MRLs for some “chemical-unlike” biological substances

Published by AGRINFO on 06 Jun 2025

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

Copyright © **COLEAD 2026,** *AGRINFO is funded by the European Union and implemented by COLEAD.*

- "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.

Disclaimer: *Under no circumstances shall COLEAD be liable for any loss, damage, liability or expense incurred or suffered that is claimed to have resulted from the use of information available on this website or any link to external sites. The use of the website is at the user's sole risk and responsibility. This information platform was created and maintained with the financial support of the European Union. Its contents do not, however, reflect the views of the European Union.*

Copyright © **COLEAD 2026,** *AGRINFO is funded by the European Union and implemented by COLEAD.*