Article 42(1) BPR)
  - some product types excluded
- Adjustments (Article 44(5) BPR)
- Comparative assessment (Article 23(3) BPR)
- Provisional authorisation (Article 55(2) BPR)

Union authorisation process (2/3)

Step 1

1 September 2013:

PTs 1, 3, 4, 5, 18 and 19

BPs containing new active substances

Step 2

1 January 2017:

PTs 2, 6 and 13

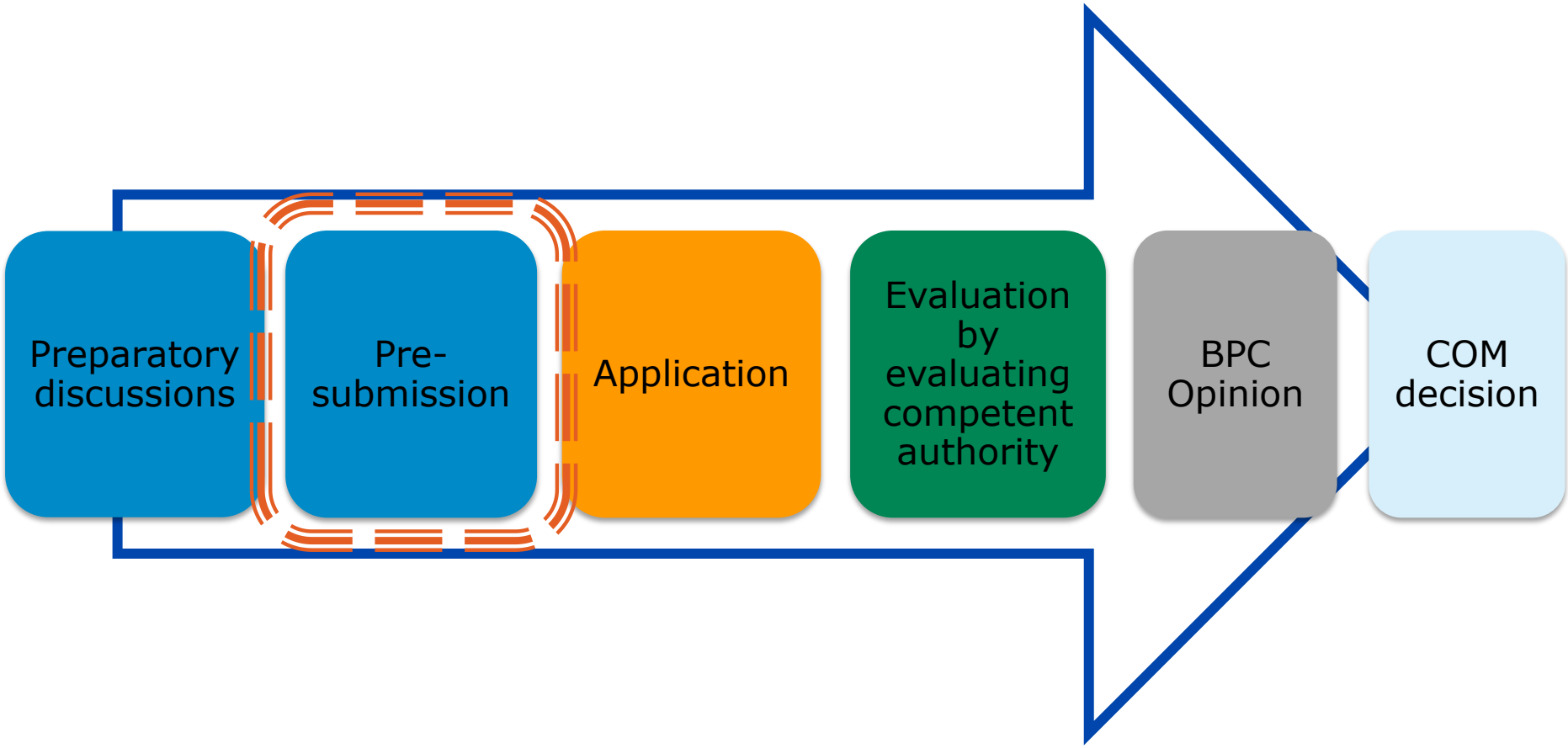
Step 3

1 January 2020:

All remaining PTs (beside those excluded)

N.B. applications can be made earlier.

Union authorisation process (3/3)



Benefits of the pre-submission

- For the applicant and the eCA:
  - Indications on the eligibility of the product:
    - falls within the scope of BPR;
    - may have similar conditions of use across the Union;
    - is in the appropriate product-type.
  - Indications on reservations of some MS
  - Indications on potential technical issues
- For ECHA:
  - Indications about potential forthcoming applications

Pre-submission steps

APPLICANT

- Contact ECHA Helpdesk
- Draft SPC and supporting document to ECHA

ECHA

Notification to MSCAs and COM

MSCAs and COM

No reactions: product deemed to have potentially similar conditions of use across the Union

MSCAs and COM

Reactions: consultation needed

Objections to the scope

Grounds for derogation (Article 37 BPR)

ECHA

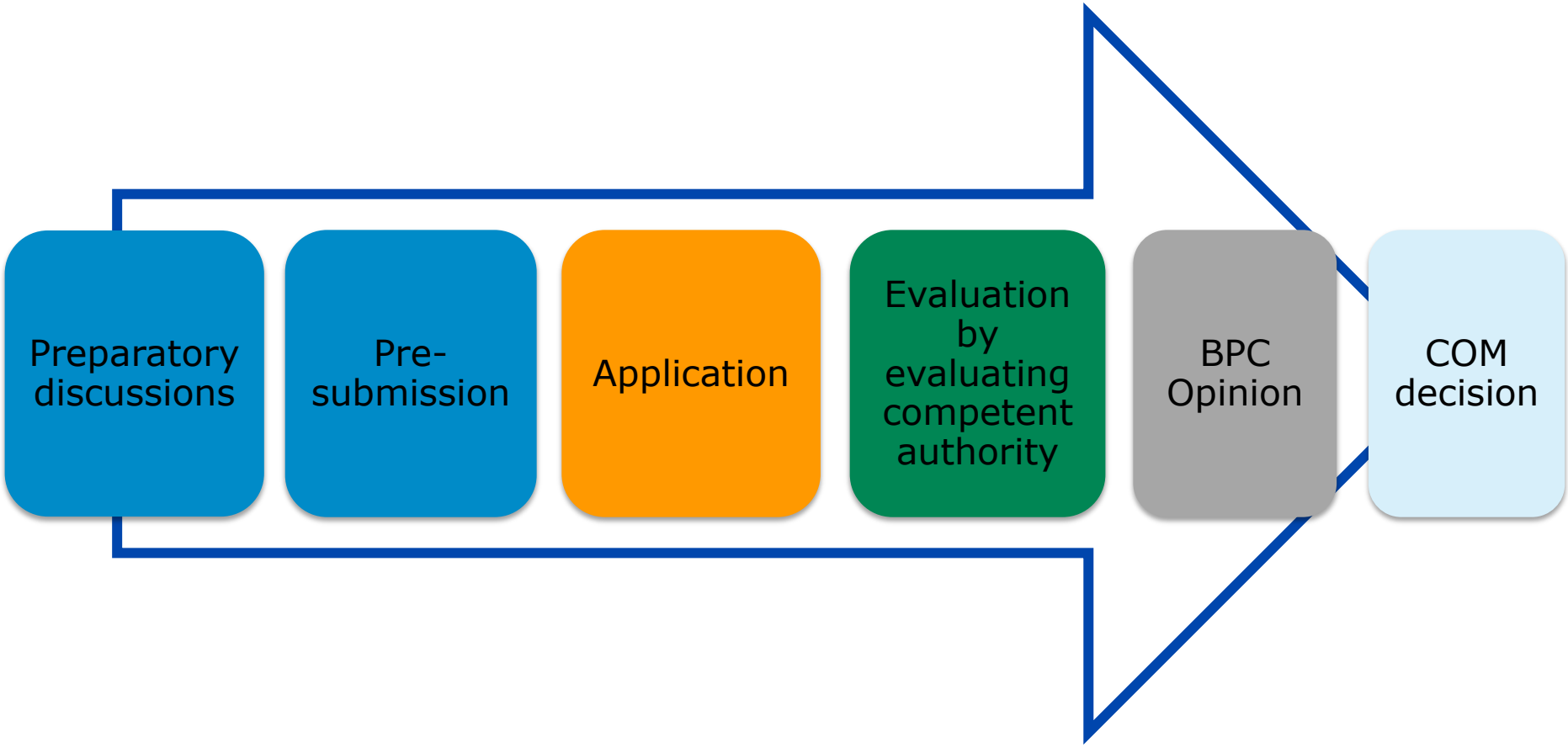
Outcome to the applicant

APPLICANT

Outcome as part of the application

As soon as possible or at the latest six months before the intended date of submission

Union authorisation process (3/3)



Overall timeline: at least 2.5 years

Expectations of Union authorisation

- Single authorisation for the entire EU market
  - Positive impact on product availability
  - Easier procedures for economic operators targeting several Member State markets
- ECHA involvement
  - Fixed deadlines → more certainty for applicants
  - Harmonised procedures → improved consistency in dossier assessment

Further considerations

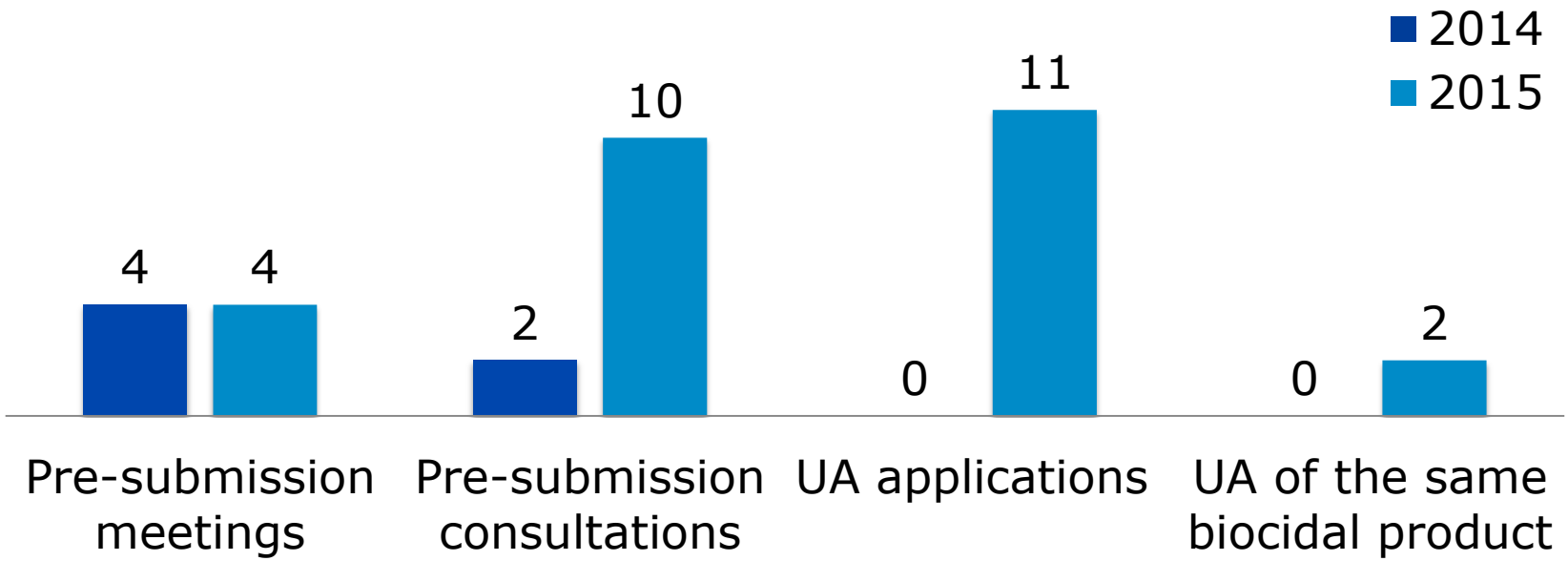
Choice of marketing strategy

New concepts to be implemented

New process

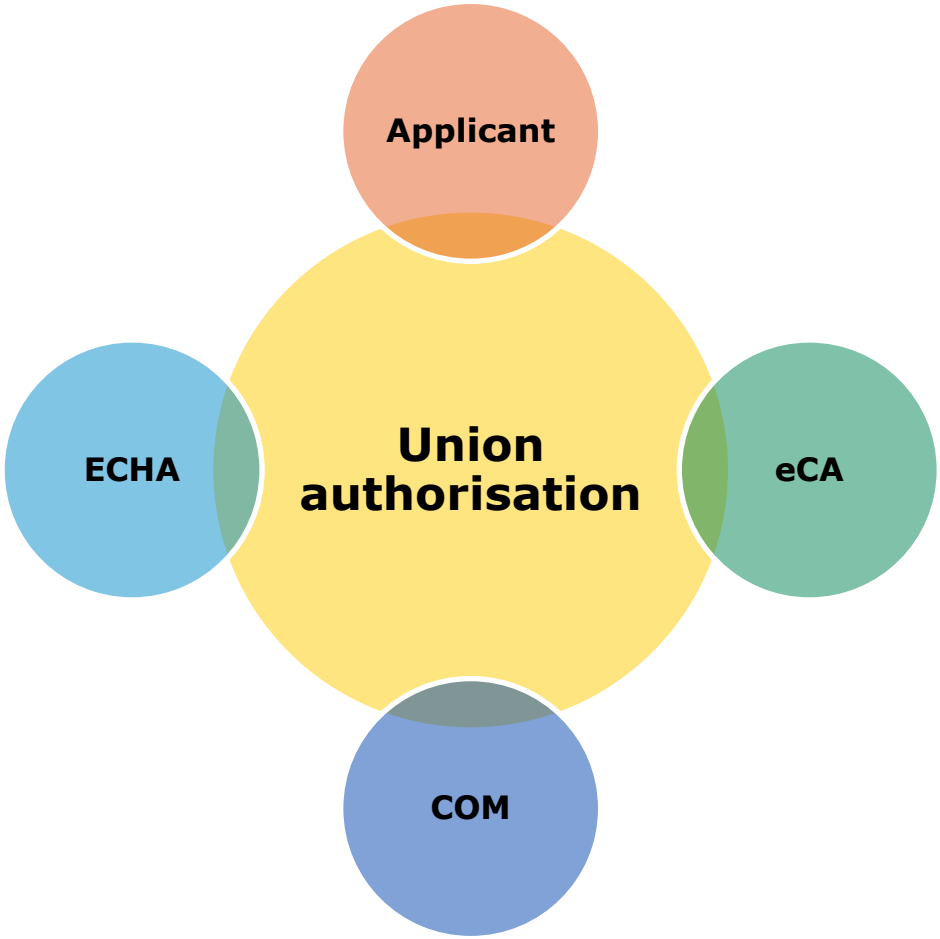
Similar conditions of use

Current figures on Union authorisation



- Biocidal product families
- Active substances:
  - Iodine and PVP-iodine
  - Octanoic and decanoic acid
  - Propan-2-ol
- Product types:
  - Human hygiene (PT 1)
  - Veterinary hygiene (PT 3)
  - Food and feed area (PT 4)

Building up capacity



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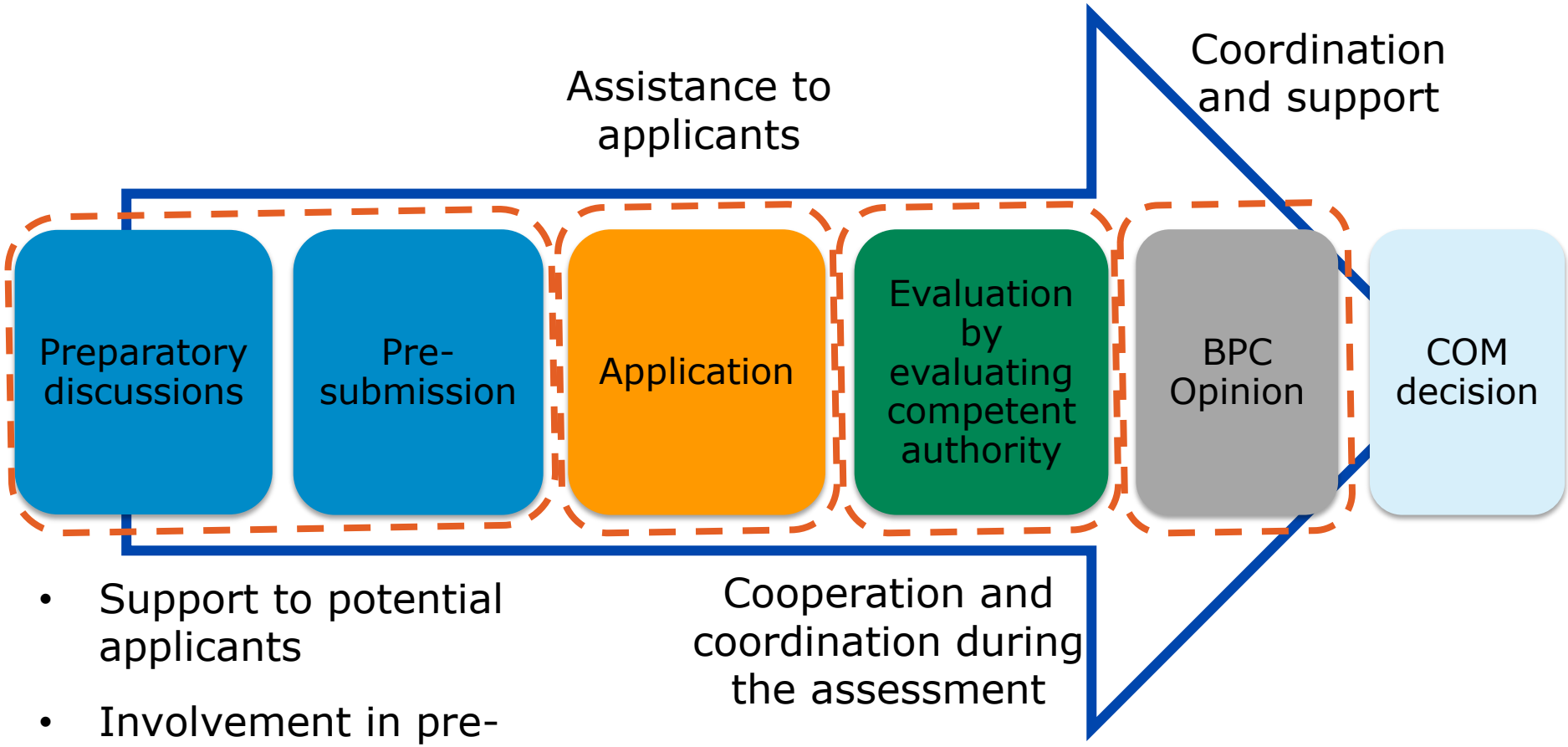
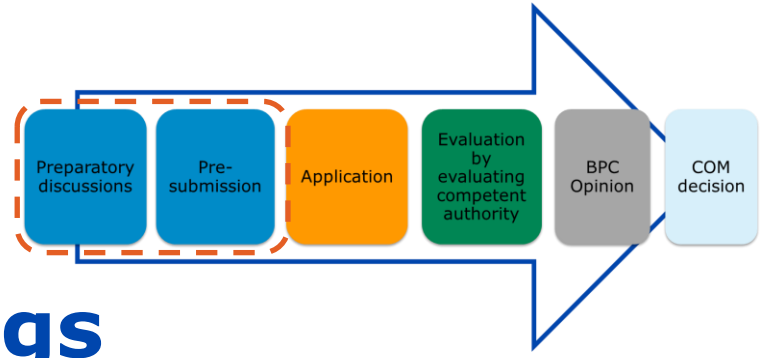
Main roles of ECHA

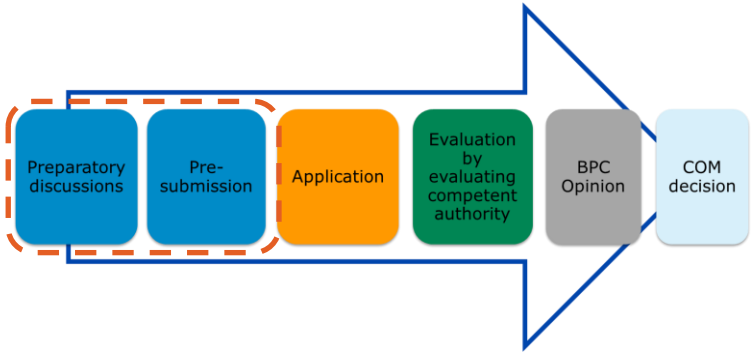


- Support to potential applicants
- Involvement in pre-submission consultations



Pre-submission meetings

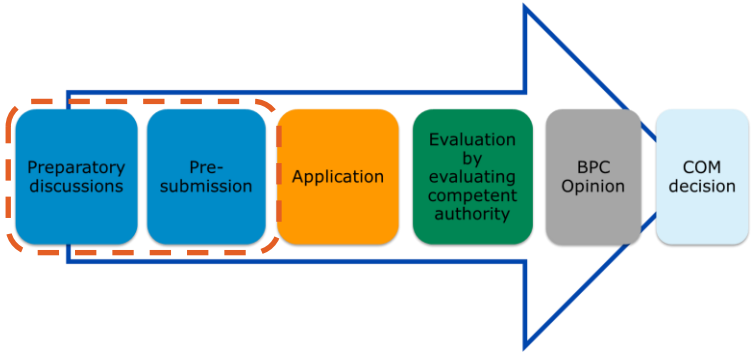
- Aim
  - Streamline the process and planning
  - Clarification of the steps and potential questions
- Participants
  - Applicant, ECHA, foreseen eCA, COM
- Timelines
  - As soon as possible
- Meeting organisation
  - Requests through the ECHA Helpdesk
  - Face-to-face meeting, teleconference, web conference



ECHA involvement in pre-submission consultations

- Helpdesk
  - Templates and instructions for the applicant
- Biocides Assessment Unit
  - Notification to MSCAs and COM
  - Dossier Manager as the focal point
  - Preparation of the outcome of the consultation
  - Informing the applicant of the outcome

Union authorisation webpage



echa.europa.eu/regulations/biocidal-products-regulation/authorisation-of-biocidal-products/union-authorisation

Union authorisation

The Biocidal Products Regulation (BPR) introduces the possibility to have certain biocidal products authorised at Union level. This will allow companies to place their biocidal products on the market throughout the entire Union, without the need to obtain a specific national authorisation.

Union authorisation will give the same rights and obligations in all the Members States as those provided by national authorisations.

Union authorisation can be granted to biocidal products with similar conditions of use across the Union, except those containing active substances meeting the exclusion criteria and those belonging to product-types 14, 15, 17, 20 and 21. The timeframe for initiating the authorisation process is different depending on whether the product contains new or existing active substances.

New active substances

A product containing new active substances, also in combination with existing active substances, is eligible for Union authorisation from 1 September 2013.

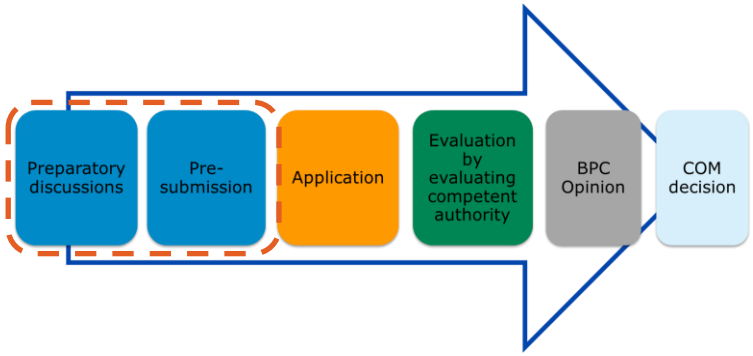
Existing active substances

For biocidal products containing only existing active substances, Union authorisation will be available in three different stages, depending on the product-type:

1. From 1 September 2013 for product-types 1, 3, 4, 5, 18 and 19
2. From 1 January 2017 for product-types 2, 6 and 13
3. From 1 January 2020 onwards to the remaining product-types 7, 8, 9, 10, 11, 12, 16 and 22.

The list of biocidal products with Union authorisation will be published on the ECHA website.

News and events



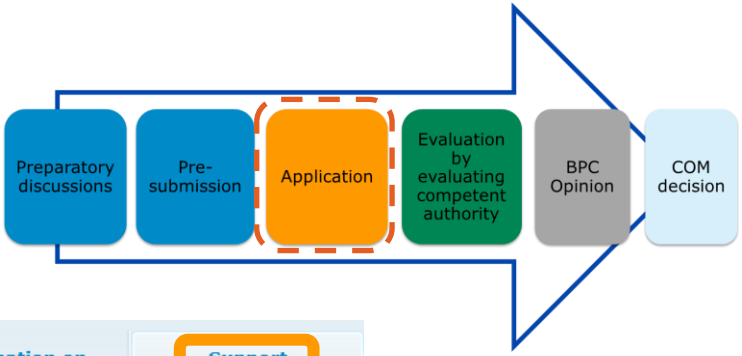
Biocides

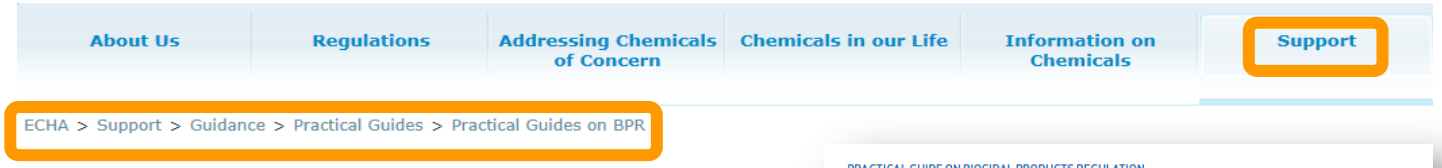
First applications for Union authorisation submitted

The first two applications for Union authorisation of biocidal products have recently been submitted to ECHA, according to the procedure established by the Biocidal Products Regulation. The first two applications are for biocidal product families containing the active substance iodine. The products are used as disinfectants for veterinary hygiene purposes.

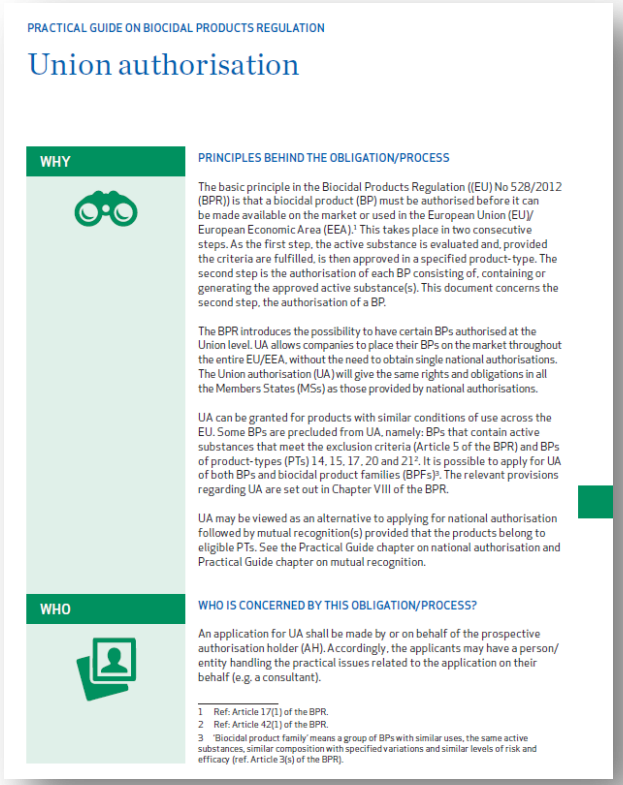
Press release | Union authorisation

Practical guide





- Published on ECHA website in September 2014
- Practical information on BPR requirements



PRACTICAL GUIDE ON BIOCIDAL PRODUCTS REGULATION

Union authorisation

WHY

PRINCIPLES BEHIND THE OBLIGATION/PROCESS

The basic principle in the Biocidal Products Regulation ((EU) No 528/2012 (BPR)) is that a biocidal product (BP) must be authorised before it can be made available on the market or used in the European Union (EU)/ European Economic Area (EEA).[1] This takes place in two consecutive steps. As the first step, the active substance is evaluated and, provided the criteria are fulfilled, is then approved in a specified product-type. The second step is the authorisation of each BP consisting of, containing or generating the approved active substance(s). This document concerns the second step, the authorisation of a BP.

The BPR introduces the possibility to have certain BPs authorised at the Union level. UA allows companies to place their BPs on the market throughout the entire EU/EEA, without the need to obtain single national authorisations. The Union authorisation (UA) will give the same rights and obligations in all the Members States (MSs) as those provided by national authorisations.

UA can be granted for products with similar conditions of use across the EU. Some BPs are precluded from UA, namely: BPs that contain active substances that meet the exclusion criteria (Article 5 of the BPR) and BPs of product-types (PTs) 14, 15, 17, 20 and 21[2]. It is possible to apply for UA of both BPs and biocidal product families (BPFs)[3]. The relevant provisions regarding UA are set out in Chapter VIII of the BPR.

UA may be viewed as an alternative to applying for national authorisation followed by mutual recognition(s) provided that the products belong to eligible PTs. See the Practical Guide chapter on national authorisation and Practical Guide chapter on mutual recognition.

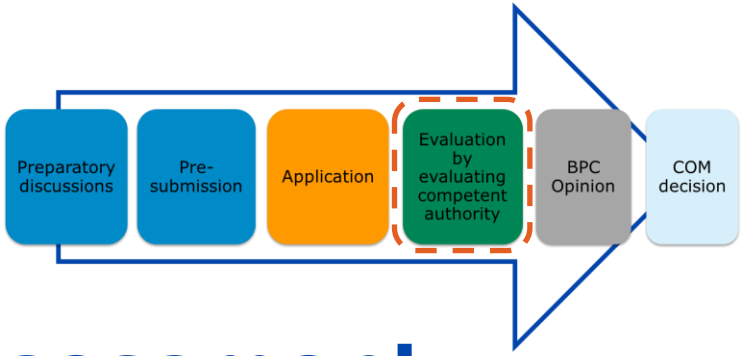
WHO

WHO IS CONCERNED BY THIS OBLIGATION/PROCESS?

An application for UA shall be made by or on behalf of the prospective authorisation holder (AH). Accordingly, the applicants may have a person/ entity handling the practical issues related to the application on their behalf (e.g. a consultant).

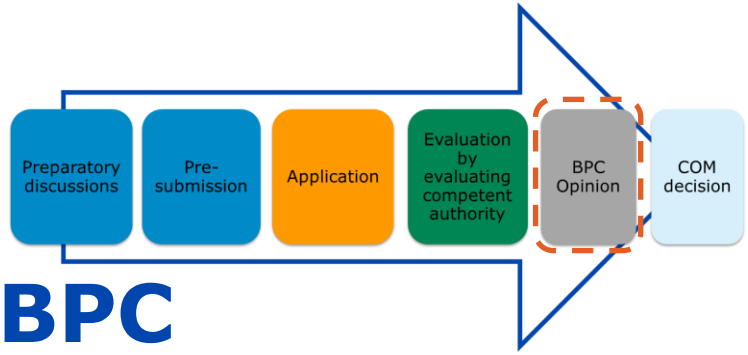
1 Ref: Article 17(1) of the BPR.
2 Ref: Article 42(1) of the BPR.
3 'Biocidal product family' means a group of BPs with similar uses, the same active substances, similar composition with specified variations and similar levels of risk and efficacy (ref. Article 3(s) of the BPR).

echa.europa.eu/documents/10162/21742587/pg_on_bpr_9_union_authorisation_en.pdf



ECHA coordination with eCAs during the assessment

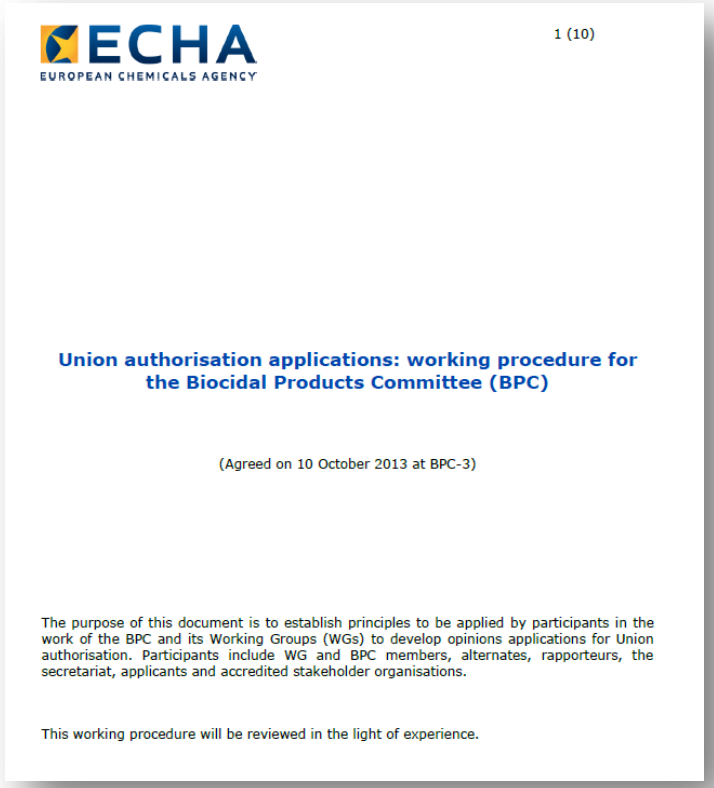
- Cooperation between ECHA and eCAs
- Validation and evaluation stages
- Coordination with eCAs in case of related applications
- Dossier Manager in ECHA as the contact point



Working procedure for BPC

- Agreed by BPC in 2013
- Steps to be taken during the process of Union authorisation

echa.europa.eu/documents/10162/4221979/bpc_working_procedure_union_authorisation_en.pdf



ECHA
EUROPEAN CHEMICALS AGENCY

1 (10)

Union authorisation applications: working procedure for the Biocidal Products Committee (BPC)

(Agreed on 10 October 2013 at BPC-3)

The purpose of this document is to establish principles to be applied by participants in the work of the BPC and its Working Groups (WGs) to develop opinions applications for Union authorisation. Participants include WG and BPC members, alternates, rapporteurs, the secretariat, applicants and accredited stakeholder organisations.

This working procedure will be reviewed in the light of experience.

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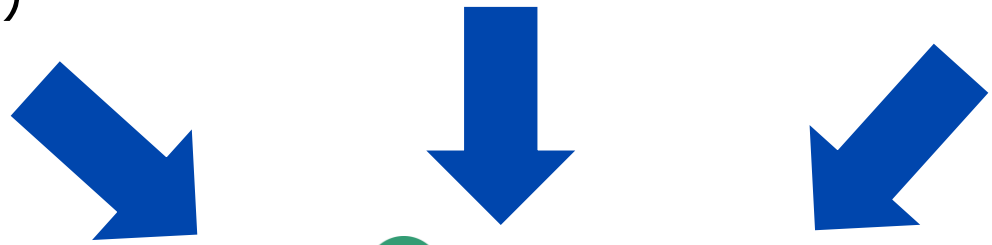
Content of the application

IUCLID dossier
(.i5z format)

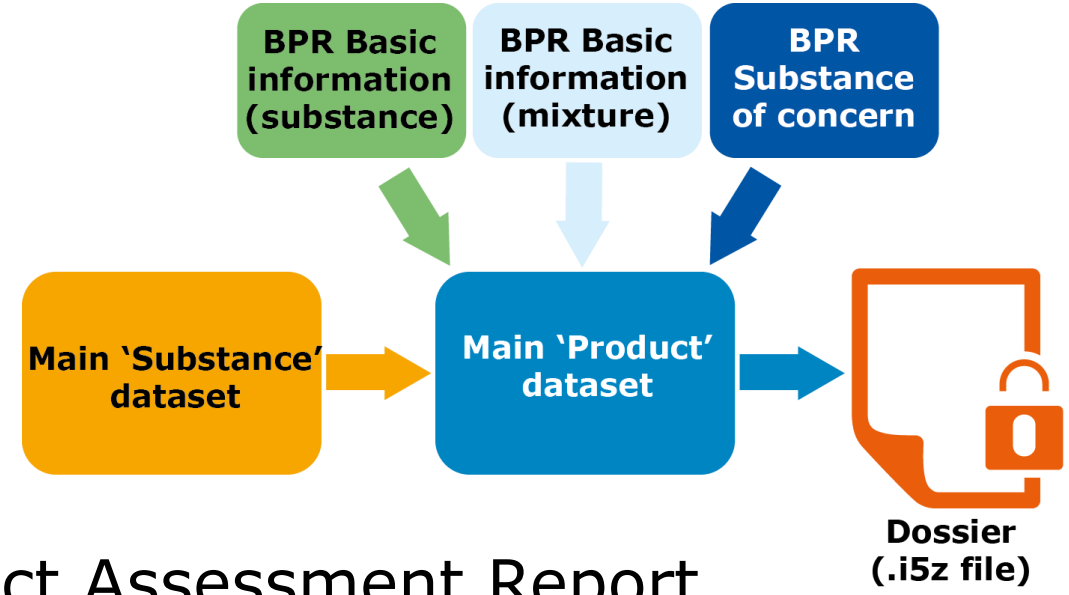
Summary of Product Characteristics (SPC)
(.xml format)

Supporting documents
(.doc, .pdf)



R4BP 3

IUCLID dossier



- Product Assessment Report
- Where relevant:
  - Decision on technical equivalence
  - Letter of access
  - 'Permission to refer' to data granted by ECHA (Article 63 BPR)

Summary of Product Characteristics

- Requirement for applications (Article 20 BPR)
- Specific instructions for biocidal product families
- Before the authorisation:
  - applicant to submit SPC in all official languages of the Union
  - MSCAs to check the translations
  - ECHA to coordinate the translation check and transmit the SPC to COM

Other supporting documents

- Agreement from the eCA
- Outcome of the pre-submission consultation
- Where relevant:
  - Supporting document for biocidal product family structured in meta-SPCs
  - Supporting document for provisional authorisation
  - Supporting document for application for authorisation of same biocidal product
- Available on the ECHA website

echa.europa.eu/support/dossier-submission tools/r4bp/supporting-documents

Before applying

Does Union authorisation fit your needs?

Find your eCA

Ask for a pre-submission meeting

When applying

Is the documentation ready?

Create an ECHA account to access R4BP 3

Apply well before the deadline

After applying

Monitor your case in R4BP 3

Talk with your eCA

If needed, contact your ECHA Dossier Manager

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Conclusions

- Making it work
  - Building up capacity
  - Reducing uncertainties
  - Gaining experience

- Building trust
  - Cooperation
  - Exchange

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