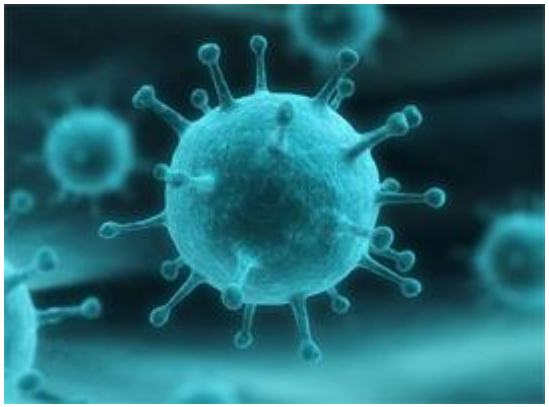
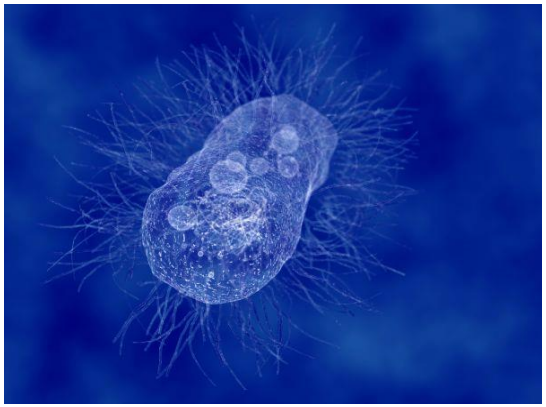
Update on BPR from a supplier (distributor) view

- Biocides - Introduction
- What BPR implies to distributors, formulatorer and end users
- Some requirements and opportunities
- Can Brenntag Nordic help you ?

EU's Biocidal Products regulation (EU 528/2012)

- The purpose of the Biocidal Product Regulation (BPR) is in short:
  - To improve the functioning of the internal market through the harmonisation of the rules on the making available on the market and the use of biocidal products
  - To ensure a high level of protection of both human and animal health and the environment





Biocidal Active Substances and Biocidal products

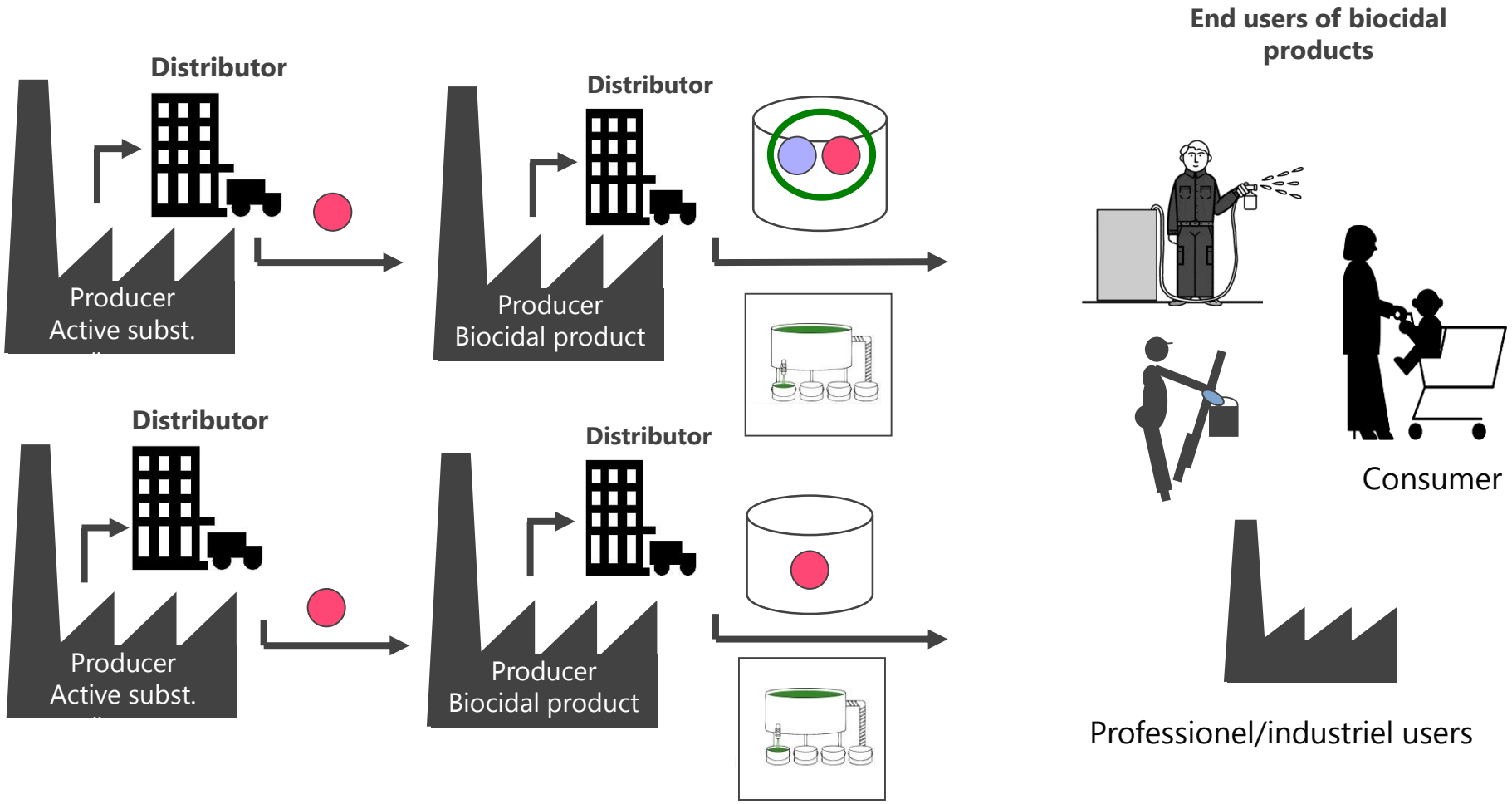
Active substances

- A substance or a micro-organism that has an action on or against harmful organisms
- Requirement for approval at EU level

Biocidal products

- A product 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.
- Requirement for approval at national level(s) or at EU level

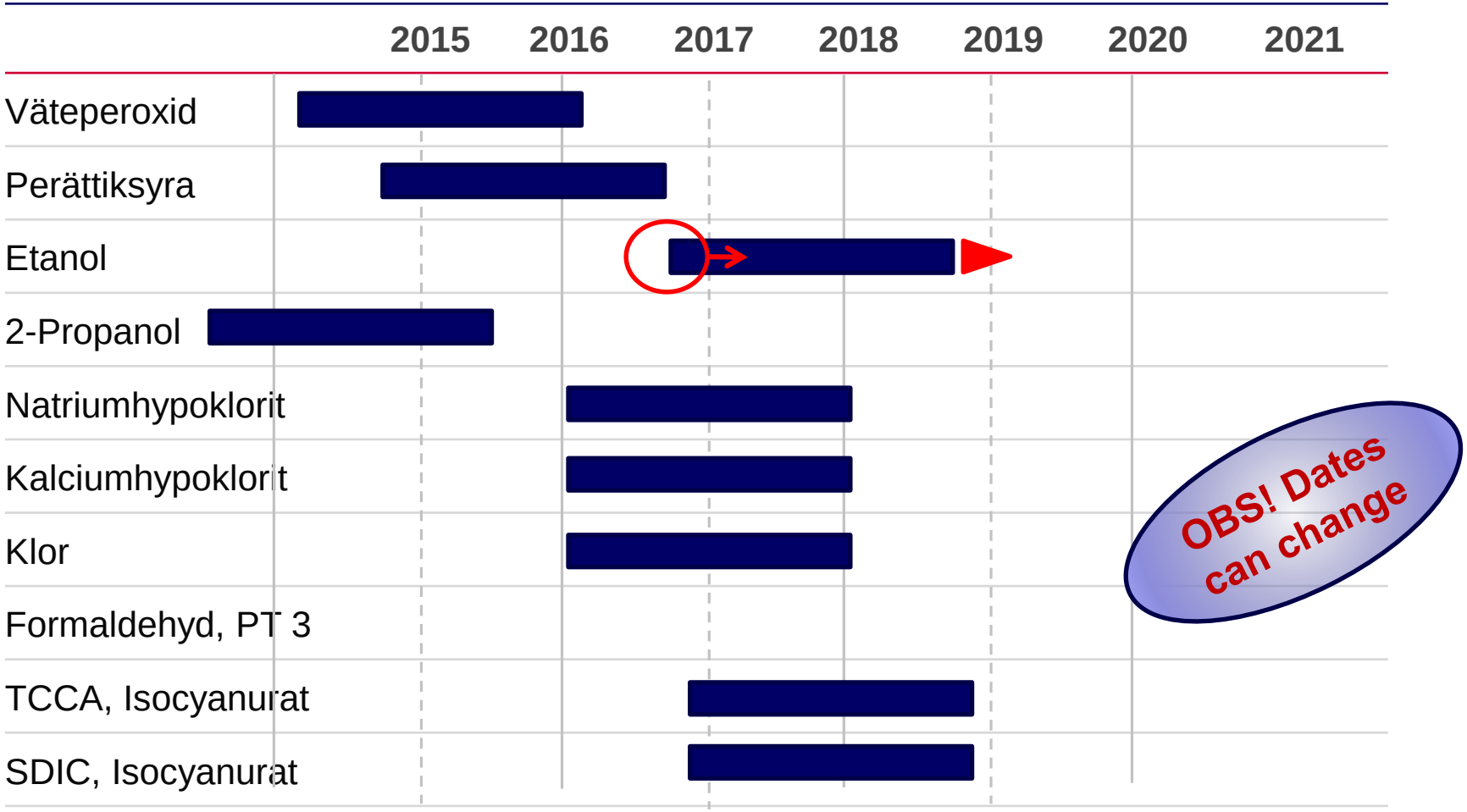
INTRODUCTION



OBS! A biocidal product can be a mixture including multiple substances - or just including the active substance. It is the usage that determines if biocidal product or not.

TIME LINES FOR APPROVAL OF SOME ACTIVE SUBSTANCES

Biocidal Product applicants have 2 years for the submission of their application, from the date when the Active Substance has been approved at EU-level



BIOCIDAL PRODUCT REGULATION (BPR)

What it implies

Distributor

- As a distributor we do not have a full picture of our customers biocide usages. Several substances can have multiple application areas, here under technical as well as potential biocide usages.
- We depend on input from our customers
- As a distributor we check amongst our suppliers for support of usages like Biocide Active Substances and Biocidal Products
- As a distributor we may have to establish separate logistic lines, here under separate storage tanks depending on the usages – even for some old “commodity”chemicals

New

Formulator

- Map own Biocidal Products inclusive Active Substance components, Product Types a.o.

- Be aware that Active Substances should be included in ECHA’s Article §95 list: substance name, product type (PT), approved suppliers (requirement since September 2015).

- Be advised to communicate well with your distributor /supplier

BIOCIDAL PRODUCT REGULATION (BPR)

§95

Article 95-list

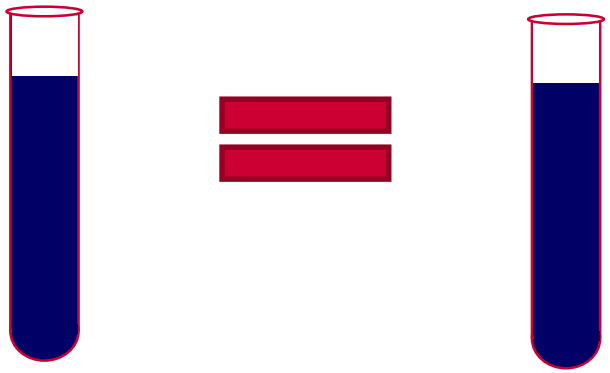
- A list of active substances and the approved suppliers
- The list is available from the the European Chemicals Agency (ECHA) web page. Supplier names are listed per active substance, in combination with supported Product Types. Not all suppliers of the same Active Substance support the same Product Types.

Link: https://echa.europa.eu/documents/10162/17287015/art_95_list_en.pdf

Propan-2-ol		**EC: 200-661-7**		**CAS: 67-63-0**
Product Type: 1				
Accuron Biozide GmbH	Germany	Substance Supplier	RP Participant	30-Jan-15
Alcoholes Montplet S.A.	Spain	Substance & Product Supplier	Art.95 submission	25-Aug-15
Aug. Hedinger GmbH & Co. KG	Germany	Substance & Product Supplier	Art.95 submission	08-Jul-15
AVT Abfüll- und Verpackungstechnik GmbH	Germany	Substance Supplier	RP Participant	30-Jan-15
B. Braun Melsungen AG	Germany	Substance Supplier	RP Participant	24-Sep-14
BCD Chemie GmbH	Germany	Substance Supplier	Art.95 submission	28-Aug-15
Berner Oy	Finland	Substance & Product Supplier	Art.95 submission	31-Aug-15
BODE Chemie GmbH	Germany	Substance & Product Supplier	RP Participant	24-Sep-14
Brauns-Heitmann GmbH Co. KG	Germany	Product Supplier	Art.95 submission	29-Jul-15
Brenntag GmbH	Germany	Substance Supplier	Art.95 submission	28-Aug-15
Brenntag Nederland B.V.	Netherlands	Substance Supplier	Art.95 submission	29-Jul-15
Brenntag SA	France	Substance Supplier	Art.95 submission	07-Jan-16
Brenntag Schweizerhall AG	Switzerland	Substance & Product Supplier	Art.95 submission	17-May-16

Technical Equivalence (TE)?

- The documentation for an approved Active Substance is based on a referance sample of the active substance
- Suppliers ,who are not the reference source of this sample, must apply for "Technical Equivivalence "(TE). Purpose: to ensure and prove similarity with the approved Active Substance.
- This imply a need to check if suppliers listed in the §95 list are "reference source" or if they have documented TE !



An experience from Brenntag

- Brenntag has an external IPA-supplier who is included in the §95-list. In February 2016 the supplier informed us that they would not apply for TE
  - This message was completely unexpected !
- During the summer in 2016 the supplier had reconsidered – they would now start to apply for Technical Equivalence. In the meantime Brenntag had decided to make an own application to ensure a well working supply chain for IPA via Brenntag.
- Our experience from this:
  - To be included in the §95-list may not always be sufficient
  - Always check for reference source and Technical Equivalence

BIOCIDAL PRODUCT REGULATION (BPR)

What it implies

Distributor

- Distributor needs input from Formulator
- Distributor can check if own suppliers:
  - Offers LoA on Active Substance
  - Will support the Active Substance by applying for Biocidal Product authorization for one or more products (family concept) => Offers LoA for Biocidal Product
  - Will support the Active Substance by applying for Biocidal Product authorizations in a family concept

  => Offers customers to become integrated in (onboard) their application.

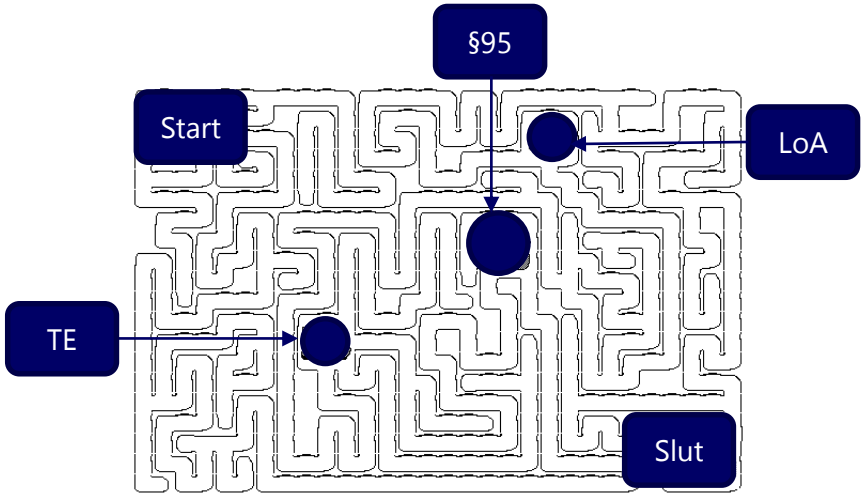
Formulator

- Communicate in a clear way to your distributor
- Multiple routes can lead to authorization of Biocidal products, such as:
  - Seek Authorization for a unique product formulation and based on LoA for the Active Substance
  - Benefit from a “Same Product Authorization” based on LoA for another, yet identical Biocidal Product
  - Get onboard in an application for a Biocidal Product family Authorization

BIOCIDAL PRODUCT REGULATION (BPR)

Communication with distributor

- Dialogs in the supply chains are extreamly important
  - A precondition for us as distributor to see how the ends can tie together and to identify options.
  - Cooperation will pay off
- We need a good understanding of customer's biocidal usages /needs
  - Even questionaires may prove useful
- The factor of time is very important
- It can be expensive
  - Choose your route carefully



BIOCIDAL PRODUCT REGULATION (BPR)

Brenntag IPA product family (Desinfectants)

- Validity period 10 years
- Contract between Brenntag and customers:
  - "Marketing authorization" – customer product integrated directly
  - "Same product authorization" – LoA for a product to customer
- The customer receives a letter from Brenntag including submission numbers for for his product brands
  - Can stay on the market while awaiting authorization numbers
- The LoA makes it possible for the customer to apply for"Same Product Authorization" and have his own authorization number when
  Brenntag has been granted the authorization*
  - * Expected in 2018.

BIOCIDAL PRODUCT REGULATION (BPR)

Next Active Substance in focus - Ethanol

- Approved suppliers of ethanol are included in ECHA's §95-list
- Ethanol is expected to become approved as Active Substance Q3 2018 (postphoned from October 2017)
- Test requirements for Technical Equivalence expected to be published a few month later
- Applications for etanol-based Biocidal Products and for Etanol/IPA blends to be submitted within 2 years from that date (expected Q3 2020).
- LoA for Ethanol as Active Substance
  - 7400 EUR + fee 490 EUR.

BIOCIDAL PRODUCT REGULATION (BPR)

What it implies

Distributor

- Distributor needs input from Customers
- Distributor may not in all cases be aware if customers would use our delivery directly as a Biocidal product (Ex: ……)
- Distributor will check supply options for Biocidal products

Enduser

- Communicate well with your supplier
- End users receive detailed information on biocidal products via the labels once the products are approved under BPR.

What it implies – Good label information to end users

- Mention active substance and it’s concentration in metric units
- Nano materials need to be mentioned if included in the product
- Registration number
- Name and address of the registration holder
- What kind of formulation (e.g. emulsion, solution)?
- Approved applications (Product Types)
- Use instructions
- Safety and personal protection instructions
- Reference to technical datasheet
- Disposal
- Batch number
- If applicable, safety time before use
- If apl. Category of users (Ex: professional users only)
- If apl. Environmental risks
- If apl. micro-organisms should be mentioned if included

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Thank you