EU Data Requirements for a Biopesticide Approval

Biopesticide approval in the EU requires compliance with regulatory frameworks. The data packages must align with Regulations (EU) No 283/2013 and No 284/2013, as mandated by Regulation (EC) No 1107/2009, and address the evaluation of safety, efficacy, and environmental impact before market authorisation. The assessment process, similar to that of other pesticides, involves EU-level approval of the active substance followed by national authorisation. However, specific guidance for novel pesticides is still under development, and regulatory authorities still have limited experience.

Illustrative Example of EU Data Requirements for a Novel Biopesticide Product

This overview summarises the regulatory requirements to fulfill EU data points. Specific regulatory strategies are diverse, since they are refined depending on the nature of biopesticidal active substances and novel biotechnologies.

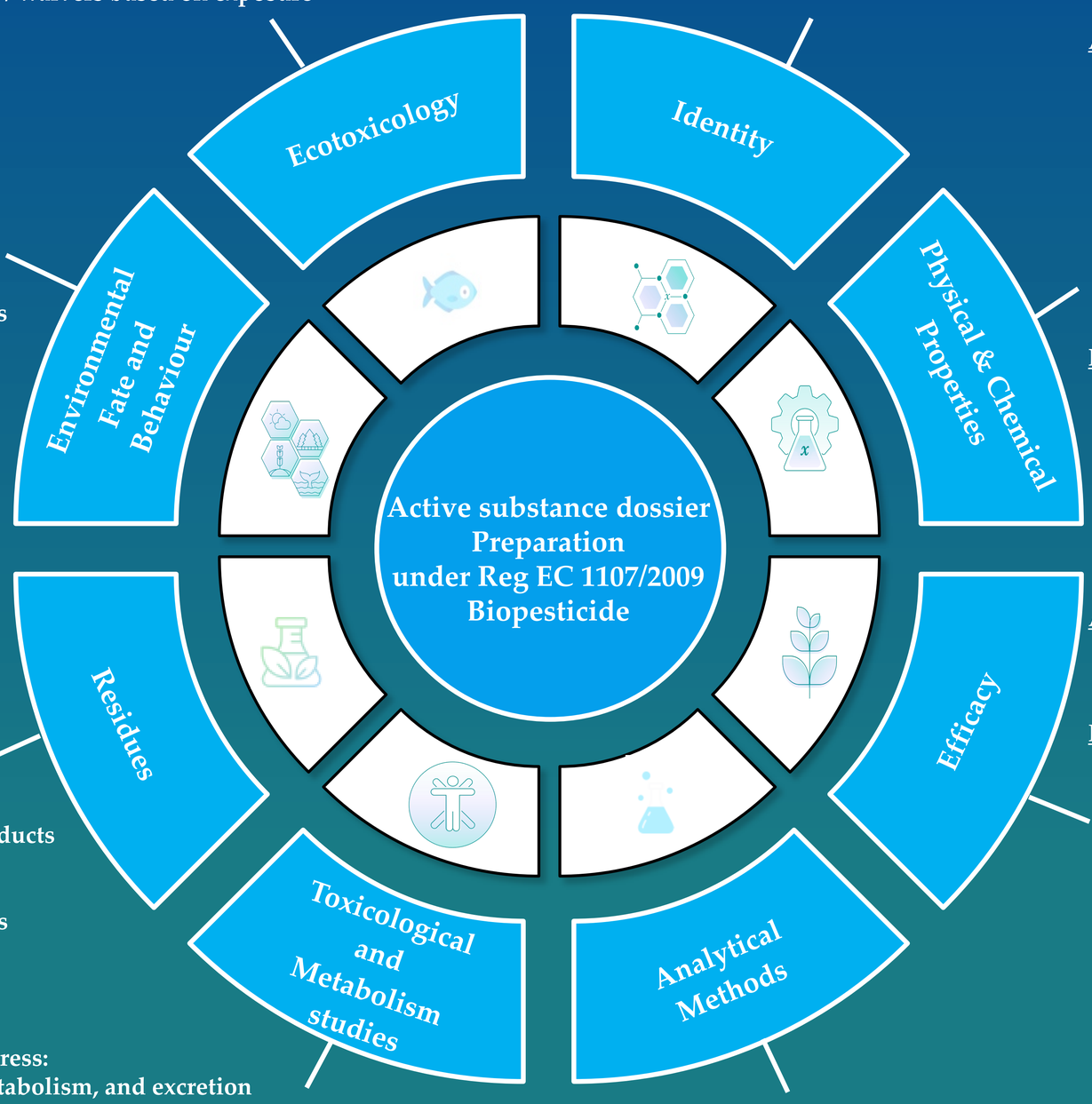
(AS- active substance, PPP- plant protection product)

AS (CA 8)
- Data or waivers to address:
- Effects on terrestrial vertebrates
- Effects on aquatic organisms (vertebrate, invertebrate, algae)
- Effects on arthropods including bees
- Effects on earthworms and other soil meso- and macrofauna
- Effects on nitrogen transformation
- Effects on Biological Methods for Sewage Treatment
- Evidence that active has no effects on non-target organisms

PPP (CP 10)
- Additional studies may be required based on formulation
- Detailed risk assessments / waivers based on exposure

AS (CA 1)
- Specification of the 'active substance''
- 5-batch GLP analysis
- Quantify AS & impurities (if relevant)
- Validation: SANCO/3030/99
- Impurity: structural comparison, QSAR, CLP (if relevant)

PPP (CP 1)
- Quantitative and qualitative information on the composition of the PPP



AS (CA 7)
- Data or waivers to address:
- Routes and rates of soil degradation
- Degradation in water bodies
- Air degradation pathways and rates

PPP (CP 9)
- Soil environmental concentrations
- Water environmental concentrations
- Air environmental concentrations

AS (CA 2)
- Data or waivers to address:
- Melting point, boiling point, and vapour pressure
- Appearance, including physical state and colour
- Spectra analysis and optical purity
- Solubility in water and organic solvents
- Partition co-efficient n-octanol/water
- Flammability, self-heating, and flash point
- Explosive and oxidising properties
- Surface tension and other relevant studies
- Long-term storage stability - 2 years

PPP (CP 2)
- EU data requirements vary by formulation type
- Few data points covered by AS
- Storage stability and shelf-life effects

AS (CA 6)
- Data or waivers to address:
- Storage stability of residues
- Metabolism in plants and livestock
- Residues in crops
- Residues in livestock
- Processing effects on residues
- Residues in rotational crops
- Residue definitions and MRLs
- Dietary exposure levels
- Residue levels in pollen and bee products

PPP (CP 8)
- Residue data covered by AS
- Consumer exposure risk assessments

AS (CA 3)
- Summary of agricultural uses and mode of action
- Resistance risk and management
- Precautionary measures and measures in emergencies

PPP (CP 6)
- Additional efficacy data required for each EU state
- Test effectiveness in relevant EPPO climate zones
- Assess minimum effective dose with trials
- Evaluate crop safety and phytotoxicity
- Check transformation processes and taint
- Verify impact on propagation materials
- Resistance risk assessment
- Risk assessment to succeeding and adjacent crops
- Repeat cleaning test if formulation changes
- 1 season's data for AS approval
- 2 season's data for PPP zonal authorisations

AS (CA 5)
- Data or waivers to address:
- Assess absorption, metabolism, and excretion
- Acute and short-term toxicity
- Genotoxicity and long-term carcinogenicity
- Reproductive toxicity and neurotoxicity
- Metabolites toxicity
- Endocrine disruption
- Review medical data and surveillance
- Summarize mammalian toxicity and health relevance
- Establish toxicological reference values (if relevant)

PPP (CP 7)
- Acute toxicology of the PPP
- Combined toxicity (if relevant)
- Dermal absorption
- Assessment of operator, worker, bystander and resident exposure

AS (CA 4)
- Data or waivers to address:
- Methods for the analysis of pure AS and impurities
- Validation of analytical methods in all generated studies
- Post-approval monitoring methods
- MRL compliance, soil/water monitoring, air analysis of AS, metabolite analysis in tissues

PPP (CP 5)
- Additional methods to determine pure AS and impurities in PPP
- Methods for the determination of residues in various matrices
- Post-approval monitoring methods

Conclusions

Navigating the EU approval process for biopesticides requires adherence to regulatory frameworks and bespoke regulatory strategies based on pivotal understanding of the biological mode of action and/or biotechnologies. Regulation (EC) No 1107/2009 requires that efficacy, human health, and environmental impact are robustly addressed. Costs can vary significantly; some data requirements may be waived based on product characteristics, sound science and technological advancements. Thorough planning is essential. Overall, a meticulous approach and understanding of evolving regulations are key to successful market entry.

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