European Biocidal Products Forum

A sector group of Cefic

European Chemical Industry Council - Cefic aisbl

Legislation on Biocides

BCCI Workshop - Innovation in Bulgarian chemical industry and new HSE Legislation

Hotel Forum, Sofia

14-11-19

Dr. Boris VAN BERLO

EBPF - A Sector Group of Cefic

European Biocidal Products Forum (https://specialty-chemicals.eu/ebpf)

- Spokesperson for the biocide business community vis-à-vis the European Commission (COM) and the Member States (MS)
  - > 70 members: companies, associations & national federations
- Engages in implementation BPR & regulatory developments
  - Policy matters (ED, sustainable use) & technical issues (guidance development, IT tools,…)
- Representation as accredited stakeholder & observer
  - Competent Authority Meetings (COM)
  - Biocidal Products Committee & its Working Groups (ECHA)
  - Coordination Group (ECHA)

BPR

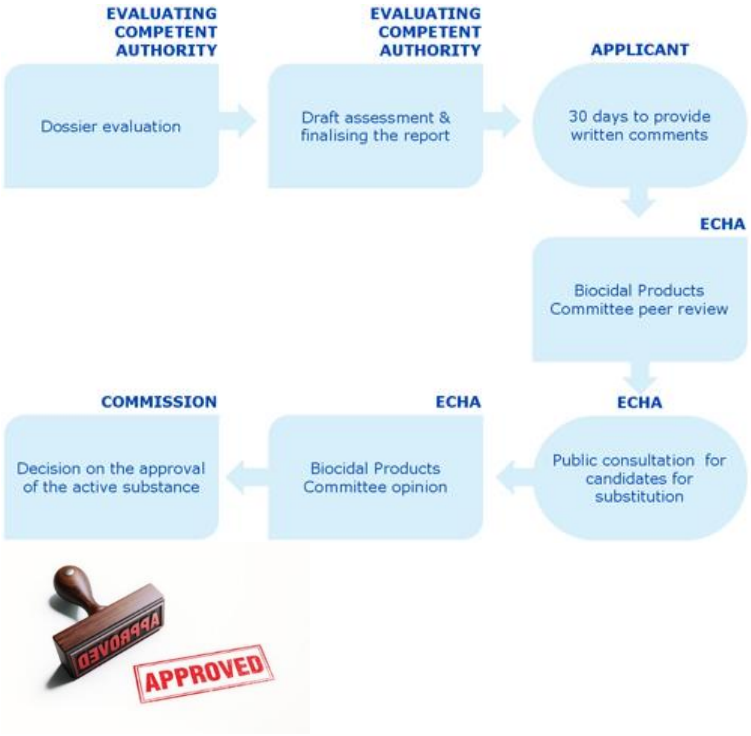
Biocidal Products Regulation ((EU) No 528/2012)

- Placing on the market & use of biocides
  - Aims to improve functioning of EU biocidal products market
  - Aims to ensure high level of protection for humans and the environment
- Two step process
  - Active Substance (AS) approval
  - Biocidal Product (BP) authorisation

Active Substance Approval

Approval if at least one BP containing that AS may be expected to meet the criteria of Art. 19(1)(b) BPR

- Not exceeding 10 years
- Renewable
- Approval date marks start of BP authorisation procedures

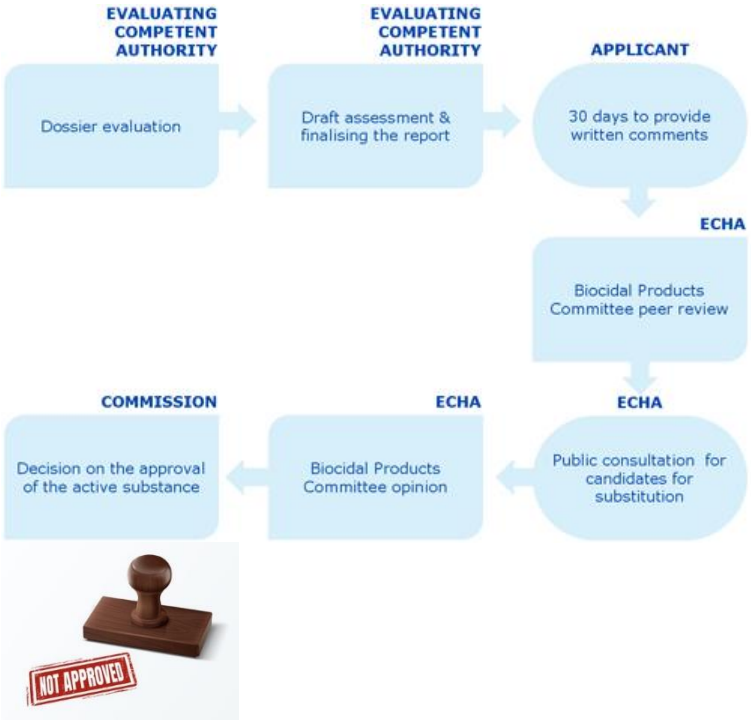


This schematic and all others on BPR process-flows courtesy of ECHA

Active Substance Approval

In principle no approval if AS meets the **Exclusion Criteria** - Art. 5(1) BPR

- Carcinogen cat. 1A or 1B (CLP)[1]
- Mutagen cat. 1A or 1B (CLP) [1]
- Reprotoxic cat. 1A or 1B (CLP) [1]
- Endocrine Disruptor [2&3]
- Persistent, Bioaccumulative & Toxic (REACH) [3]
- very Persistent & very Bioaccumulative (REACH) [3]



[1] Regulation (EC) No 1272/2008; [2] Regulation (EC) No 2017/2100; [3] Regulation (EC) No 1907/2006

Active Substance Approval

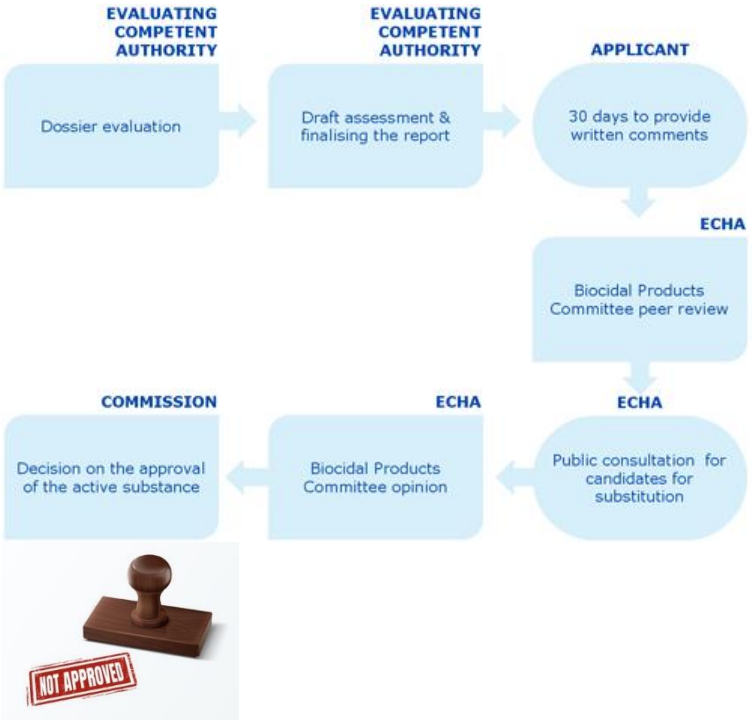
In principle no approval if AS meets the **Exclusion Criteria**

Derogation possible if at least one of these conditions is met - Art. 5(2) BPR:

- Risk from exposure in BP negligible
- AS essential to prevent/control serious danger to HH or ENV
- Not approving disproportionate negative impact on society

Key: are there sufficient suitable alternatives available?

Public consultation to collect information



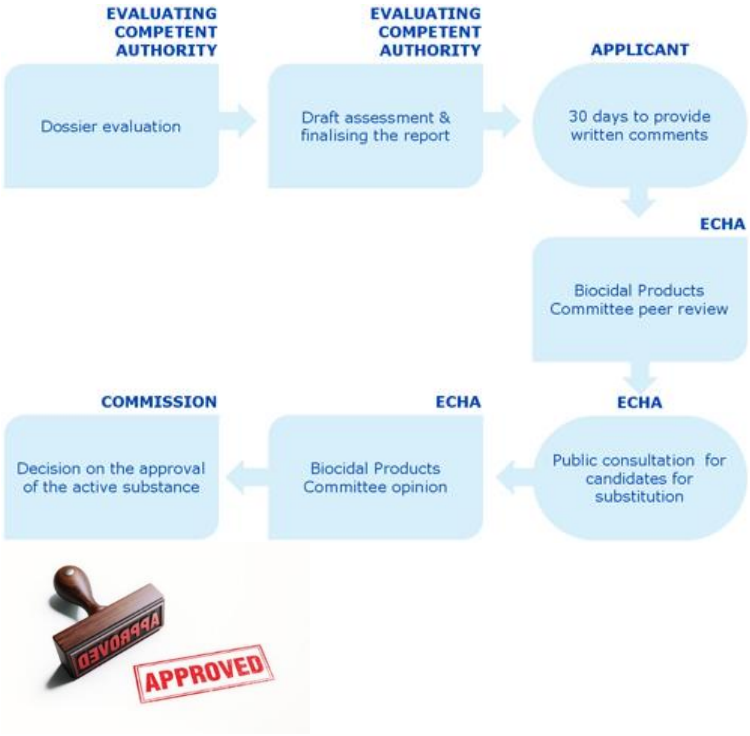
Active Substance Approval

In principle no approval if AS meets the **Exclusion Criteria**

Derogation possible
(Guidance: *CA-March14-Doc.4.1* & *CA-Nov14-Doc.4.5*)

Approval possible

- For maximum 5 years
- For restricted uses
- MS may only authorise BP if conditions met in their territory



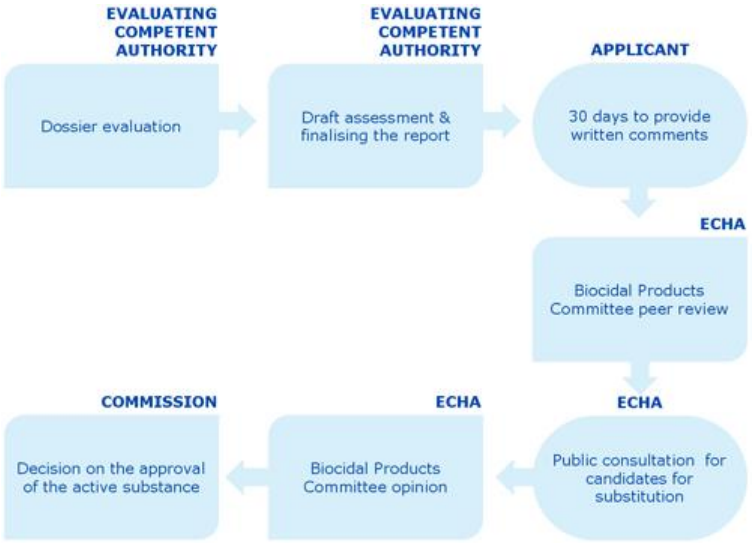
Active Substance Approval

Substitution Criteria - Art. 10 BPR

Objective: identify AS of particular concern to HH or ENV and ensure they are phased-out and replaced by more suitable alternatives

AS candidate for substitution if:

- Derogates from exclusion
- Respiratory Sensitiser (CLP) [1]
- Meets 2 of the PBT criteria (REACH) [3]



[1] Regulation (EC) No 1272/2008; [3] Regulation (EC) No 1907/2006

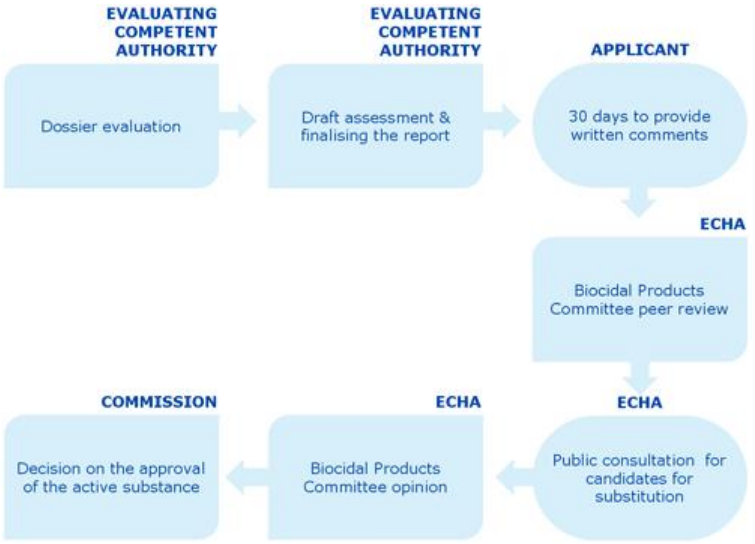
Active Substance Approval

Substitution Criteria - Art. 10 BPR

Objective: identify AS of particular concern to HH or ENV and ensure they are phased-out and replaced by more suitable alternatives

AS candidate for substitution if:

- Tox ref. values significantly lower than those of alternatives [4]
- Concerns HH & ENV even with very restrictive RMM [4]
- Contains significant proportion non-active isomers/impurities [4]



[4] *CA-March14-Doc.4.1*

Active Substance Approval

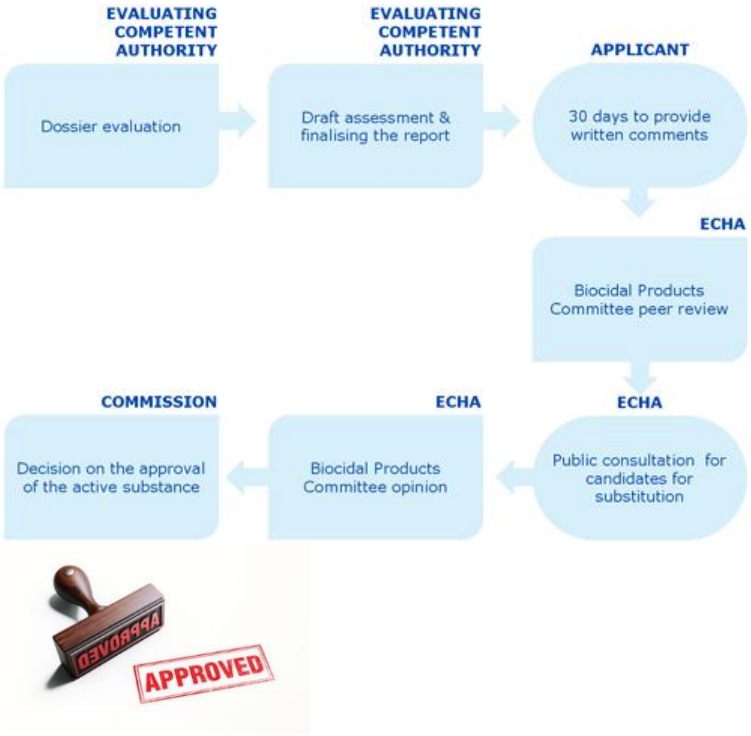
Candidate for Substitution

Public consultation to collect info

Cooperation with RAC, PBT EG,...

Approval possible

- Not exceeding 7 years
- If exclusion criteria: only 5 years
- Also for renewal
- BP containing candidate for substitution subject to comparative assessment
- List & guidance available on CIRCABC



Authorisation of Biocidal Products

General

Start to prepare well in advance of approval date:

- Build your dossier using all relevant ECHA IT Tools
- Consciously choose your preferred BP application-type
- Be aware of all requirements & most recent applicable guidance
- Find eCA/rMS and get written confirmation of their commitment to act as such
- Request pre-submission meeting(s) with eCA/rMS
- Get external help if necessary
- Stay in contact/communicate with your eCA/rMS

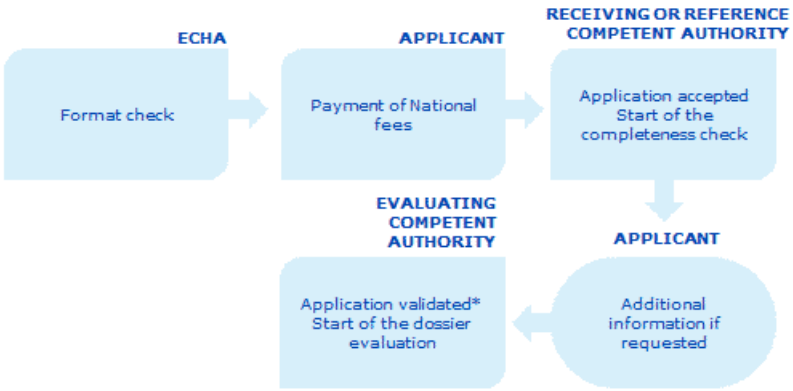
Authorisation granted for a maximum period of 10 years - renewable

Authorisation of Biocidal Products

National Authorisation (NA) - Art. 29-31 BPR

If you are only interested in one single local market

- Payment: 30 days
- Validation: 30d + *90d stop the clock* + 30d

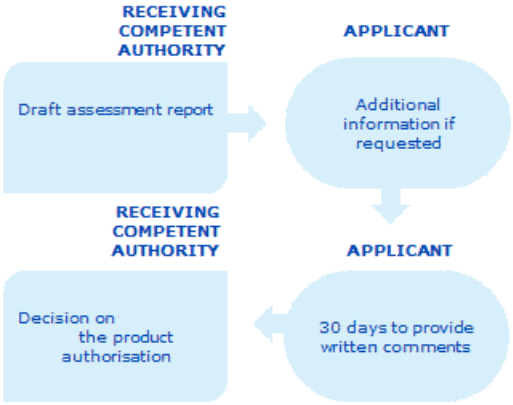


Authorisation of Biocidal Products

National Authorisation (NA) - Art. 29-31 BPR

If you are only interested in one single local market

- Payment: 30 days
- Validation: 30d + *90d stop the clock* + 30d
- Evaluation: 365d + *180d stop the clock*
- Including 30d commenting period applicant on draft PAR
- Finalisation: grant/refuse authorisation



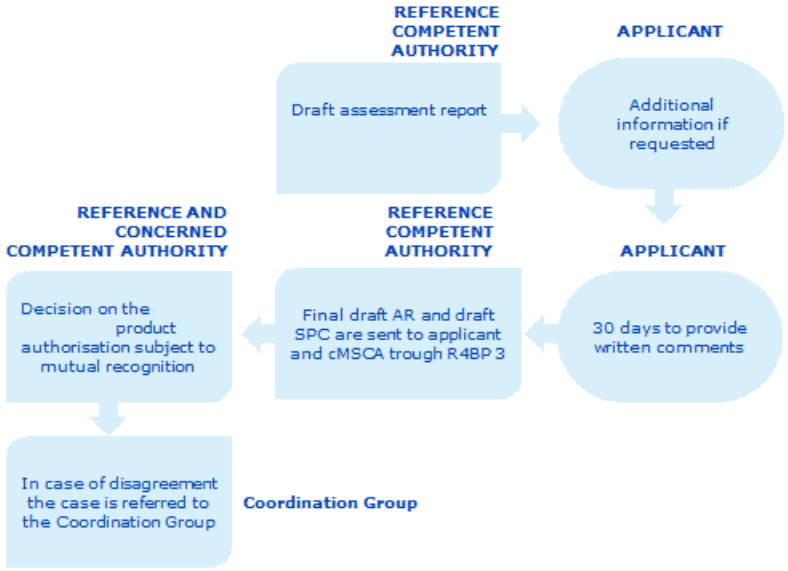
Authorisation of Biocidal Products

Mutual Recognition in Parallel (MRP) - Art. 34 BPR

If you are interested in several markets

Submitted at same time as NA

- Payment: 30 days
- Validation: 30d + *90d stop the clock* + 30d
- Evaluation: 365d + *180d stop the clock*
- Including 30d commenting period applicant on draft PAR

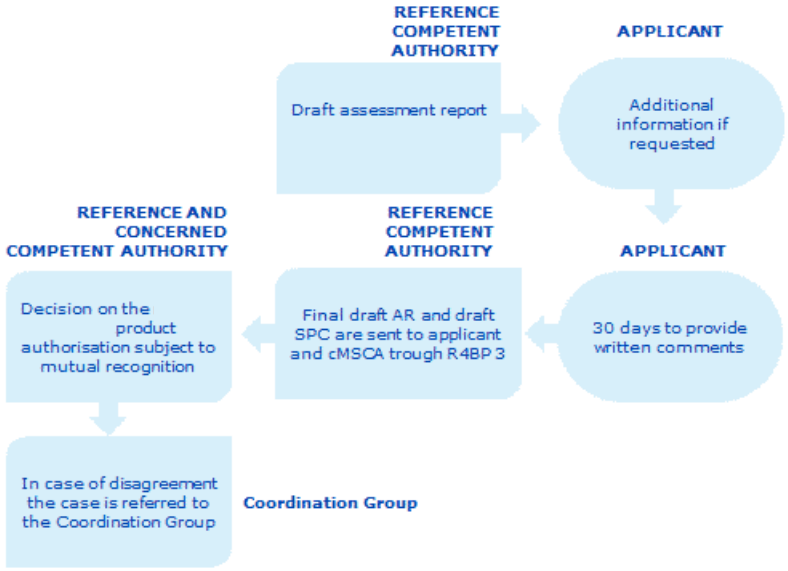


Authorisation of Biocidal Products

Mutual Recognition in Parallel (MRP)

Mutual Recognition Phase (90d)

- 1st step: 40d cMS commenting period
- 2nd step: 50d bilateral exchange
- If agreement on PAR & SPC: 30d to grant authorisation
- If no agreement on PAR & SPC: submission of referral to Coordination Group (CG)



Authorisation of Biocidal Products

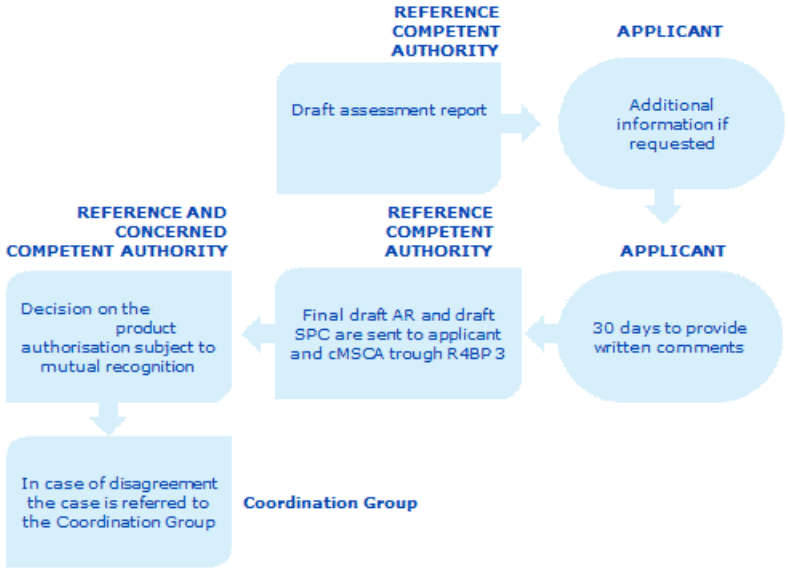
Mutual Recognition in Parallel (MRP)

CG Referral Procedure (60d) - Art. 35-36 BPR

- Discussion in CG (during meeting, teleconference or written procedure)
- Applicant should be heard
- If agreement after 60d: finalisation by granting/refusing authorisation
- If no agreement: referral of disagreement to COM according to Art. 36 BPR

COM to adopt decision (implementing act)

Possibility to ask ECHA opinion according to Art. 38 BPR



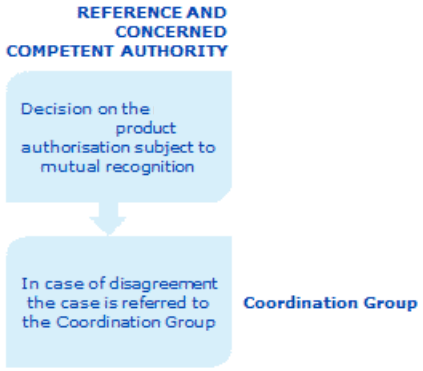
Authorisation of Biocidal Products

Mutual Recognition in Sequence (MRS) - Art. 33 BPR

If already existing NA in a MS and you are interested in additional market(s)

Submitted at any time

- Payment: 30 days
- Validation: 30d
- Mutual recognition phase: 90d
- Procedure similar to MRP



Authorisation of Biocidal Products

Union Authorisation (UA) - Art. 41-46 BPR

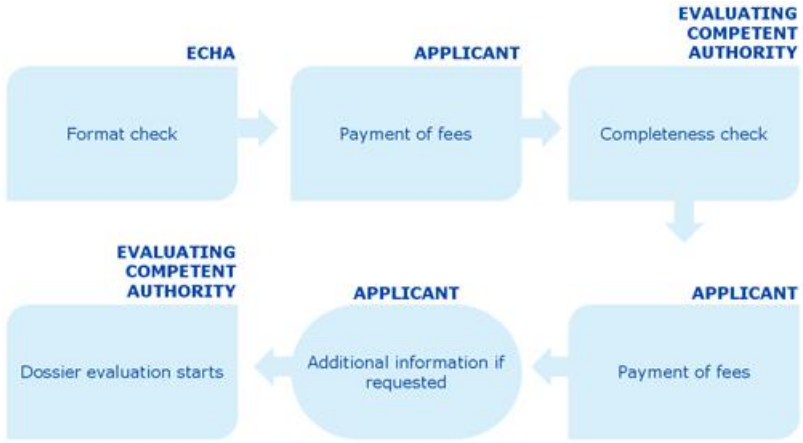
If you are interested in whole EU market or substantial amount of markets

- Decision by COM (implementing act) after BPC peer-review & BPC opinion
- For BP with similar conditions of use across the EU
- Highly recommended to perform ECHA pre-submission application for UA
- Not for BP containing AS meeting exclusion criteria
- Not for BP of PT 14, 15, 17, 20 & 21
- Sequential start-up: last phase 1 January 2020, then available for all other PTs
- Fee for ECHA (submission + annual fee) & fee for eCA

Authorisation of Biocidal Products

Union Authorisation (UA)

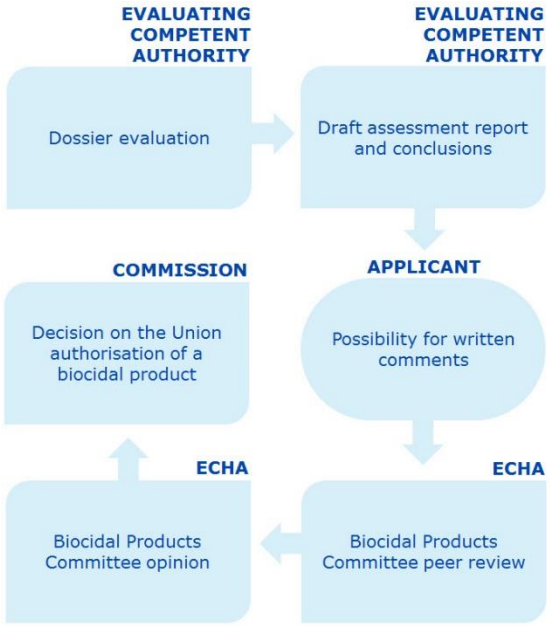
- Payment ECHA: 30d
- Acceptance ECHA
- Validation eCA: 30d + *90d stop the clock* + 30d
- Payment eCA: 30d (part of validation)
- Acceptance eCA



Authorisation of Biocidal Products

Union Authorisation (UA)

- Evaluation eCA: 365d + 180d *stop the clock*
- Including 30d commenting period applicant
- eCA submits draft PAR & SPC to ECHA
- Peer-review process: 180d
- WG discussion possible
- BPC opinion mandatory
- ECHA submits BPC opinion & final PAR to COM
- SPC translation in all official languages of EU: 30d
- If UA granted: COM to adopt implementing regulation
- If UA not granted: COM to adopt implementing decision



Authorisation of Biocidal Products

Simplified Authorisation (SA) - Art. 25-27 BPR

To encourage the use of less harmful BPs

BP to comply with all these conditions:

- AS on Annex I BPR (& comply to specified restrictions)
- Not containing substances of concern (SoC)
- Not containing nanomaterials
- Demonstrate sufficient level of efficacy
- Not requiring any personal protective equipment (PPE) for intended use & handling

Authorisation of Biocidal Products

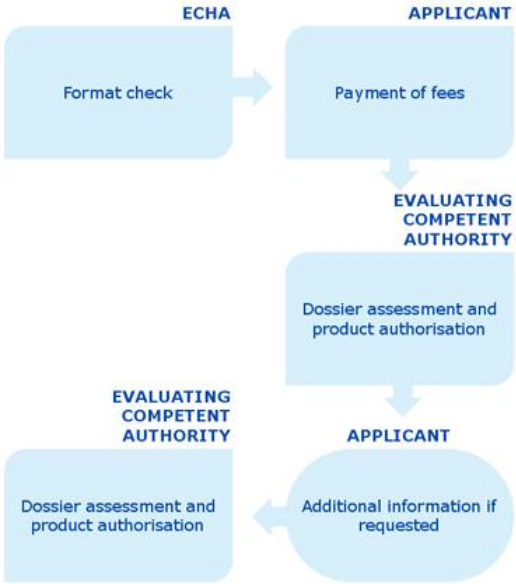
Simplified Authorisation (SA)

Procedure similar to NA

Å Shorter timelines
- Payment: 30d
- Evaluation: 90d + *90d stop the clock* + 90d
- Finalisation: grant/refuse authorisation

Å Different/lower data requirements

Å Can be made available on MS markets without need for MR
- Notification 30 days before placing BP on MS market



Authorisation of Biocidal Products

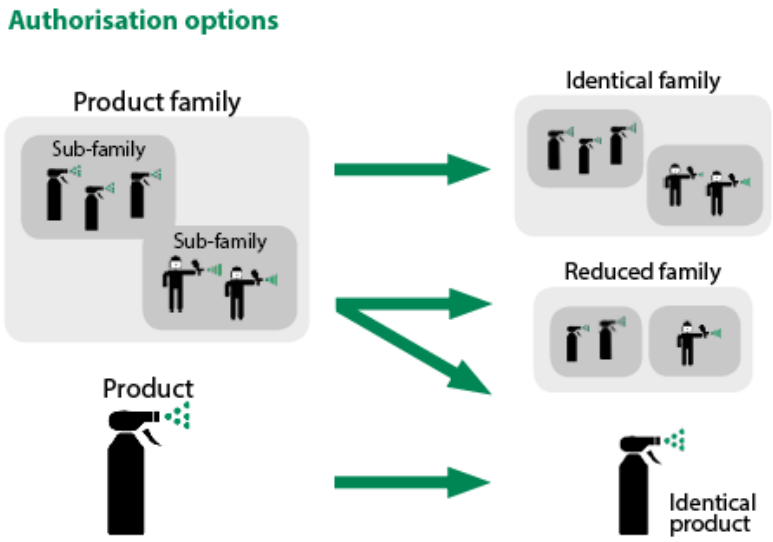
Same Biocidal Products Authorisation

Regulation (EU) 414/2013

amended by Regulation (EU) 2016/1802

- For identical products
- For identical biocidal product families
- To reduced authorisation
- To reduced market (UA → NA)

Same biocidal product has always different authorisation number than reference product



Authorisation of Biocidal Products

NA of Same Biocidal Product

Reference product has been authorised by NA or is subject of authorisation application

- Adapted data requirements
- eCA validation: 30d
  - Check that differences between same product and reference product is only info which can be subject of an administrative change ((EU) No 354/2013)
- eCA to grant/refuse authorisation: 60d
  - Either from validation
  - Either from adoption decision concerning the reference product

UA of Same Biocidal Product

Reference product has been authorised by UA or is subject of authorisation application

- Adapted data requirements
- ECHA validation: 30d
  - Check that differences between same product and reference product is only info which can be subject of an administrative change ((EU) No 354/2013)
- ECHA to prepare opinion and send to COM: 30d
  - Either from validation
  - Either from date submission opinion on reference product

Technical Equivalence

Definition

- Similarity, as regards the chemical composition and hazard profile, of a substance produced either from a source different to the reference source, or from the reference source but following a change to the manufacturing process and/or manufacturing location, compared to the substance of the reference source in respect of which the initial risk assessment was carried out

Principle

- To guarantee that for an active substance (AS) the level of hazard for human health (HH) and the environment (ENV) is comparable regardless of the source of the AS

Technical Equivalence

Reference Source

- Established during AS evaluation, defined by:
  - Applicant
  - Manufacturer
  - Manufacturing location
  - Manufacturing process
  - Set reference specification

Legal base

- Art. 54 BPR
- Regulation (EU) No 837/2013 amending Annex III BPR

Technical Equivalence

Who to apply for it?

- Any operator in the supply chain for the AS or the corresponding BP:
  - AS manufacturer of alternative source
  - AS supplier of alternative source
  - BP formulator
  - Person/entity representing the operator (e.g. a consultant)

Who to assess it?

- Under BPR: European Chemicals Agency (ECHA)
- Before under BPD: Member State competent authority (MS CA)

Technical Equivalence

When to apply for it?

- Only after adoption COM decision on approval AS
- Well ahead of foreseen submission date BP

Alternative: Chemical similarity check (CSC)

- Intended for AS without COM decision on approval
- Risk: final approved reference source may differ
- Cannot replace TE assessment
- Useful for e.g. prospecting applicants seeking confirmation that different sources of the same AS could be assessed jointly before they submit AS approval application

Technical Equivalence

Reasons to apply for it?

Å AS used in BP differs from reference source of approved AS (alternative source):

- different manufacturer
- same manufacturer: change in manufacturing process
  - change in starting materials
  - change in starting materials ratio
  - change in process solvent
  - change in synthesis pathway
  - change in processing steps
  - change in process conditions
  - …
- same manufacturer: different manufacturing location
- same manufacturer: additional manufacturing location
- change from pilot plant to large-scale production

Technical Equivalence

Relation with Art. 95 BPR

- TE is not required for Art. 95 purposes
- Listing in Art. 95 does not automatically imply TE
- But, benefits from requesting TE, e.g. prior to purchasing rights to data used to establish reference source
  - some guarantee that the data is relevant
- AS not yet approved: requesting CSC, e.g. before investing in letter of access (LOA) for Art. 95 inclusion, might provide similar benefits

Technical Equivalence

How to apply for it?

- Application must contain a IUCLID dossier
- Application must be submitted through R4BP3 (TE-APP)
- Separate application for each alternative source (no grouping)
- Can cover several PTs if those PTs have same reference specification
- Tiered assessment approach
- Applicant to decide on appropriate Tier (self-assessment)
- Validation + invoice (30d to pay fee)
- 90d for assessment + maximum *180d stop the clock*
- Follow-up & all communications through R4BP3
- Outcome communicated to applicant and MSCAs
- Appeal possible: ECHA Board of Appeal according Art. 77 BPR

Technical Equivalence

Information requirements

- 5-batch analysis is always requested
- Spectral data to confirm identity
- Methods of analysis should be validated
- For the rest depending on choice Tier I or Tier II application
  - Details in ECHA Guidance on BPR, volume V

Prerequisite

- Alternative source & reference source have same identity

Technical Equivalence

Tier I assessment

- Covers only comparison of compositional info based on analytical data
  - Same identity
  - Minimum purity alternative source ≥ reference source
  - No new impurity/additive
  - Limit each relevant impurity/additive not exceeded
  - Limits all significant but not relevant impurities not exceeded
- All conditions have to be met for positive outcome

Technical Equivalence

Tier II assessment

- Determine if unacceptable change in hazard profile of alternative source as a result of change in composition
  - Classification: more severe?
  - Effects on HH and ENV: unacceptable increase?
  - PBT/vPvB: unacceptable change?
  - ED: unacceptable change?

Technical Equivalence

Possible outcomes

- Tier I +: alternative source and reference source are equivalent, or
- Tier I -: no conclusion on TE, Tier II required
- Tier II +: alternative source and reference source are equivalent, or
- Tier II -: alternative source and reference source are not equivalent

Positive decision

- To be attached to the application for product authorisation/change

Technical Equivalence

Fees

- 5.000 EUR for Tier I (difference limited to manufacturing location)
- 20.000 EUR for Tier I (difference beyond manufacturing location)
- 40.000 EUR for Tier II (includes also Tier I assessment)
- But: if Tier II was not choosen from beginning, and Tier I leads to no conclusion, total cost will be already payed 5.000 EUR/20.000 EUR plus full 40.000 EUR
  - If there is any doubt, worth to consider going directly for Tier II

Treated Articles

Articles treated with, or intentionally incorporating, one or more BP

Treatment only with BPs containing ASs approved in the EU

Companies to provide consumers with information about the biocidal treatment

- Within 45 days
- To be provided free of charge

Treated Articles

Manufacturers & importers to ensure correct labelling according to CLP and additional requirements BPR

If claim is made need for clearly visible & easily understandable label with:

- Statement that TA incorporates BPs
- The attributed biocidal property
- Name of all ASs in the BPs
- Name of all nanomaterials in the BPs
- Any relevant instructions for use (including any precautions to be taken)

Treated Articles

Complex & controversial

Still disagreements between MSs wether article is TA or BP

Often case-by-case decision

Additional guidance & literature:

- ECHA key information document
- Note for guidance: *CA-Sept13-Doc.5.1.e*
- Allowed ASs
- COM decision on impregnated horse rug pursuant to Art. 3(3) BPR

Links to Legislation, Guidance & Information Documents on BPR

- Understanding BPR (ECHA)
- BPR Legislation (ECHA)
- CA Meeting documents (COM) (in particular "*Documents finalised at CA meetings*")
- Guidance on BPR (ECHA)
- Technical Agreements on Biocides – TAB & BPC Working Group documents (ECHA)
- Practical Guides on BPR (ECHA)
- Biocides Submission Manuals (ECHA)
- Public documents Coordination Group (ECHA)
- Formats & Templates (ECHA)
- Supporting Documents for BPR Applications (ECHA)
- Biocides @ DG SANTE (COM)

Glossary

AS	Active substance
BP	Biocidal product
BPR	Biocidal products regulation
CA	Competent authority
CLP	Classification, labelling and packaging
cMS	Concerned member state
COM	European commission
EBPF	European biocidal products forum
eCA	Evaluating competent authority
ECHA	European chemicals agency
ED	Endocrine disruptor
EG	Expert group
ENV	Environment
HH	Human health
LOA	Letter of access
MR	Mutual recognition
MRP	Mutual recognition in parallel
MRS	Mutual recognition in sequence
MS	Members state
NA	National authorisation
PAR	Product assessment report
PBT	Persistent, bioaccumulative & toxic
PPE	Personal protective equipment
PT	Product type
RAC	Committee for risk assessment
REACH	Registration, evaluation, authorisation and restriction of chemicals
RMM	Risk management measures
rMS	Reference member state
SA	Simplified authorisation
SoC	Substance of concern
SPC	Summary of product characteristics
TA	Treated article
TE	Technical equivalence
UA	Union authorisation

Thank you…