LIFE SCIENCES

EU BIOCIDES REGULATORY BPR

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Why is a regulation required for Biocidal products ?

- Prior to European wide legislation:
  - Some Member States(countries) had a fully established biocidal products authorization process(example – Netherlands).
  - Whilst other Member States had a simple notification system (Germany, France)
  - Some Member States had no system to control biocidal products on the market(UK).
  - Biocidal active substances were not defined and were uncontrolled.

There was no previous harmonized approach in the EU on how to regulate Biocidal Active Substances and products.

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Goals of the Biocidal Product Regulation (EU) No 528/2012

The objective of the BPR is to ensure:

- Harmonization and free movement of biocidal products of biocidal actives and biocidal products on the European market
- A high level of protection to human health, animal health and the environment
- That biocidal products can only enter the European market if they are authorized with sufficient efficacy

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What is the geographical scope of the BPR ?

In addition to all European Union countries, there are 4 European Free Trade Association countries that fall under the remit of the regulation

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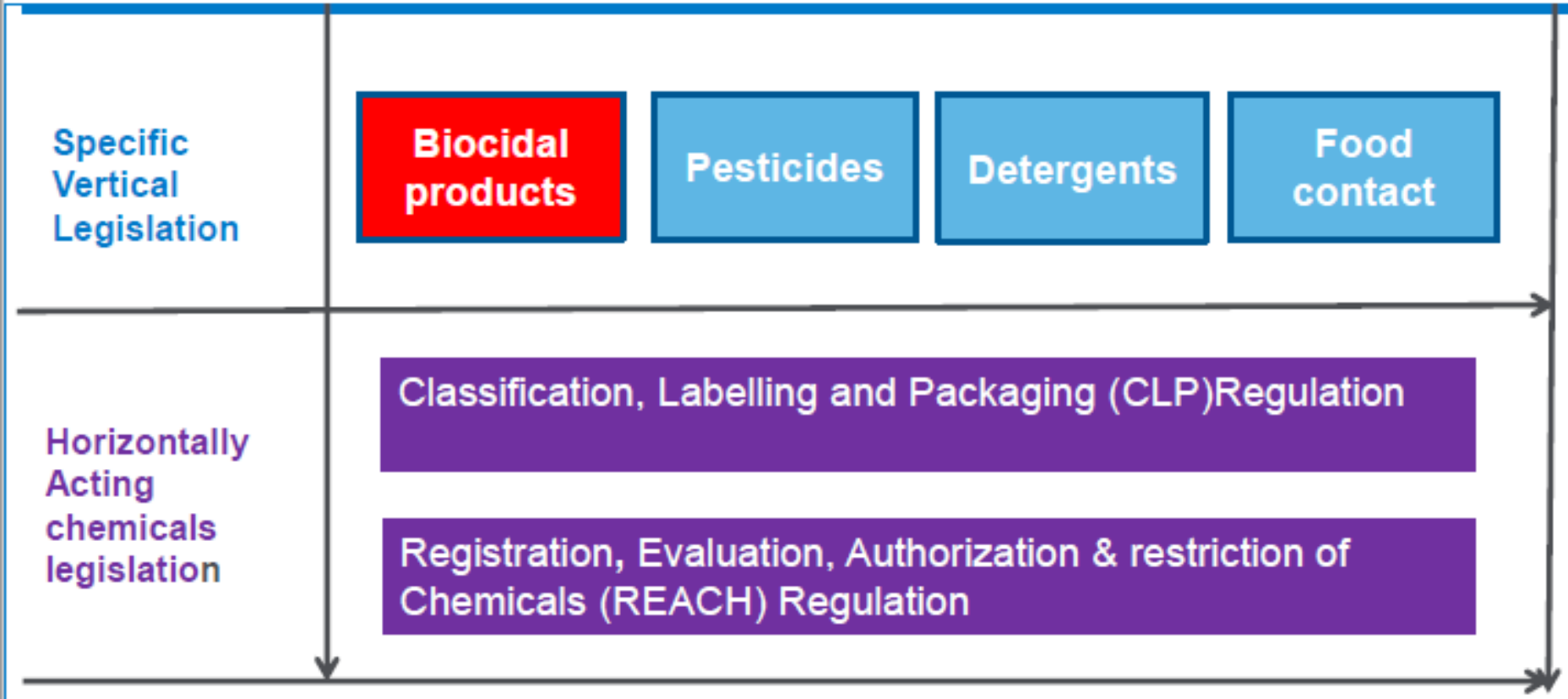
BPR and other EU Chemicals Legislation & their interaction



The BPR is an example of vertical legislation . Biocidal product manufacturers also need to comply with the labelling requirements of the CLP regulation, and with the REACH regulation. Biocidal actives are exempt from the REACH regulation, but other substances used in the product formulation need to be REACH registered.

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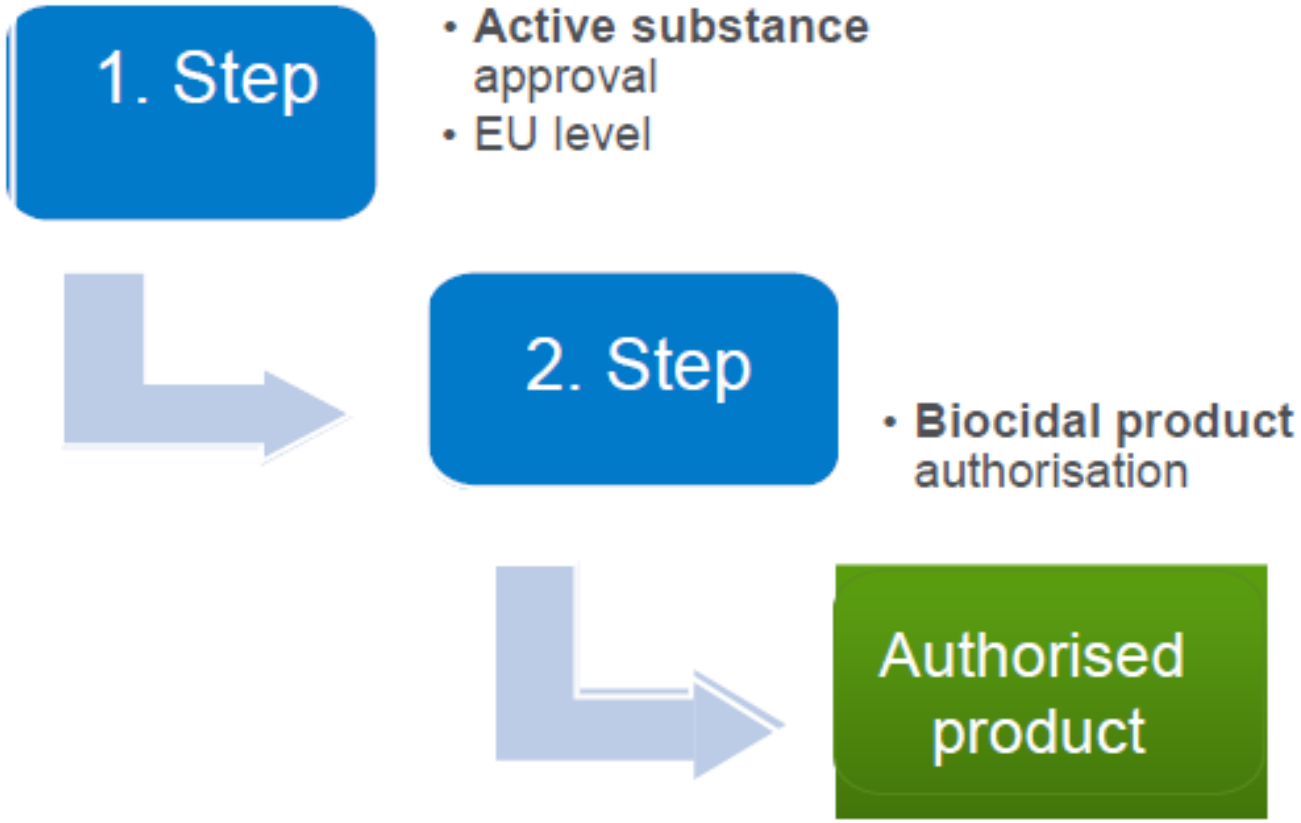
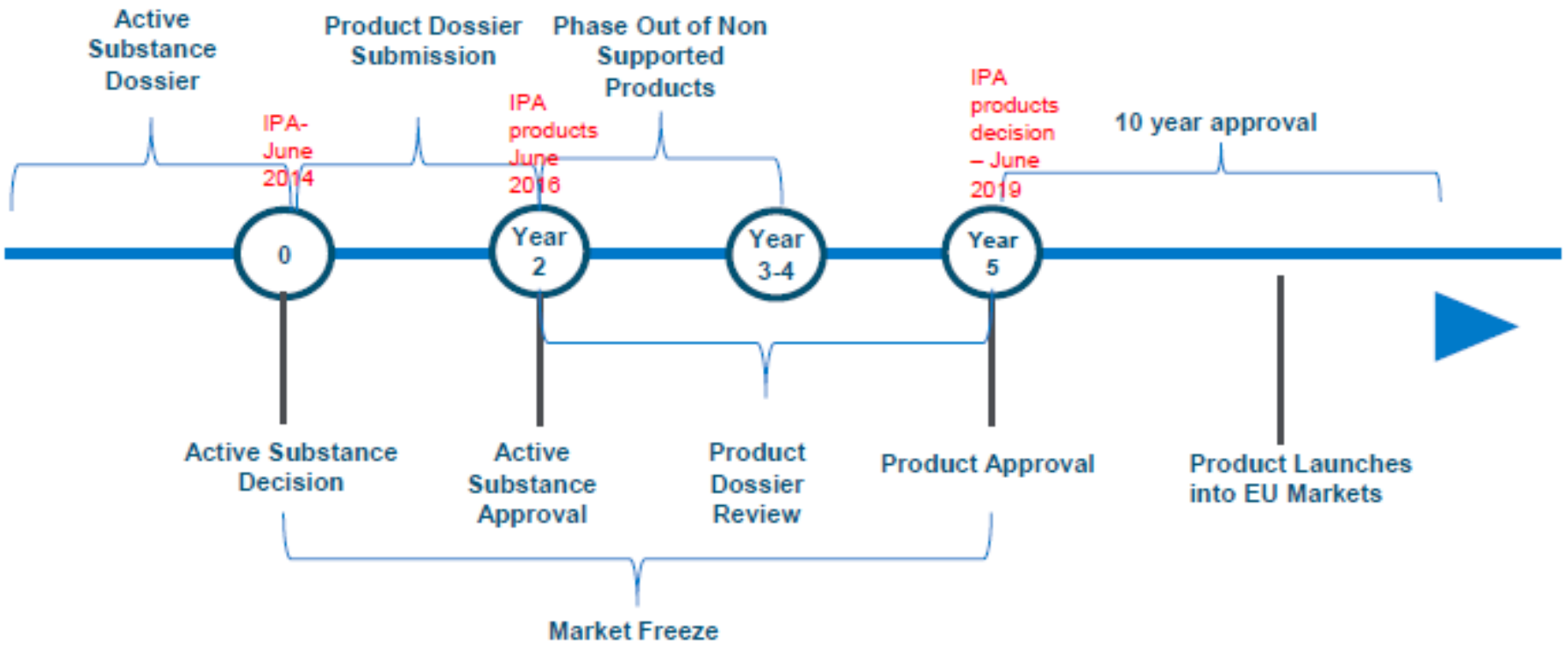
BPR: A two step approval process



Biocidal products may only be registered under the BPR once the active substance approval decision has been made each active substance has a different review and decision date, the timelines for a biocidal product authorization under the BPR is dependent on the active substance/s within the product formulation. Example IPA based products were submitted in June 2016 for BPR authorization whereas Ethanol based products are only due in 2022.

BPR TIMELINES Example Isopropanol



Sales of Biocidal products without a BPR submission will need to be stopped 6 months after the BPR submission deadline

Once a product BPR application has been submitted ,the products may remain on the country markets via authorization renewals .

No country authorizations are possible whilst the BPR product applications are being reviewed for 3 years.

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BPR TIMELINES

Disinfectants	Active/s	Date for EU BPR product submission (or anticipated date)	Approval date (typically 3 years after submission)	Status
Disinfectants based on Isopropanol	Propan-2-ol	June 2016	June 2019	expected Q2/Q3 2019
Disinfectants based on Hydrogen Peroxide	Hydrogen peroxide	February 2017	February 2020	expected Q4 2019
Disinfectants based on Peracetic acid	Peracetic acid	October 2017	October 2020	expected Q4 2020
Disinfectants based on Hypochlorite	Sodium hypochlorite	December 2018	December 2021	
Disinfectants based on Ethanol	Ethanol	Q1 2022	Q1 2025	

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BPR , Article 95 and industry "home brew" alcohols & biocides

- Alcohol and biocide solutions prepared at any sector industry site, that are used for disinfecting purposes are within the scope of the BPR
- The BPR scope includes:
  - The placing on the market of biocidal products - sales of biocidal products.
  - The use of biocidal products - using a product for biocidal purposes in any form.
- Example for a home brew alcohol product that is being used within any manufacturing site for biocidal purposes:
  - The alcohol purchased needs to be from a BPR Article 95 listed supplier(i.e approved supplier) . Refer to https://echa.europa.eu/information-on-chemicals/active-substance-suppliers for the downloadable list of approved suppliers
  - The alcohol solution prepared on site is within the scope of the BPR as it is being used for biocidal purposes (even though this is internal use). It requires authorization under the local schemes or BPR.

REGULATION (EU) No 528/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 22 May 2012

concerning the making available on the market and use of biocidal products

(Text with EEA relevance)

Article 3

Definitions

1. For the purposes of this Regulation, the following definitions shall apply:

(a) 'biocidal product' means

— any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action,

— any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action,

BPR – What are the Implication for the Pharmaceutical industry?

- Pharmaceutical industry customers need to be careful in choosing a biocidal product supplier:
  - The biocidal active needs to be approved as per Article 95 of the BPR.
  - Biocidal products are registered in the relevant country that the pharma manufacturing site is based in.
  - Has the supplier made a BPR registration commitment so that sustainable product supply is guaranteed?
- Additional control of biocidal use – it is illegal to sell or use an unapproved biocidal product under the BPR.
- Improved focus on health and safety via use of safer chemicals .

Thank you

Questions?