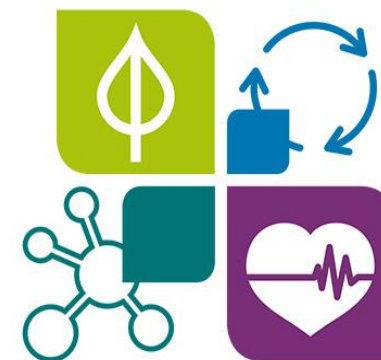


**A.I.S.E. CLEANING & HYGIENE FORUM 2020**  
THE FUTURE OF AN ESSENTIAL INDUSTRY IN  
THE CONTEXT OF THE EU CHEMICALS STRATEGY  
2 DECEMBER 2020 • VIRTUAL EVENT



**The specific case of biocidal products:** Learnings from the industry on the implementation & workability of the EU Biocidal Products Regulation

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# BIOCIDES - A VERY LONG PROCESS

## Directive 98/8/EC (BPD)

Program to review the  
active ingredients of  
existing biocides

## Regulation (EU) 528/2012 (BPR) replaced BPD

Review program to be  
adapted to the BPR.

## Regulation 1062/2014

Review program of  
existing active  
ingredients referred to  
Article 89 of the BPR

1998 → 2020

**less than half of the  
process completed**



# AND EVEN VERY COMPLICATED

- High number of work committees and documentation produced
- Different restrictions and behaviors at national level
- Wide range of interpretations (Commission vs Member States)
- Substantial differences between PT and therefore the difficulty (if not impossibility) of uniform application of the rules
- Need for harmonization (products of similar use/characteristic at European level, e.g. disinfectants) vs need for elasticity (products with a strong local specificity, e.g. insecticides)

➤ **Uncertainty .....but awareness of the importance of biocides**



# COVID-19 HAS UNDERLINED MANY PROBLEMS

- Emergency useful products (PT1/PT2) are halfway through the review plan
- E.g. ethanol-based products are subject to national legislations (where present) while propanol-based products are subject to BPR
- It would have been very useful to have a common approach at the European level but it was necessary to proceed with different approaches at the local level
- Costs for the authorization of products, complex rules, slowness of authorization processes plus difficulties in supplying raw materials (active substances, plastics, coformulants)

➤ **scarce quantity of biocides available**



# NOT ONLY COVID IS AN EMERGENCY

- As of 4 October, Italy has reported \* **239 chikungunya cases** in the Lazio region (146 confirmed and 93 probable) and six confirmed autochthonous cases among 55 reported cases in the city of Guardavalle Marina, Calabria region. Several probable and confirmed cases were reported in other regions of Italy (i.e. Emilia-Romagna, Marche) and other EU Member States (France and Germany)...

*\*Source: ECDC*

- A total of **401 autochthonous human West Nile Virus (WNV) infections** have been reported by European countries this year\*\*, as of 16 August 2018, including 22 deaths, according to data from the European Centre for Disease Prevention and Control (ECDC). The most affected countries include Serbia (126 cases), Italy (123), Greece (75), Hungary (39) and Romania (31). These areas have all been affected by WNV in the past.

*\*\* Source: WHO*



# CONCLUSIONS

- Biocides are **essential products for human health**
- The review program appears to be **very complex** with very restrictive evaluation criteria
- Uncertainty due to long evaluation times, possible introduction of new, more restrictive criteria and the size of markets (often niches) considerably **limit the possibility of product innovation**
- Need for a **more flexible and simple approach** in order to - for example:
  - avoid limitation in the availability of preservatives
  - maintain specific products (insecticides, etc.) for some areas of Europe increasingly affected by disease vectors or local geographical needs
  - ensure sufficient products in the event of a health emergency

