



Innovation for Biocides: a Supplier's Perspective

Rodolphe Qu erou, Global Regulatory Affairs Leader
DuPont Microbial Control

Preservation of Paints & Detergents: Workshop on Innovation & Industry challenges
15 May – Radisson Blu Royal Hotel

www.aise.eu

www.cepe.org

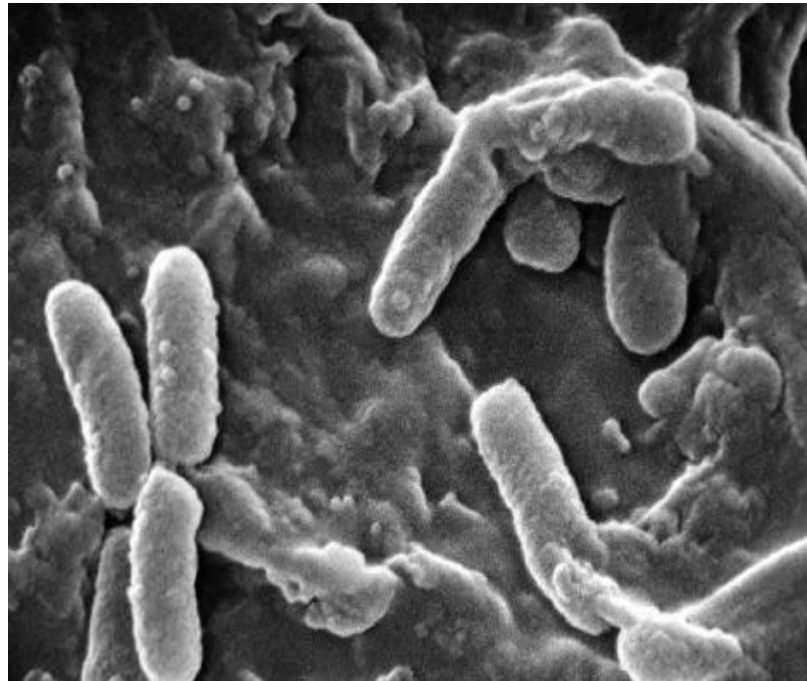


Content

- What is innovation in the biocides industry ?
- What are the Incentives for Innovation ?
- What are the Challenges for innovation ?
- What way forward ?



What is Innovation in the Biocides Industry ?





Biocide Industry Objectives

- Our purpose is to provide means to kill or control harmful organisms in order to protect products, people and the environment
- Our goal is to continuously innovate to reduce risk and ensure safety for man and the environment



How to Innovate in Biocides? The Industry is Taking a Holistic Approach to Solving Today's Challenges

- New Microbial Control strategies
- New active substances
- New formulations (end-use biocides)
- New dosing systems
- New packaging





New Microbial Control Strategies are being Explored by Industry Participants Due to Pressure on Existing Technologies

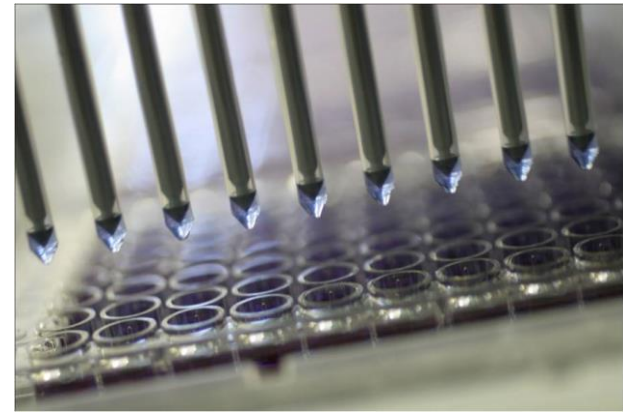
Strategy	New techniques	Comments/Limitations
Reduce contamination	Enhanced plant hygiene	Need efficient biocides: <ul style="list-style-type: none"> • Disinfectants • Fast kill preservatives • Long-term preservatives
	Advanced diagnostic	
« Non-synthetic chemical » control (non petrol-based)	Biologically-derived chemicals	Not different from synthetic chemicals
	Microorganisms	Still conceptual
	Pasteurization, UV, ...	Technical issues Cost, energy consumption No persistence of action
Optimize efficacy of preservatives	Boosters Blends of actives	Regulatory uncertainty

Efficacy is key, we cannot jeopardize the protection needed or favoring resistances ... which would negatively impact health and environment.



New Biocidal Active Substances Are Demanding more Specificity and Selectivity for Target Organisms.

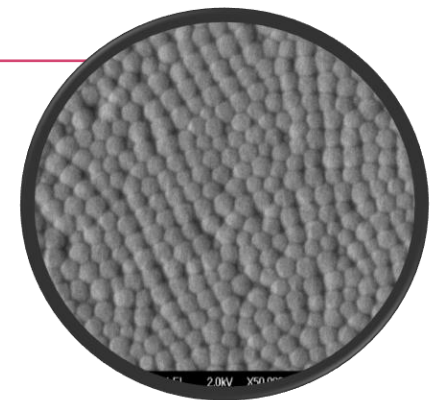
- Active options can originate from chemical synthesis or biological derivation
- Phenotypic or target based exploratory screening for new chemicals requires extensive investment
- New substances require earlier screening for toxicity and sensitization as part of selection process
- More simple option is to look at variations of existing chemical families or sourcing from adjacent markets (like eg. Plant Protection)





New Formulations and Innovative Delivery System May Help Leverage Existing Active Technologies More Effectively

New biocides fomulations	New packaging	Advanced dosing systems
Reduced bioavailability	Reduce industrial worker exposure	
Controlled-release	No impact on end-users	
Precursors of actives		
Blends of actives		





What are the Incentives for innovation ?

27.6.2012 EN Official Journal of the European Union L 167/1

(Legislation)

REGULATIONS

REGULATION (EU) No 528/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 22 May 2012
concerning the marketing available on the market and use of biocidal products
(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,
placed on the market unless all active substances contained in the biocidal products with which they were treated or with which they come into contact are approved in accordance with this Regulation.

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Economic and Social Committee⁽¹⁾,

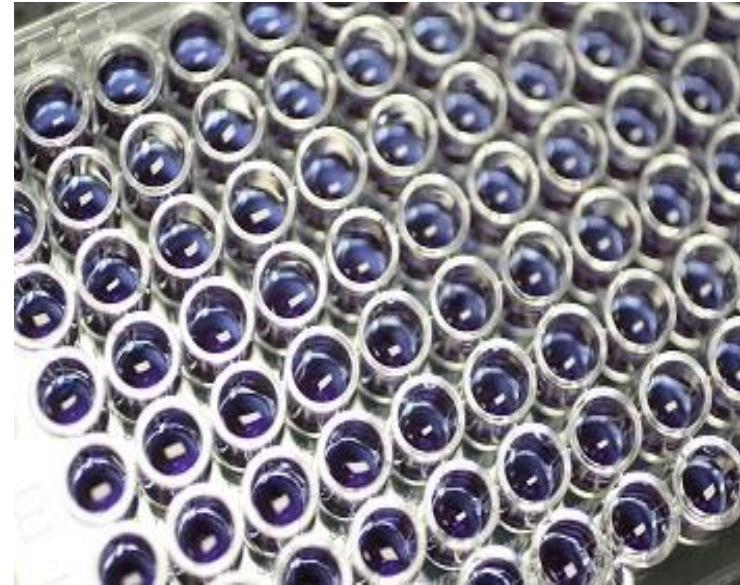
Acting in accordance with the ordinary legislative procedure⁽²⁾,

Whereas

The purpose of this Regulation is to improve the free movement of biocidal products within the Union while ensuring a high level of protection of both human and animal health and the environment. Biocidal products should be put on the market of vulnerable groups, such as pregnant women and children. This Regulation should be underpinned by the precautionary principle to ensure that the manufacturing and marketing available on the market of active substances and biocidal products do not result in harmful effects on human or animal health or a considerable effect on the environment. With a view to ensuring, as far as possible, absolute safety in biocidal products, they should be laid down for the approval of active substances and the marketing available on the market and use of biocidal products, including rules on the correct application of substances and on packaging.

- (1) Biocidal products are necessary for the control of organisms that are harmful to human or animal health and for the control of organisms that cause damage to material or man-made structures. However, biocidal products can pose risks to human, animal and the environment due to their intrinsic properties and associated use patterns.
- (2) To ensure a high level of protection for human health, animal health and the environment, this Regulation should apply with the same principle as Union legislation on safety in the workplace and environmental and consumer protection.

18 Rule concerning the marketing available on the market of...



DPR



Key drivers and expectations for innovation

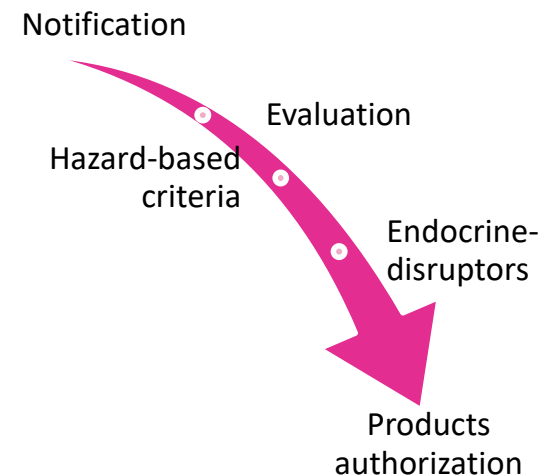
- **Societal demand**
 - Hygienic and healthy environment
 - Safe and environmental friendly products
 - Quality and long lasting products
- **Industry demand and market expectations**
 - Efficient use of energy and raw materials, reduction of waste
 - Efficient control of harmful organisms, protection of products and processes
 - Protection of workers, consumers and the environment





Regulatory framework as an incentive for innovation

- Since 2000 more than 2/3rd of the active substances have disappeared
- Exclusion/substitution criteria will impact > 30% of remaining substances
- The most efficient substances are expected to be banned or severely restricted
- Multiple market gaps have been appearing, ... but ...
- ... in 19 years, < 20 new active substances for all PTs

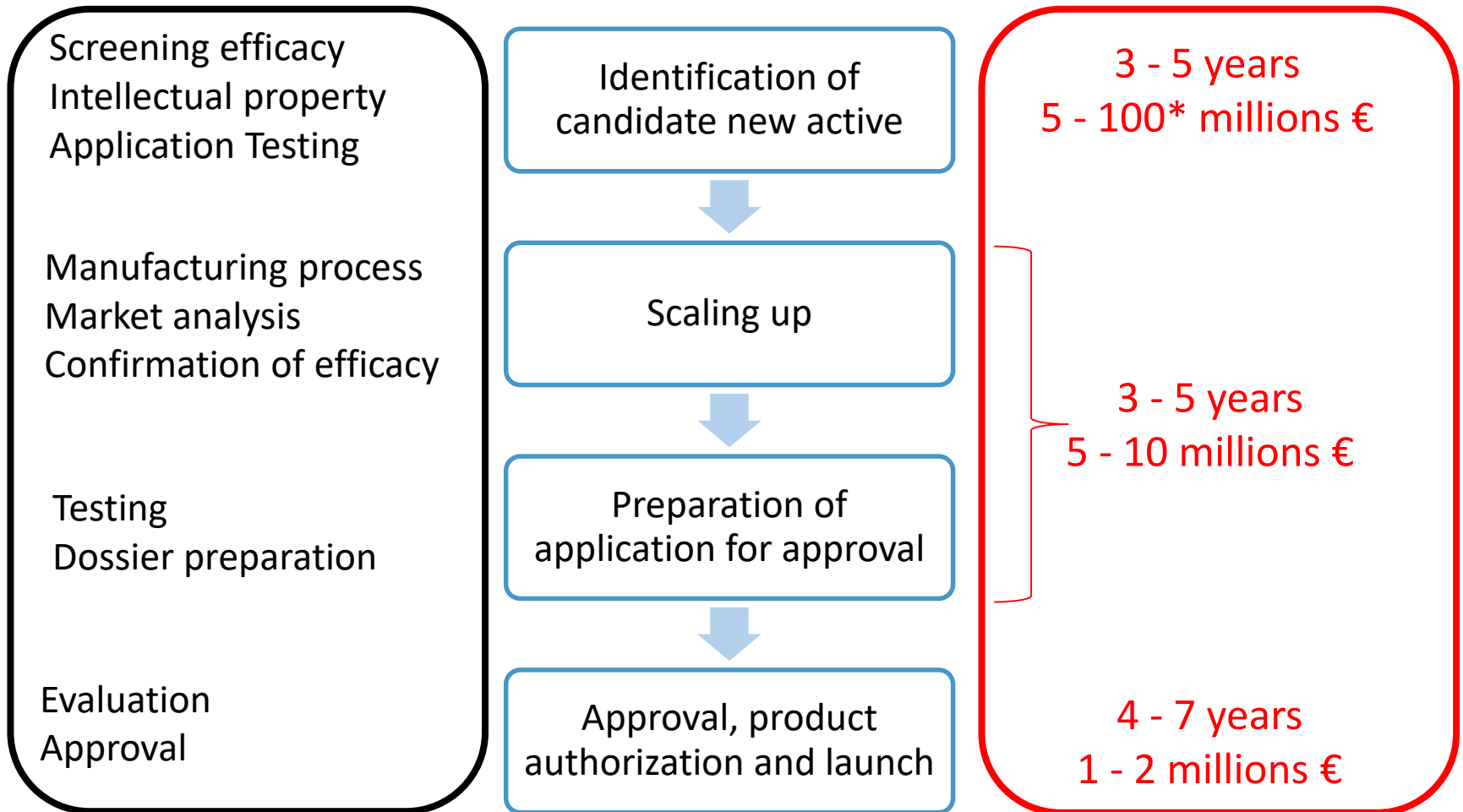


What are the Challenges for innovation ?





From invention to innovation

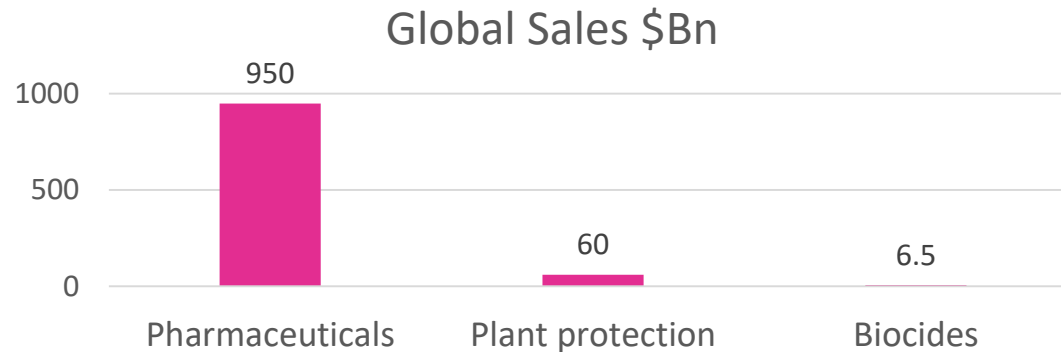


*Depends on the % of failure/type of application



Market challenges for innovation

- Biocides is a small market:



- R&D investments in biocides cannot be compared with other life science industries (pharmaceuticals in EU: € 50 Bn/year), but similar diligence is requested in identifying compounds
- Diverse and fragmented, targeted market often < €50MM
- Not all downstream users sectors are ready to/can pay for innovation



Technical and regulatory challenges for new actives

Technical challenge	Regulatory challenge
Diversity of target organisms	Very long time to the market
Wide spectrum needed	Very expensive/market size
Come back to same mode of actions with same toxicological properties	Unstable regulatory environment (guidances, fees, approval criteria, ...)
Application Compatibility is a critical parameter	No exclusivity
	High risk and low predictability

High cost, long process, small market and lack of visibility on the return on investment ...

... not so attractive for internal decision makers and external investors ...



A few example of PT6 « new » actives

	Dossier filed	Approved	Comment
MBIT	2009	2018	Isothiazolinone family CLP rules changed in 9 yr => SCL at 15 ppm for sensitization
Folpet	2009	2016	Organochlorinated Only fungicide, only in paints (PT6/PT7)
CIT	2017		Isothiazolinone family
Sodium azide	2017		Limitation on use (R&D reagents)
Benzyl alcohol	2018		Limitation on use (R&D reagents)
Ethanol	2016		Limitation on use (R&D reagents)

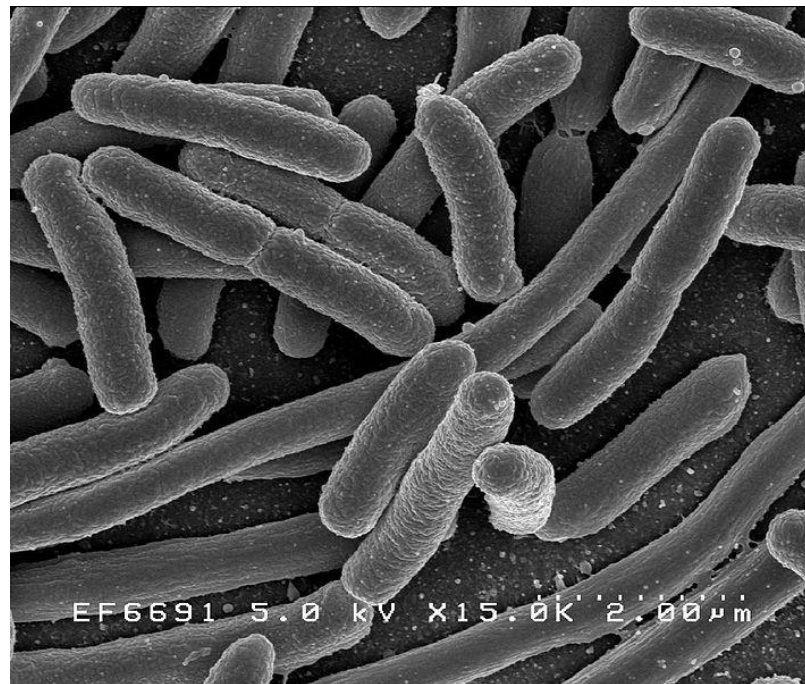


Regulatory challenges for innovation at product level

- Time to the market, cost, uncertainty
- Market dynamic, partly driven by regulation
- Since 2000, all resources are mobilized to support existing products
- Specific uncertainty with mixture toxicity
- Limited possibility to reverse at product level restrictions imposed at substance level (sensitization)



Which path forward ?





How can innovation be stimulated ?

- Facilitate R&D testing and provisional authorizations
- Fast-track for new active substances
- Regulatory stability (regulations, guidances, ...)
- Science-based transparent decisions
- Accept new products as a way to mitigate risk (mixture toxicity, sensitization, ...)





Possible innovation pathways

- Advanced diagnostic with proper combination of fast kill biocides and long term preservatives
- New biologically-derived actives: numerous candidates from academic R&D, but **broad efficacy is challenging** and manufacturing process feasibility are key for success
- Advanced formulations: encapsulation, reduced bioavailability, ...
- Mixtures of actives, use of boosters



Conclusion

The biocides industry needs help to reduce risk and accelerate development of new solutions that are necessary for many of the products and processes utilized globally

... an innovation-friendly regulatory environment

... and time to develop these solutions !





Thank you for your attention !

Rodolphe Quérrou

Global Regulatory Sciences and Product Sustainability Manager

DuPont Microbial Control

Mobile: +33 6 74 41 69 26

rodolphe.querou@dupont.com