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# Antimicrobial Resistance in the Context of Microbial Biocontrol Agents: Current Approaches and the Need for Regulatory Integration

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## Introduction

Microbial-based biofungicides are increasingly used as an environmentally safer alternative to chemical plant protection products within the framework of sustainable agriculture and the One Health concept. However, their widespread implementation is accompanied by emerging biological risks, including the development of antimicrobial resistance (AMR), horizontal gene transfer of resistance determinants, and the production of metabolites that may disrupt ecosystem balance. Insufficient integration of these risk assessments into regulatory procedures creates prerequisites for the formation of uncontrolled environmental AMR reservoirs.

In 2022, the European Union adopted Regulations (EU) 2022/1438–1441, which for the first time introduced mandatory requirements for strain genomic characterisation, AMR and HGT assessment, and the analysis of so-called “metabolites of concern” (MoC). In contrast, microbial biofungicides in Ukraine are still regulated under general pesticide legislation without consideration of their specific biological risks.

## Methodology

- **Comparative legal analysis** — to compare EU and Ukrainian regulatory requirements for microbial biofungicides.
- **Content analysis of regulatory documents** — to identify provisions related to AMR, HGT and MoC.
- **System analysis** — to evaluate the integrity of regulatory frameworks and identify gaps.
- **Expert-based One Health compliance assessment** — to assess consideration of risks for humans, animals and the environment.
- **Regulatory benchmarking** — to determine the level of harmonisation of Ukrainian procedures with EU standards.

## Aim

To compare the EU and Ukrainian regulatory approaches to microbial biofungicides with a focus on:

- integration of antimicrobial resistance assessment;
- consideration of horizontal gene transfer risks;
- analysis of metabolites of concern;
- the impact of these approaches on biosafety and the One Health concept.

## Results

| Criterion | European Union (Reg. EU 2022/1438–1441) | Ukraine (current model) |
|---|---|---|
| **AMR assessment** | Mandatory phenotypic and genomic evaluation of strain susceptibility to antimicrobials; detection of resistance genes. | Not required as a distinct regulatory step; AMR assessment is absent or fragmentary. |
| **HGT analysis** | Mandatory identification of mobile genetic elements and evaluation of horizontal gene transfer potential. | Not regulated; risks of gene transfer are not assessed. |
| **Metabolites of Concern (MoC)** | Mandatory identification and toxicological/ecotoxicological assessment of metabolites of concern. | No specific requirements for analysis of microbial metabolites. |
| **Genomic characterisation** | Whole-genome sequencing and data submission as part of the registration dossier. | Not a mandatory requirement. |
| **Ecosystem risks** | Systematic assessment of effects on non-target organisms and environmental microbiomes. | Focus on user toxicology; ecosystem risks are largely neglected. |

**Table 1** Comparison Table of Regulatory Approaches

**Figure 1. Pathway of AMR emergence linked to microbial biofungicides**

Microbial biofungicides exert selection pressure on environmental microbiota, promoting AMR development and dissemination via horizontal gene transfer from environmental reservoirs to clinical settings.

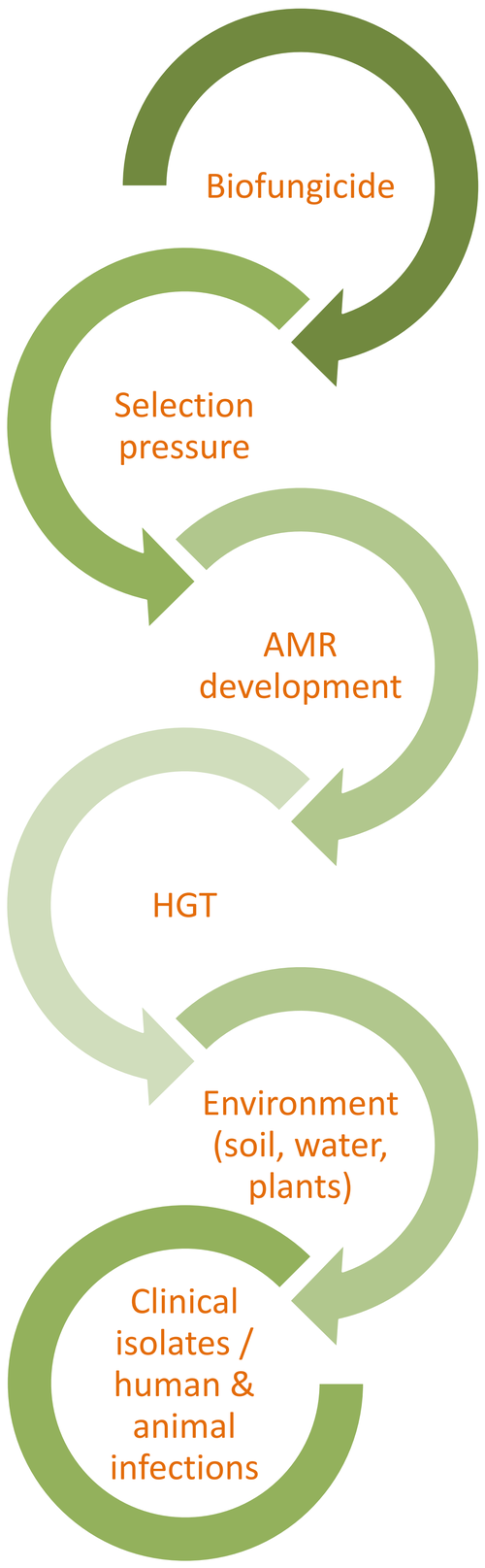
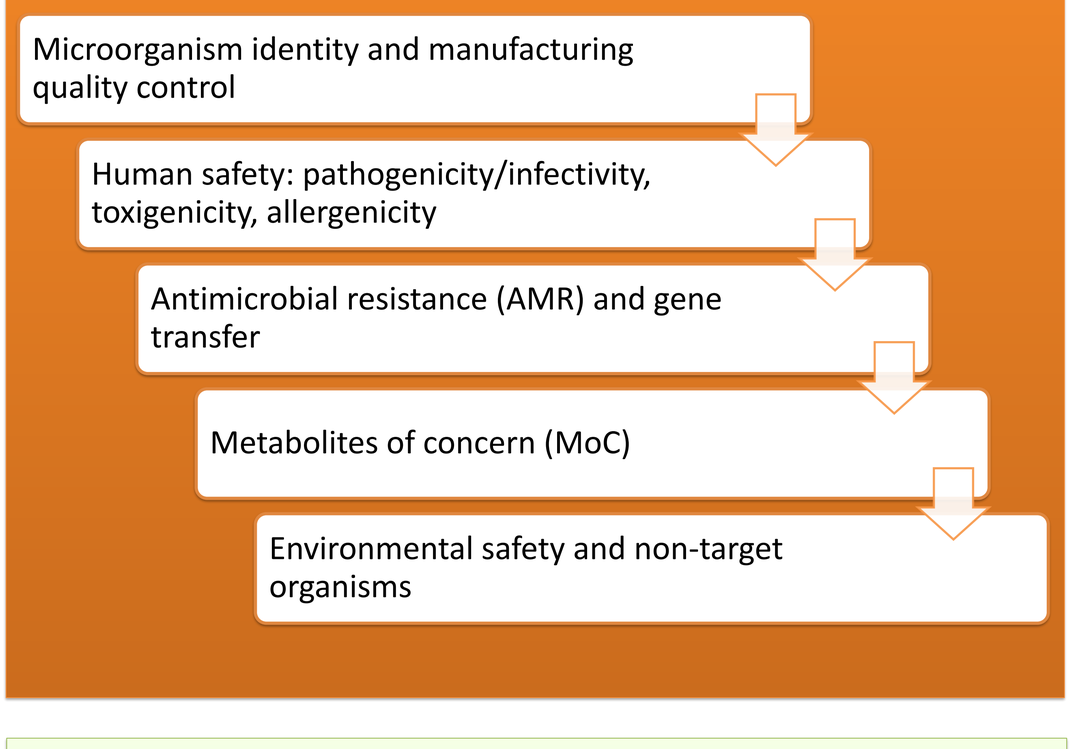



**Figure 2. Benchmark model of the registration dossier for microbial plant protection products (biofungicides) according to the EU regulatory framework 2022/1438–1441**

This scheme presents the benchmark structure of the registration dossier for microbial biofungicides under the EU regulatory framework, integrating strain identity and manufacturing quality control, human safety assessment, antimicrobial resistance and horizontal gene transfer evaluation, identification of metabolites of concern, and environmental risk assessment. The model is proposed as a reference framework for harmonisation of national regulatory procedures.




## Conclusion

**The European regulatory model for microbial biofungicides provides comprehensive control of biological risks by integrating AMR assessment, evaluation of horizontal gene transfer, and analysis of metabolites of concern. In Ukraine, the absence of such approaches creates a critical gap in the biosafety system, posing a threat to agro-ecosystems as well as veterinary and clinical medicine.**

**Implementation of European standards into national legislation is a necessary step to prevent the formation of environmental reservoirs of resistance and to integrate Ukraine into the global strategy for combating AMR within the One Health framework.**