



Global Perspectives on the Regulation of Natural Substances

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ABIM 2020
Session: Minor uses and regulatory challenges

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The business of sustainability

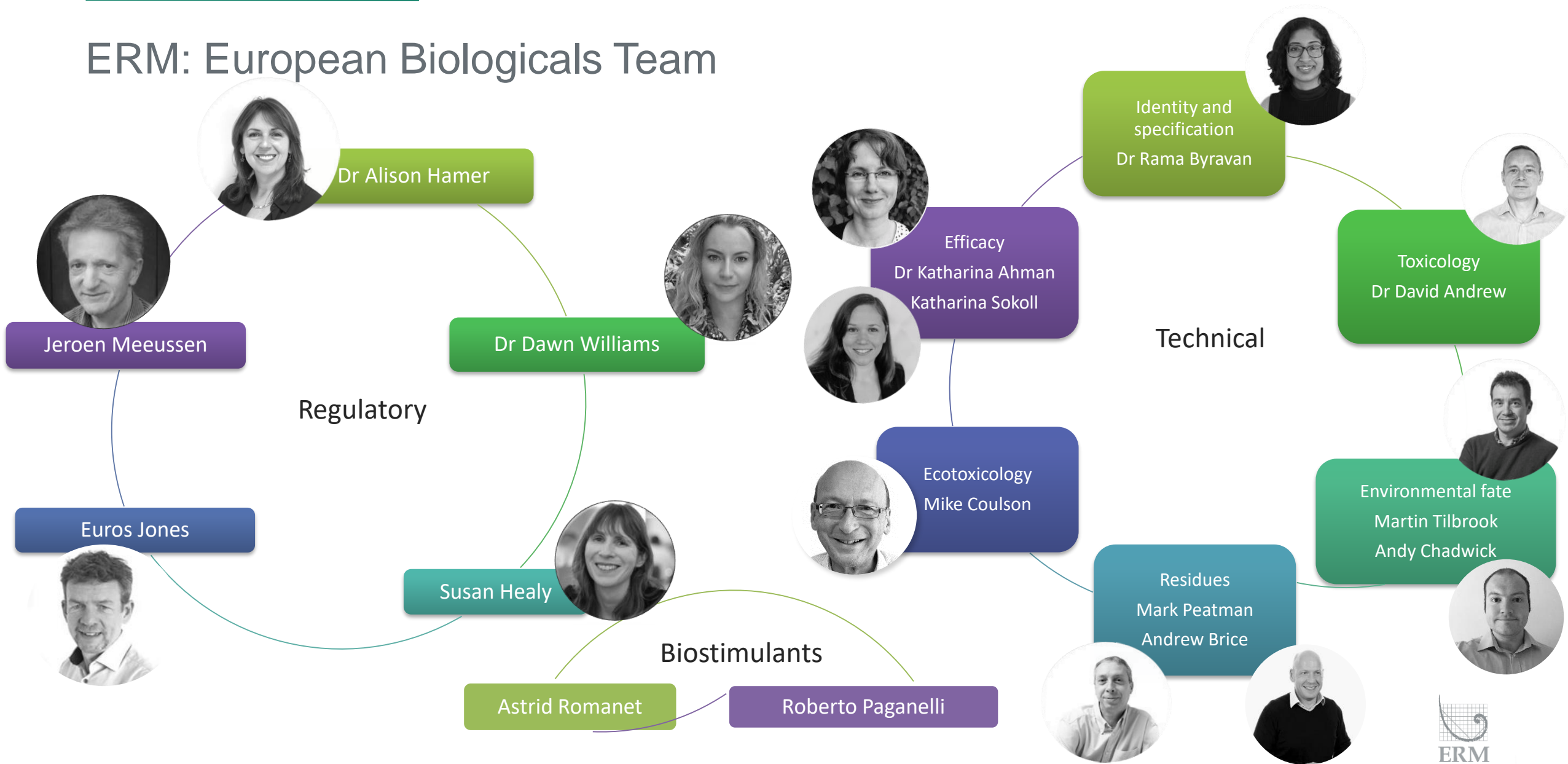


Presentation outline:

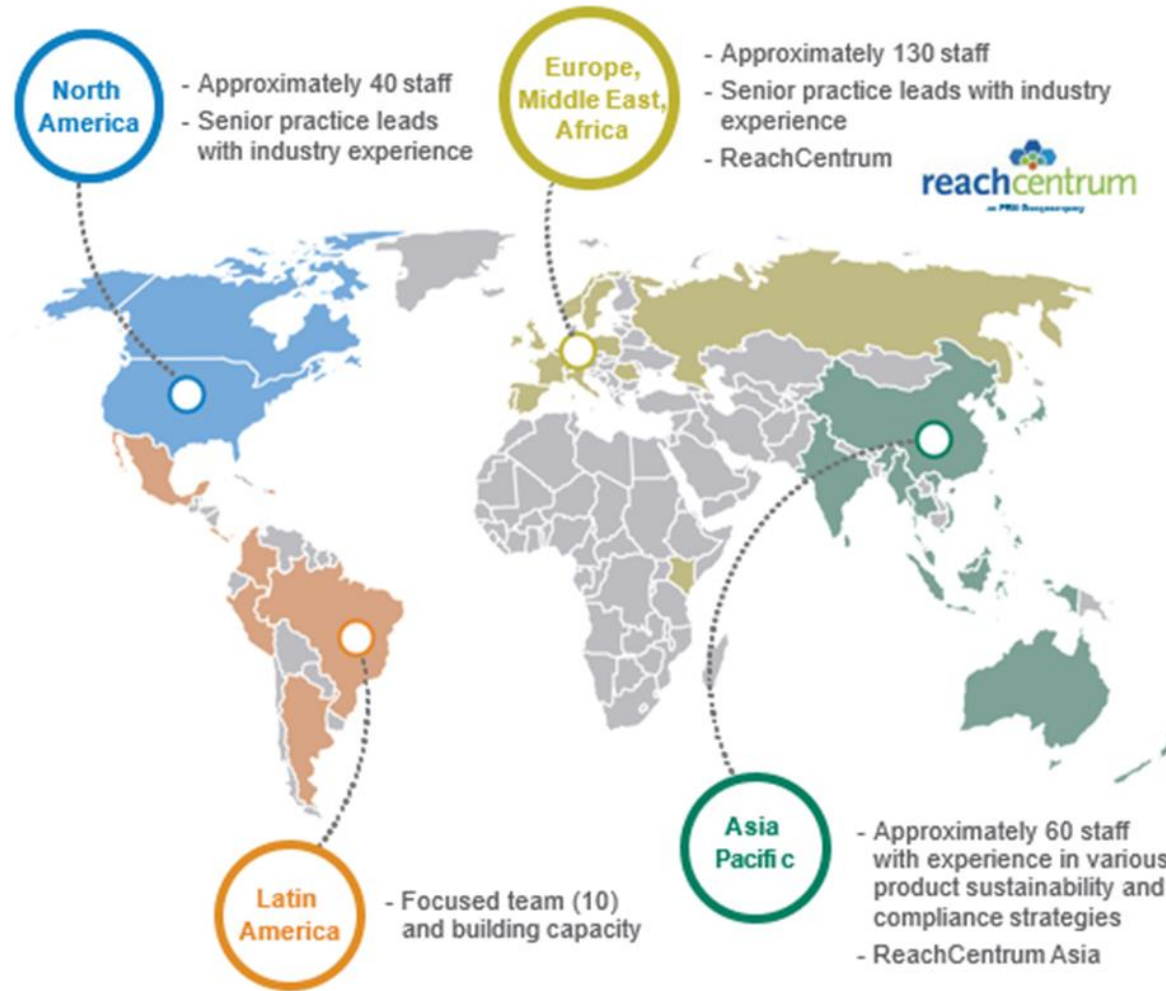
- Introduction
- Sustainability
- Natural substances
- Global pathways
- Regulatory requirements
- Learnings



ERM: European Biologicals Team



ERM: Global product stewardship and regulatory affairs



Strong, globally connected team with both local and global knowledge of the market drivers and regulatory landscape to support our client's needs.

Global Centers of Excellence established for technical excellence and consistency.

Strong working relationships with other ERM practice areas (e.g., Digital Services, EMIS, Compliance Auditing, Transaction Services)

Sustainability



Corporate Sustainability and Climate Change

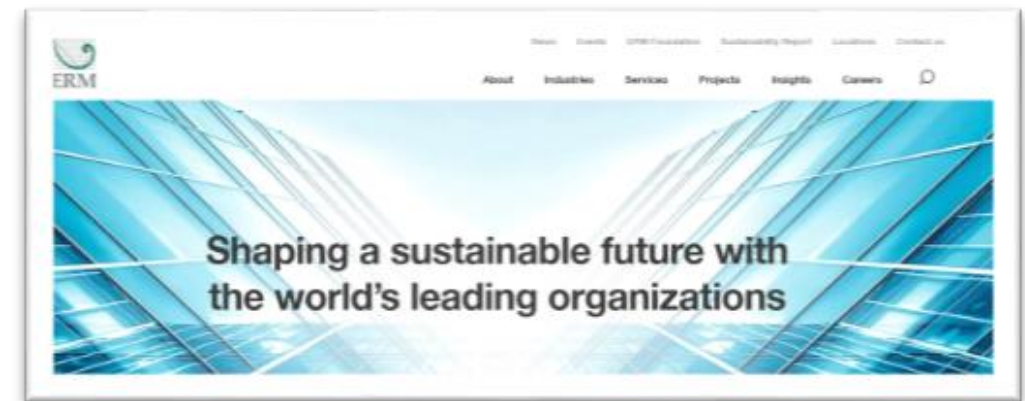
Partnering with leading organizations to address complex sustainability challenges, from climate change risk to human rights, by clarifying strategic direction, designing corporate programs, and enhancing transparency and the robustness of public disclosures.



Product Stewardship

Helping clients bring products to market safely, sustainably, and in compliance with global regulations, in a way that also meets their business goals and satisfies key stakeholders.

at ERM: we walk the talk....



<https://www.erm.com/sustainability-report/>

ERM: The business of sustainability

'Farm to Fork' strategy published in May 2020

Part of the European Green Deal put in place by the new Commission

Linked to:

Evaluation of Regulations 1107/2009 & 396/2005

Review of Sustainable Use Directive (2009/128/EC)



Commission committed to “...enhance provisions on IPM, and promote greater use of alternative ways to protect harvests from pests and diseases”.

Farm-to-Fork strategy: Evaluation of Regulations 1107/2009 & 396/2005

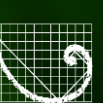
16 improvement areas identified...

1. Better implementation – addressing delays and increasing transparency
2. Improved implementation of the cut-off criteria
3. ***Simplify the comparative assessment of candidates for substitution***
4. Cumulative risk assessment
5. Environmental- and Bio-monitoring
6. Define Environmental Protection Goals and update Guidance Documents
7. Improve the zonal system for authorisation of PPPs
8. ***Solutions for minor uses***
9. Increase oversight of emergency authorisations
10. Further reduce the need for vertebrate animal testing
11. ***Promote sustainable plant protection, low-risk solutions and efficient risk mitigation***
12. Better enforcement of the PPP Regulation
13. Better enforcement of the MRL Regulation
14. Faster response to emerging MRL issues and to technical progress
15. ***Using green diplomacy to promote our green agenda for pesticides***
16. Increase internal coherence and consistency with EU legislation

Proposal expected to amend Annex IV of
Reg. 1107/2009



Global Definitions: Natural substances



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IBMA Definition

Natural Substances (NS)

consist of one or more components that originate from nature, including but not limited to: plants, algae/microalgae, animals, minerals, bacteria, fungi, protozoans, viruses, viroids and mycoplasmas. They can either be sourced from nature or are nature identical if synthesised. This definition excludes semiochemicals and microbials.



Definitions

EU Guidance Document on Botanicals

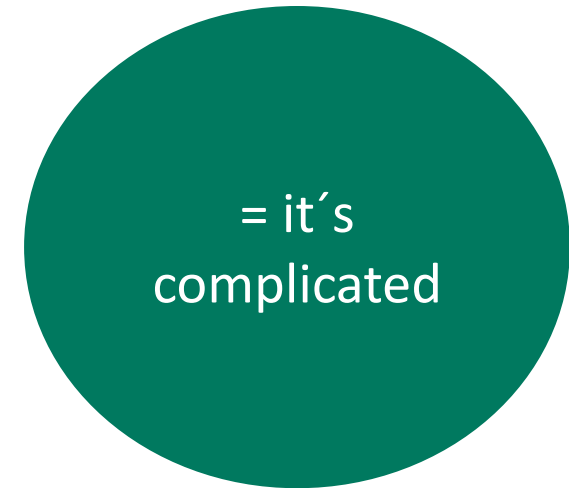
Botanical active substances

an extremely heterogeneous group of substances, powders, processes. Furthermore, highly refined (substance) or mixture of components, only some are botanical. Refers to active substances derived from plant material, referred to as analogues, natural-identical synthetized molecules and biosimilars covered

BPIA Biochemical products

naturally occurring compounds or synthetically derived compounds that are structurally similar (and functionally identical) to their naturally occurring counterparts.

Source	Title	Definition	Status	Remarks & Sources
FAO	No real definition, more a comment	This situation has encouraged the development of new products for plant protection and nutrition based on microorganisms such as bacteria, algae, protozoa, viruses and fungi, natural substances such as pheromones or semi-chemicals , macroorganisms and invertebrates such as insects and nematodes, as well as botanical extracts . The use of this type of products, sometimes called Biopesticides or Biofertilizers, or Biostimulants depending on their functionality, is increasing in world agriculture as a complement or alternative to the use of traditional pesticides. However, the scientific and technical literature is not clear regarding the formal definitions of these concepts, nomenclatures, properties and potential risks for people's health associated with their use, nor is the translation of this type of products in other languages. Biofertilizers, and other farm input.	Final	No specific definition for natural substances Source: Guidelines for the Registration of Microbial, Botanical and Semiochemical pest control agents for plant protection and public health uses, FAO/WHO 2017, WHO/HTM/NTD/WHOPE/2017.05; http://www.who.int/whopes/resources/WHO_HTM_NTD_WHOPE_2017.05/en
OECD	Botanical active substance	No specific definition for natural substances No formal definition for Biopesticides or Biocontrol		
Botanical Guidance and CTGB	Botanical active substance	A 'botanical active substance' consists of one or more components found in plants and obtained by subjecting plants or parts of plants of the same species to a process such as pressing, milling, crushing, distillation and/or extractions. The process may include further concentration, purification and/or blending, provided that the chemical nature of the components is not intentionally modified/ altered by chemical and/or microbial processes.	Final	Addition CTGB: 'Botanicals are not per se non-toxic to the environment and humans' Source: SANCO/11470/2012-REV. 8, 20 March 2014 GUIDANCE DOCUMENT ON BOTANICAL ACTIVE SUBSTANCES USED IN PLANT PROTECTION PRODUCTS
Ecocert, OMRI	Botanicals	Plant-chemicals - Plant group - Semiochemicals - Largest challenge: naming and constituents		
REACH	Substances which occur in nature	Means a naturally occurring unprocessed or processed chemical or gravitational material, by flotation, by extraction, steam distillation or by heating, soluble in water, or which is extracted from air		
FOD (Belgian authority)	Des produits à base d'extraits de plantes	Un ensemble large de produits phytopharmaceutiques de natures différentes. Cet ensemble varie entre des produits à base d'extraits de plantes non transformés à des produits subissant de multiples transformations. P.ex.: azadirachtine, pyrèthrine, huiles végétales, ...	To be changed	New definition collaboration
BPIA	Biochemical products	Biologicals are naturally occurring compounds or synthetically derived compounds that are structurally similar (and functionally identical) to their naturally occurring counterparts.		
EPA	Biochemical pesticide	A biochemical pesticide is a pesticide similar and functionally identical to naturally occurring substances, or in part naturally occurring, and the environmental toxicity, or in part derived biochemically, to humans and the environment is minimal. (i) Has a naturally occurring target pest(s).		



Source: IBMA NSPG background paper Natural Substances Definition 2019, Annex I
<https://www.ibma-global.org/upload/documents/nspgbackgroundpapernaturalsubstancesdefinition.pdf>

Global Pathways

- Many similarities
- Different terminology
- Boundaries of product categories differ
- Speed and clarity of processes differ
- Influences the numbers of actives registered



Global Requirements

USA

- BPPD
- biochemicals
- OPPTS guidelines

LATAM

- Special biopesticide regulations (botanicals) recognised in some countries

North America

- Approximately 40 staff
- Senior practice leads with industry experience

Europe, Middle East, Africa

- Approximately 130 staff
- Senior practice leads with industry experience
- ReachCentrum



China

- Special pesticides
- biochemical (vs botanical pesticides)
- efforts to harmonise with OECD regulations

Asia Pacific

- Approximately 60 staff with experience in various product sustainability and compliance strategies
- ReachCentrum Asia

Latin America

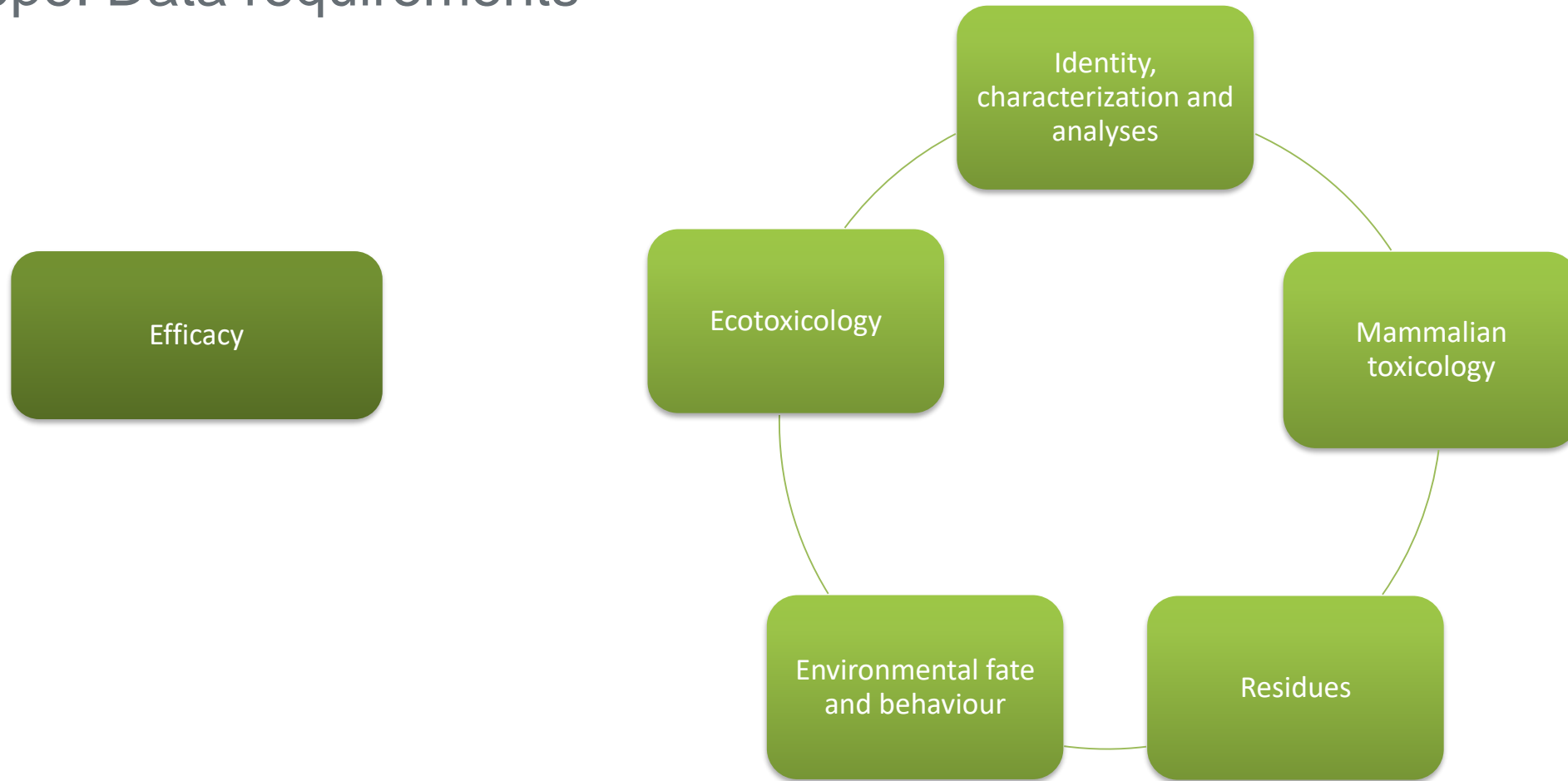
- Focused team (10) and building capacity

Europe: Relevant documents to facilitate evaluation and assessment of NS

- In Europe defined as pesticides under 1107/09, Regulation 283-2013 “Part A” Data requirements
- Low risk (EU) 2017/1432
- EPPO guidance for efficacy testing of low-risk substances (PP 1/296 (1))
- EU “Guidance Document on botanical active substances used in plant protection products” (SANCO/11470/2012– rev. 8. 20 March 2014)

Criteria, interpretation and cost vary between MS

Europe: Data requirements



Large volume of papers and corresponding high cost to comply with EFSA literature search guidance

Global challenges: Product characterisation

- Manufacturing consistent quality/composition of the active ingredient(s)
- Quantifying those components
- Characterisation of active substances as complex mixtures
- Understand how the mode of action of the substance relies on specific components of the mixture

Global challenges: Mammalian toxicology

- Endocrine Disruptor – importance of understanding historical data and details of Mode of Action
- Requirement for repeat dose toxicity studies to set regulatory reference values for use in risk assessment
- Risk mitigation (can affect low risk PPP status)

Global challenges: Residues and crop metabolism

- Regulatory approach usually relies on waivers against the need to provide residues data
- Sometimes metabolites- can trigger extensive chemical data requirements
- Specific issues can be triggered depending on the nature of the natural substance (e.g., possibilities of secondary growth)
- Requests for new studies may be issued by reviewers late in the process – in the face of great time constraints



Global challenges: Environmental fate and behaviour

- Need to address data requirements such as adsorption and route and rate degradation in soil, water and sediment with an exposure assessment for the soil, surface water and groundwater compartments
- Expensive, sometimes impossible to radiolabel, expensive and challenging to perform such studies unlabelled
- Alternative methods may be necessary in order to derive crucial soil degradation and sorption end points
- Importance of Ready Biodegradability to generate data on degradation
- Use of QSAR models to estimate K_{FOC} values, a measure of soil adsorption
- Use of a 'marker component' approach comparing components common to the botanical pesticide and cropped plants

Global challenges: Ecotoxicology

- Matrix effects - what to measure, how to measure in certain matrices (e.g., feeding solutions)
- Inadvertent effects at required test concentrations (e.g., sugars/aquatic plants)
- Rapid degradation (flow through)
- Harmonisation between geographies (species/density)

justification to develop an adapted set of test guidelines more fit for purpose?



EFFICACY



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Global challenges and opportunities: Efficacy

Challenges:

- Greater influence of edaphic, cropping and weather conditions
- Apparent lower, delayed and/or variability compared to chemical pesticides
- Testing combinations together with chemical products (e.g. for proving efficacy of spray sequences in IPM programs)

Opportunities (regarding minor uses):

- Lower number of required supportive efficacy trials compared to conventional product
- Extrapolation tables can also be used for major/minor uses of low-risk products

considerations:

- Comparability of target biology
- Comparability of crop (e.g. leaf structure)
- Direct/indirect mode of action

Learnings

- A global dataset will never be fully achievable but efforts can be made to make harmonisation easier and optimise investment
- Strong relationships with regulators – locally and internationally – are essential
- Guidance could be improved, but successful approvals have been coming out of Europe. Expertise is increasing
- Long term thinking is crucial to success, use partners that really understand regulatory goals, get the best out of studies





Thank you

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