

Overview of the Biocidal Product Regulation

**The Seminar to Japanese Industry on the
EU Chemicals Legislation: REACH, CLP &
BPR**

3 April 2015 / Tokyo, Japan

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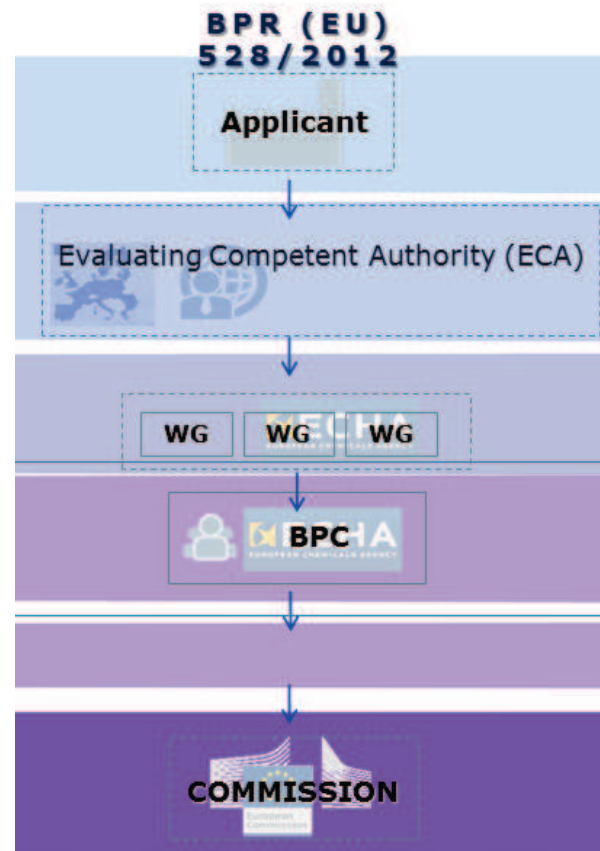
New Regulation

- **Biocidal Product Regulation (EU) 528/2012**
 - Replaces the Biocidal products Directive (98/8/EC)
- Adopted in May 2012
- Entered in the **operation 1 September 2013**
- Link to the text via ECHA website
<http://echa.europa.eu/regulations/biocidal-products-regulation>
- Covers biocidal products not regulated by:
 - pesticides, veterinary medicines, cosmetics legislation



Why from Directive to Regulation?

- Improve the functioning of the EU market for biocides
- Ensure high level of protection of human health and the environment
- Simplifies and streamlines processes
- Reduces animal testing
 - Compulsory data/cost sharing
 - Encourages more flexible and intelligent approach to testing



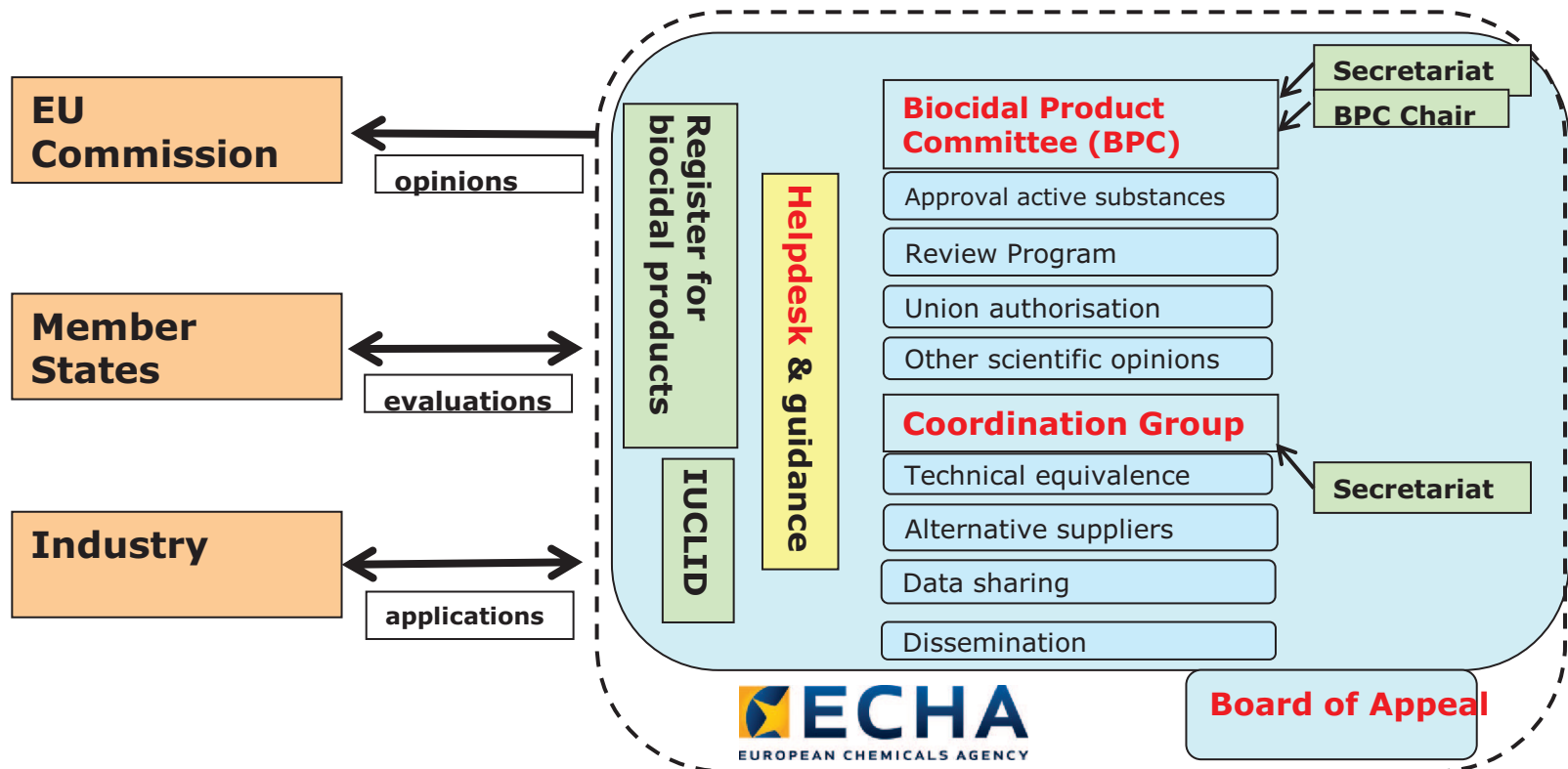
Regulation vs. Directive

- New definitions cover:
 - *in situ* generation
 - placing on the market
 - nanomaterials
- Requirements for **treated articles**
- Hazard based exclusion & substitution
- Detailed procedure for **mutual recognition**
- **Union authorisation** of biocidal products possible
- Harmonised "summary of the product characteristics" for authorisation

Directive	Regulation
98/8/EC	EU 528/2012
Annex I-inclusion	Approval
Annex I	List of approved substances
Annex IA	Annex I
Low-risk products	Products eligible for the simplified procedure
Frame formulation	Biocidal product family

ECHA & BPR

- **Coordination** of procedures & **centralisation** of tasks that are better dealt at EU level rather than at each Member State



Basic Concepts

- **Active substance:** a substance or a micro-organism that has an action on or against harmful organisms - **Approved**
 - Harmful organism: an organism, including pathogenic agents, which has an unwanted presence or a detrimental effect on humans, their activities or the products they use or produce, on animals or the environment
- **Biocidal products - Authorised**
 - Split into 22 Product Types (Annex V)

Main groups and product types

- **Disinfectants**

- human hygiene (1), public health (2), veterinary (3), food and feed areas (4), drinking water (5)

- **Preservatives**

- in-can (6), film (7), wood (8), fibre (9), construction material (10), liquid cooling (11), slimicides (12), metal working fluids (13)

- **Pest control**

- rodenticides (14), avicides (15), molluscicides (16), piscicides (17), insecticides (18), repellents (19), other invertebrates (20)

- **Other**

- antifouling products (21), embalming/taxidermist fluids (22)



Legislative situation

- **Review Programme**

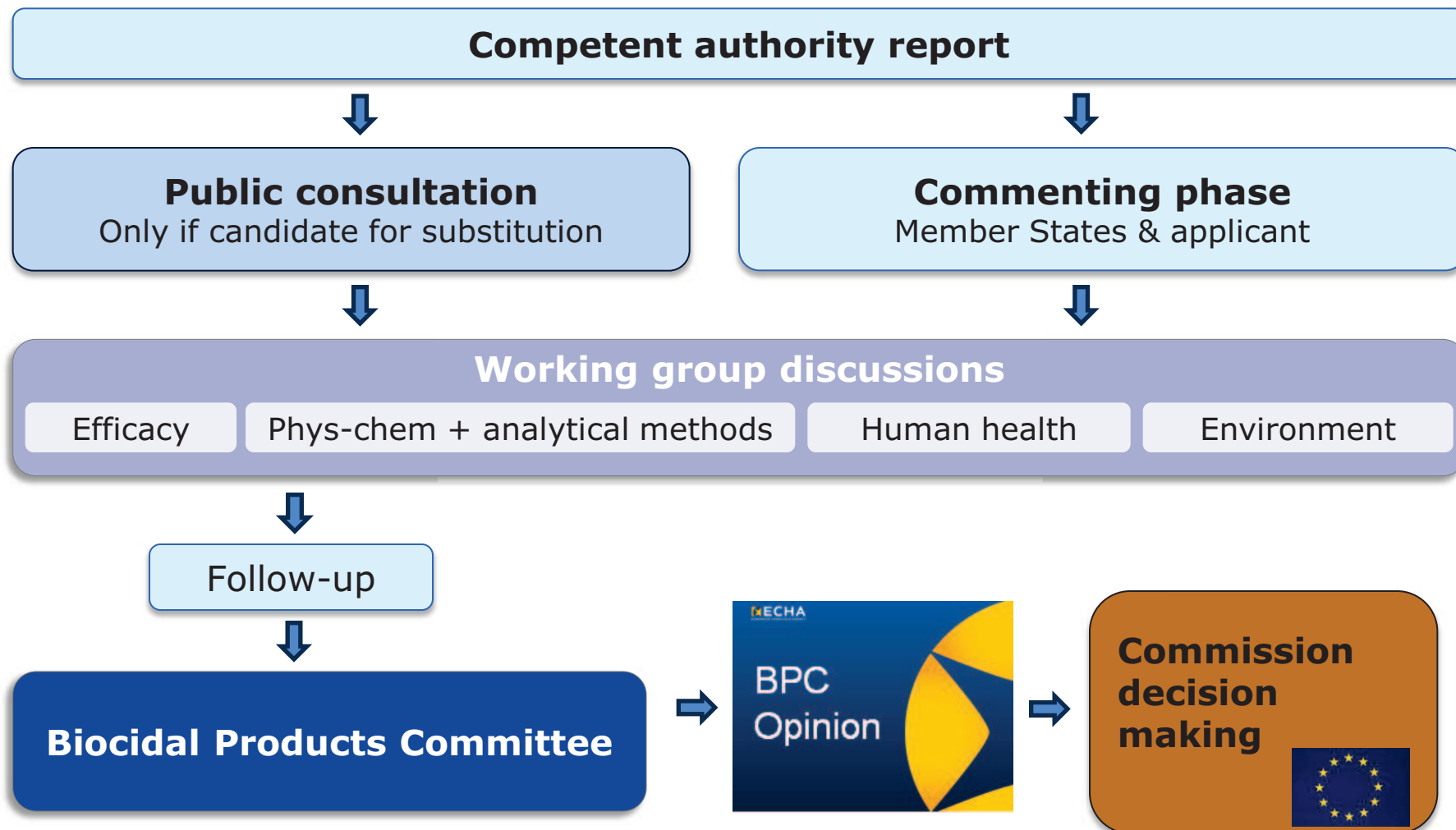
- Phasing existing active substance Product Type combinations into EU system
- Phasing in existing biocidal products via authorisation into EU system

- **All non-approved active substances** and consequently **non-authorised biocidal products** have to be removed from the market
 - EU market is in a transitional phase up to the end of the Review Programme

ECHA's role

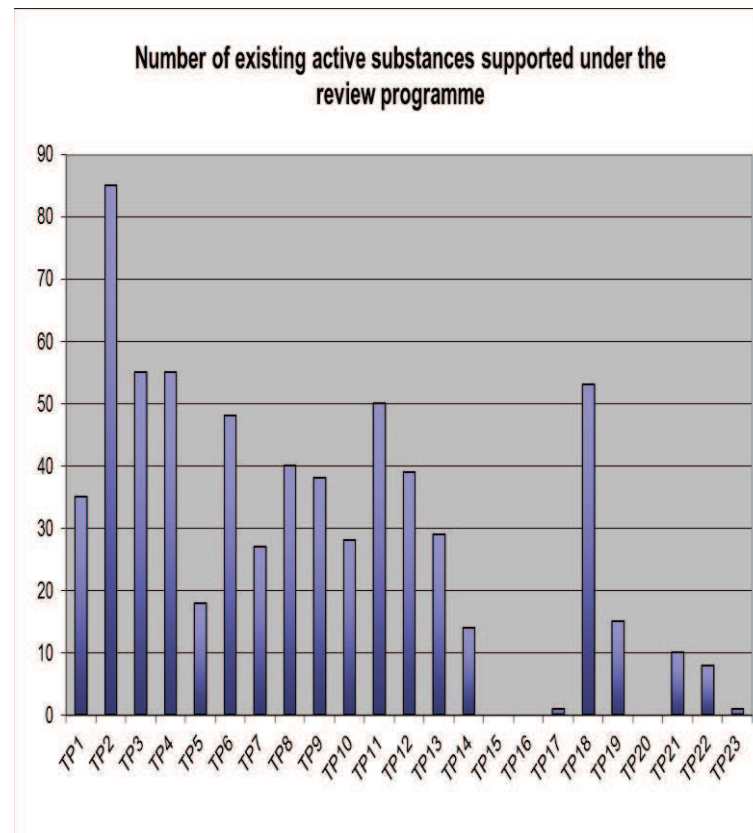
- **Centralised IT system**
 - Register for Biocidal Products R4BP 3 (hub for all applications)
 - IUCLID 5.6 including biocides functionalities.
- **Biocidal Products Committee and Coordination Group**
 - Central bodies for an EU-wide approach
 - Scientific and administrative support to members
 - Assure quality, consistency and transparency
- **Support to applicants and Member States**
 - Provide guidance and an ECHA Helpdesk / Helpnet
 - Promote a consistent approach between Member States
- **Data sharing, dissemination and technical equivalence**
 - Benefit from REACH experience
- **Communication**
 - Awareness raising with key actors and stakeholders

Review of Actives – main steps



Review Programme

- Number of **Active Substance - Product-Type** dossiers:
 - *Total: 619*
 - *Approved: 109*
 - *In peer review process at EU level: 144*
- Annually reviewed around 50 dossiers
- Extended from 14 May 2014 to 31 December 2024



Active Substance Approval

Faster process for all new applications:

- One year evaluation stage
- 270 days for opinion forming
- Possibility of stopping the clock during evaluation
 - Up to 180 days; more if justified by the nature of the data requested or by exceptional circumstances
- **Overall:** around two years from submission of application to BPC opinion
 - Followed by the European Commission implementing act

Active Substances Exclusion of “SVHC”

- Substances that:
 - are **CMR** (Carcinogens, Mutagens, or toxic for Reproduction category) **1A** or **1B**, or
 - are **PBT** (Persistent, Bioaccumulative and Toxic), or **vPvB** (very Persistent and very Bioaccumulative), or
 - have **ED** (endocrine-disrupting) properties
- “SVHC” **cannot be approved** as Active Substances **unless**:
 - Exposure is negligible, or
 - The substance is essential to control a serious danger to human or animal health or to the environment, or
 - Non-approval will have disproportionate negative impact for society

Active Substances substitution

- If an active substance is a **candidate for substitution**
 - ➔ Biocidal product is subject to comparative assessment
 - 60-day **public consultation** by ECHA:
 - Third parties to provide relevant information
 - Mainly information on available substitutes expected
- **Explicit evaluation** of the criteria in Competent Authority Report
 - Only the final outcome of assessment will confirm whether criteria are met

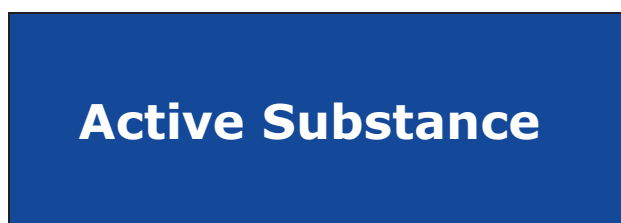
Data sharing is mandatory

- Submitted to ECHA **via R4BP**
- **Minimise testing** on animals & monopolistic situations of suppliers of Active Substances
- Applies to:
 - Data from tests on **vertebrate animals** on all tox- and eco-tox studies for existing active substances
 - with regards to alternative suppliers
- Prospective applicant & data owner must **seek agreement**
- **Compensation** for data is determined in a fair, transparent and non-discriminatory manner, share the cost of information to be submitted for this regulation
- If negotiation fails, ECHA gives prospective applicant **right to refer**, and proportionate share of the cost to be paid fixed by national courts

Active Substances Cost Sharing

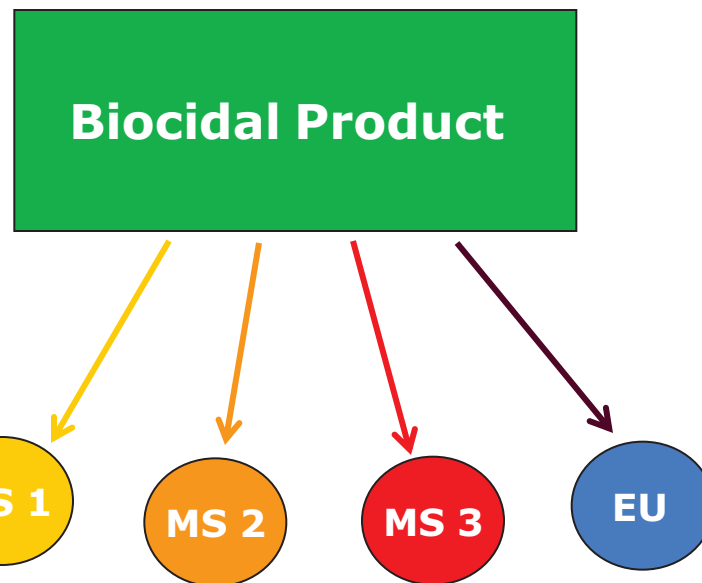
- All active substance manufacturers or importers must submit a dossier or a letter of access to ECHA as of **1 Sep 2013**
- ECHA will establish a list of manufacturers or importers who complied with this obligation
- **From 1 Sep 2015:** only biocidal products with a listed source of Active Substance can be made available on the market
- Data protection for existing substances in the review programme expires **31 Dec 2025** at the latest

Biocidal Products – a 2-step approach



Step 1

Approval of Active
Substance per Product
Type combination



Step 2

Product authorisation on national or
Union level

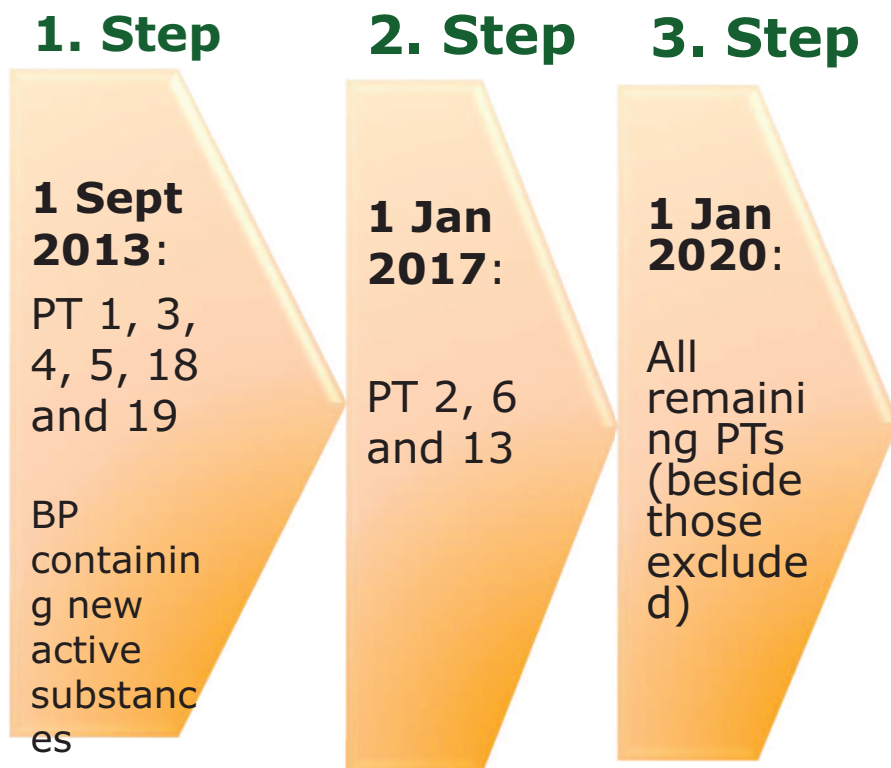
Union Authorisation

- Authorisation given by the European Commission, valid on the entire Union market
- For **single** biocidal **products or** product **families** with similar conditions of use across EU
- Excluded:
 - Products containing substances fulfilling the exclusion criteria
 - Products to control rodents, birds, fish, and other vertebrates (PTs 14, 15, 17 and 20)
 - Antifouling products (PT 21)

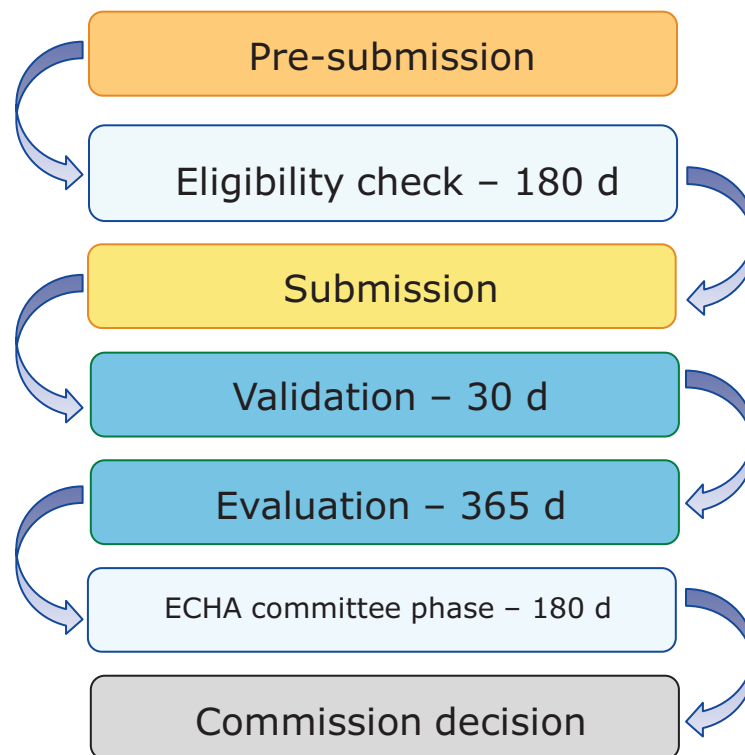


Union Authorisation

Transition



Timeline



Union Authorisation Advantages

- Facilitates the making available of biocidal products with similar conditions of use on the EU market
 - **Simplifies procedures** for economic operators targeting several Member State markets
 - **Reduces** the overall **administrative burden**
 - **Single authorisation** for the entire Union market will have a positive impact on product availability.
 - **Fixed deadlines** will provide more certainty for applicants.
 - **Harmonised procedures** will improve consistency in the dossiers' assessment.

Biocidal Products Mutual Recognition

- Clear procedures including mechanisms to deal with objections and derogations, for better enforcement
- Options:
 - **in sequence:** application when product is already authorised in one Member State, or
 - **in parallel:** application when product is not yet authorised
- **90 days** for Member States to coordinate & agree
- If no agreement, then Commission decides
 - **Disagreements** referred to the Commission, possibly based on ECHA opinion

Biocidal Products Simplified Procedure

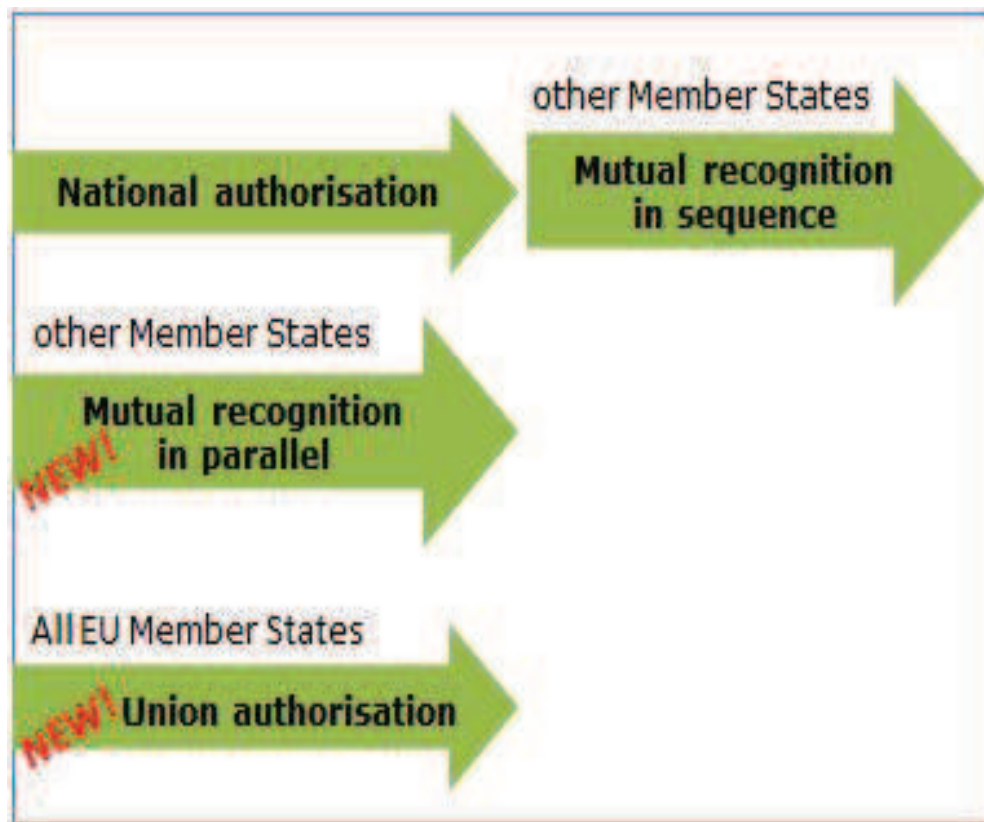
- Facilitates the marketing of product with **lower concern/better profiles** with regard to health & environment:
 - All Active Substances listed in **Annex I**
 - Contain **no substance of concern** or **no nanomaterials**
 - Sufficient **efficacy**
 - **No** need to wear **PPE** (Personal Protective Equipment)
- **Benefits** for product authorisation
 - Faster procedure: Member State evaluation in 90 days
 - Once given by one Member State, the product can be made available on the whole EU market, after a Notification to ECHA

Comparative assessment of Products

- **During** the assessment of the authorisation of:
 - Biocidal Product or
 - Renewal of authorisation (either at Member State or EU level)
- Products containing candidates for substitution will not be authorised if **alternatives**:
 - Present significantly lower risk
 - Are sufficiently effective, and
 - Present no significant economic or practical disadvantage, and
 - Chemical diversity adequate to minimise resistance

Product Authorisation Summary

Authorisation of Biocidal Products for a maximum of 10 years



Treated articles

- **Definition**
 - *Substance, mixture or article*
 - *Treated with or intentionally incorporating **biocidal products***
- **Active substance** in biocidal product with which the article is treated needs to be approved in the EU
- Technical **guidance** is being developed



Treated articles

- Conditions for **placing on the market**
 - Article has to **comply with** all relevant **conditions of approval** of the active substance
- **Substance/product-type combinations** that have not yet been approved are allowed if
 - Combination is still **in the review programme**, or
 - **An application** for approval is **submitted** before 1 September 2016



Treated articles - labelling

- **Required if**

- ***Claim is made*** regarding biocidal properties of the article, or
- ***Conditions of substance approval so require***

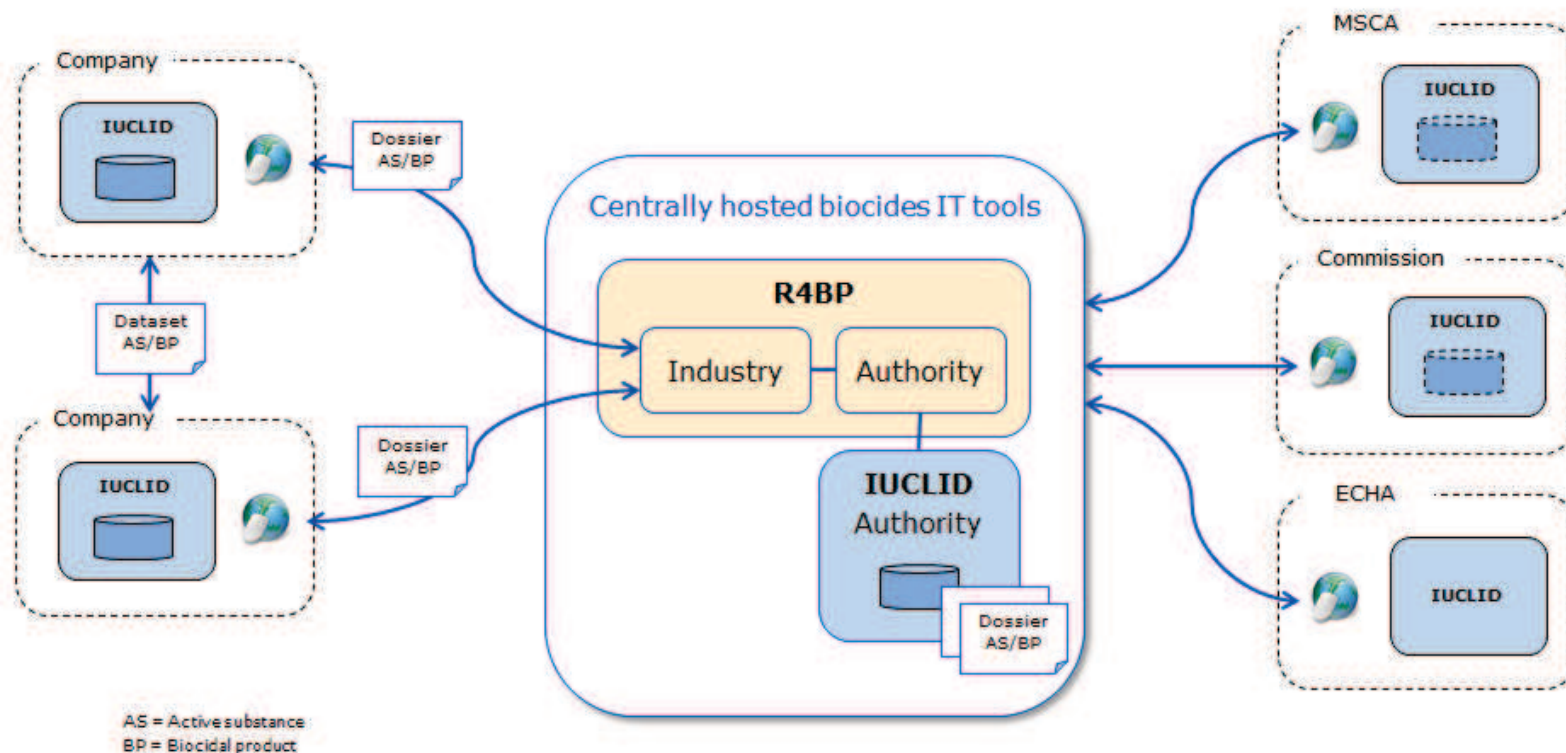
- Information to be provided in the **national language**

- *Statement that article incorporates a biocide*
- *Biocidal property of the article*
- *Name of all active substances & nanomaterials*
- *Instructions for use where necessary to protect man or environment*



DMF... dermatitis 23 days after wearing the shoes containing dimethyl furmarate.

IT tools for BPR



**R4BP3 and IUCLID: common hub
and paperless system**

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Biocidal Products Regulation

The Biocidal Product Regulation (BPR, Regulation (EU) 528/2012) concerns the placing on the market and use of biocidal products, which are used to protect humans, animals, materials or articles against harmful organisms, like pests or bacteria, by the action of the active substances contained in the biocidal product.

[Understanding BPR](#)[Legislation](#)

Processes



Companies can apply for the approval of an active substance by submitting a dossier to ECHA.

[Approval of active substances](#)

After the approval of an active substance, companies wishing to place biocidal products on the market have to apply for product authorisation at national or Union level.

[Authorisation of biocidal products](#)

Companies can ask ECHA to establish the technical equivalence of their active substance.

[Technical equivalence](#)

Manufacturers and importers not involved with the review programme of the previous legislation have to submit certain information to ECHA.

[Alternative suppliers](#)

<http://echa.europa.eu/regulations/biocidal-products-regulation>

ECHA Helpdesk advice on BPR



Customer: Applicants, particularly SMEs



Topics: Approval of Active Substance, inclusion in Annex I, Union authorisation



Scope: Advice



Communication: Helpdesk contact form

<http://echa.europa.eu/contact/helpdesk-contact-form>

Biocides Guidance

	Volume I Identity/phys-chemical/analytical methodology	Volume II Efficacy	Volume III Human health	Volume IV Environment
Part A	Guidance	Guidance	Guidance	Guidance
Part B	Under development	Under development	Guidance	Under development
Part C	Under development	Under development	Under development	Under development
Volume V Specific Guidance				
	Active substances and suppliers (Article 95 list)			Guidance
	Technical equivalence			Guidance
	Micro-organisms			Under development

Biocidal Products Regulation

Volume I Identity/physico-chemical properties/analytical methodology

› Part A: Identity/physico-chemical properties/analytical methodology, Information Requirements

› Part B: Identity/physico-chemical properties/analytical methodology, Assessment

› Part C: Identity/physico-chemical properties/analytical methodology, Evaluation

<http://echa.europa.eu/web/guest/guidance-documents/guidance-on-biocides-legislation>

Achievements BPR & PIC

Biocides

- **R4BP3** updated IT tool for biocidal applications
- Electronic submission & storage system
- **Changes** in the **regulatory system** clarified to duty holders
- **New regulatory processes** proven to work
- **Active substances review programme**
- 34 opinions in 2014

PIC

- **Smooth take over** of the regulation
- **New ePIC IT-tool** for export and import notifications
- **Successful management of notifications**
- Around 4,600 in 2014

ECHA & industry challenges in 2015

Biocides

- Company applications for **active substance supplier** status by 1 September
 - Products not covered will be out of the market
- **Planning** activities related to **biocides** under uncertainty regarding the volume of applications and related fee income
- **Union authorisation**
 - new opportunities for companies
 - New process for ECHA to manage

Worth to Remember

- BPR **streamlines the processes** & enhances the decision making
- Opportunities for businesses, but companies **need to learn** and understand their duties and timelines
- ECHA provides companies with **support, IT tools & guidance**
- Pay attention to the requirements for **treated articles & alternative suppliers**

Thank you !