



Workshop: peptide regulation

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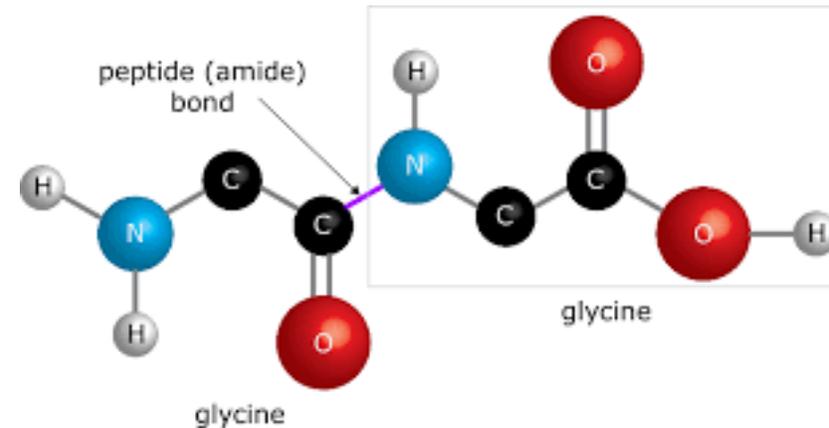
ABIM conference, Basel, 21st October 2025

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Peptide + proteins (peptides*)

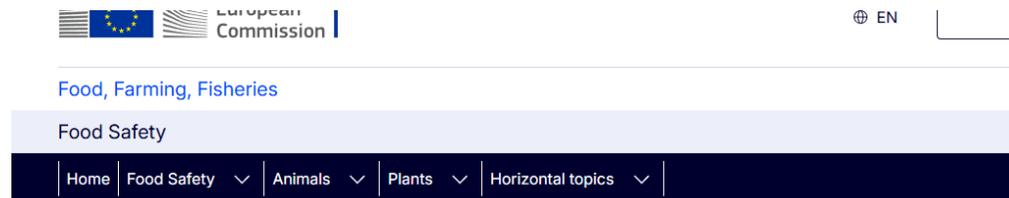
- Peptides are short chains of 2 -50 amino acids linked by peptide bonds, proteins >100 amino acids



- Peptides and proteins: differ in size, complexity and function
- Peptides can bind to lipids (lipopeptide) and other molecules
- Better definition needed for peptides*

Peptides* in PPP: only few examples in EU

- *Bacillus thuringiensis* including proteins (crystalline)
- Extract of Sweet *Lupinus albus* (polypeptide BLAD)
- Pending: Polypeptide, ASFBIOF01-02, GS-omega/kappa-HxTx-Hv1a
- Others?



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EU Pesticides Database

The EU Pesticides Database allows users to search for information on active substances used in plant protection products, Maximum Residue Levels (MRLs) in food products, and emergency authorisations of plant protection products in Member States. Users can use the following search options to find information:

- [Active substances](#)

The database contains information on active substances (including those that are low-risk or candidates for substitution) and basic substances, either approved or non-approved in the EU. Some safeners and synergists are also listed but these have not yet been assessed at EU level.

You can [find the latest updates related to active substances here](#).

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Regulatory landscape for peptides*

- Peptide*-based products must meet the same regulatory standards as traditional chemical pesticides
- In European context: According to Regulation (EC) No 1107/2009 for plant protection products this means that a peptide dossier should meet with **Part A** data requirements for chemical active substances
- **Part B** is data requirements for micro-organisms





Assessment of peptides*

Some data requirements in **part A** for active substance are a bad fit for peptides, for physical-chemical properties

- *vapour pressure

- *IR/NMR-spectra

- *solubility in organic solvents



Other sections (e.g. ecotox) may also contain data requirements that do not fit.

Current approach for assessment of dossier

Case-by-case

- In Annex to 283/2013, introduction, point 1.5: offers possibility to address data requirements in a different way

1.5. The information shall include a full and unbiased report of the studies conducted as well as a full description of them. Such information shall not be required, where one of the following conditions is fulfilled:

- (a) it is not necessary owing to the nature of the product or its proposed uses, or it is not scientifically necessary;
- (b) it is technically not possible to supply.

In such a case a justification shall be provided.

- Discussion between RMS and applicant (pre-submission meeting)
 - tip for applicant: explain, explain, explain!
- Harmonise between RMS and other member states



Towards EU harmonisation

1. Guidance to harmonise case-by-case approach for assessment based on biological properties (e.g. problem formulation)
Specific for each type of peptide?
2. Test guidelines for applicant, in case testing is needed



Some considerations

- For hybrid dossiers, if protein is produced by fermentation, assessment of the **manufacturing process according to Part B-requirements** (within a Part A dossier) will become more common. This ‘crossover’ must be better supported by **IUCLID**.
- Registration of peptides as a group could be desirable. This should be supported by the regulatory framework.
- Regulatory is based on hazard, not on “naturalness”
- The **nomenclature** of the various peptide* classes should be reconsidered
 - (e.g. name of production host in name)
- Include *in silico* (*bioinformatic*) tools to assess peptide* sequences for presumed safety. These tools should be validated for use in a regulatory context.





In summary

- Peptide*-based plant protection products offer innovative, sustainable, and specific alternatives to traditional chemicals.
- Peptides* can be assessed based on Part A data requirements
- Additional regulatory guidance is needed



- Any questions???



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