MRLs for some “chemical-unlike” biological substances

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Commission Regulation 2025/1101 concerning the assessment by the European Medicines Agency of maximum residue limits for chemical-unlike biological substances

Commission Implementing Regulation 2025/1102 as regards chemical-unlike biological substances

Commission Implementing Regulation 2025/1103 as regards the requirements for applications and requests for the establishment of a no MRL required classification for chemical-unlike biological substances

What is changing and why?

The European Medicines Agency (EMA) has concluded that the following “chemical-unlike” biological substances can be safely used in food-producing animals, and that there is no need to set a maximum residue level (MRL) for the following substances.

For all food-producing animals:

- probiotic components including bacteria and yeasts
- stem cells.

For cattle:

- bovine casein hydrolysate (bCNH) produced from sodium caseinate hydrolysed with trypsin, heat treated
- recombinant bovine IL-8 (His-tag).

For bees:

- Varroa destructor calmodulin gene-specific double-stranded interfering RNA EP15 (naked unmodified dsRNA).

Risk assessments undertaken by the EMA depend on the type of biological substance:

- “chemical-like” substances, which could be produced by chemical synthesis and raise similar concerns, are subject to a normal MRL evaluation

- "chemical-unlike" substances, which are more complex and may contain multiple chemical types, are evaluated on a case-by-case basis.

Timeline

The three Regulations apply from **24 June 2025**.

For more information see the full record on the AGRINFO website – where you can also view the latest AGRINFO Update newsletters and search the database.