

Hydrolysed Proteins

DOCUMENT M-CA, Section 6

RESIDUES IN OR ON TREATED PRODUCTS, FOOD AND FEED

Version history¹

Date	Data points containing amendments or additions and brief description	Document identifier and version number

¹ It is suggested that applicants adopt a similar approach to showing revisions and version history as outlined in SANCO/10180/2013 Chapter 4 How to revise an Assessment Report

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CA 6 RESIDUES IN OR ON TREATED PRODUCTS, FOOD AND FEED

According to EFSA Journal 2012; 10(2):2545, “*hydrolysed proteins as a plant protection product is likely to be of low toxicity and a quantitative consumer risk assessment is not needed unless the required technical specification raises a toxicological concern.*”

Considering the nature, origin, manufacturing process, composition and technical specifications of the Hydrolysed proteins as provided in Document J, there is no component of toxicological concern, thus confirming that hydrolysed proteins are of low toxicity.

Furthermore, it should be noted that Hydrolysed proteins are natural compounds derived by the hydrolysis of the animal tissue proteins. The proteins are macromolecules constituted by the union of amino acids. In the nature, there is a restricted number of amino acids, the proportion of these amino acids and their order, among other characteristics, are the origin of variability of the different proteins.

The hydrolysis consists on breaking the peptide links which join the amino acids of a protein. Depending on the intensity of the process, a variable composition of free amino acids, peptides and polypeptides will be obtained. The hydrolysis does not mean the appearance of new molecules but its defragmentation of treated proteins, these fragments do not lose their biological capacity, so they can be re-used by the cells to construct new protein tissues. This characteristic is the base of the complex metabolic process of all the animals feeding, through a part of the consumed protein feed, is transformed in new proteins.

According to their nature, it cannot be said that hydrolysed proteins generate residues but materials that can be re-used because they structurally have the same composition as the cells. Hydrolysed protein components, free amino acids and peptides, are natural substances and consequently completely biodegradable.

Besides, since proteins, free amino acids and peptides occur naturally in plants and animals, it would not possible to distinguish the naturally components from those resulting from the use of plant protection products.

Therefore, hydrolysed proteins can be exempted from the requirements of residues data.

CA 6.1 Storage stability of Residues

No data submitted, not required. Please refer to the argumentation presented under Point B 6.

CA 6.2 Metabolism, Distribution and Expression of Residues

CA 6.2.1 Metabolism, distribution and expression of residues in plants

No data submitted, not required. Please refer to the argumentation presented under Point B 6.

CA 6.2.2 Poultry

No data submitted, not required. Please refer to the argumentation presented under Point B 6.

CA 6.2.3 Lactating ruminants

No data submitted, not required. Please refer to the argumentation presented under Point B 6.

CA 6.2.4 Pigs

No data submitted, not required. Please refer to the argumentation presented under Point B 6.

CA 6.2.5 Fish

No data submitted, not required. Please refer to the argumentation presented under Point B 6.

CA 6.3 Magnitude of Residues Trials in Plants

No data submitted, not required. Please refer to the argumentation presented under Point B 6.

CA 6.4 Feeding Studies**CA 6.4.1 Poultry**

No data submitted, not required. Please refer to the argumentation presented under Point B 6.

CA 6.4.2 Ruminants

No data submitted, not required. Please refer to the argumentation presented under Point B 6.

CA 6.4.3 Pigs

No data submitted, not required. Please refer to the argumentation presented under Point B 6.

CA 6.4.4 Fish

No data submitted, not required. Please refer to the argumentation presented under Point B 6.

CA 6.5 Effects of Processing

CA 6.5.1 Nature of the residue

No data submitted, not required. Please refer to the argumentation presented under Point B 6.

CA 6.5.2 Distribution of the residue in inedible peel and pulp

No data submitted, not required. Please refer to the argumentation presented under Point B 6.

CA 6.5.3 Magnitude of residues in processed commodities

No data submitted, not required. Please refer to the argumentation presented under Point B 6.

CA 6.6 Residues in Rotational Crops

CA 6.6.1 Metabolism in rotational crops

No data submitted, not required. Please refer to the argumentation presented under Point B 6.

CA 6.6.2 Magnitude of residues in rotational crops

No data submitted, not required. Please refer to the argumentation presented under Point B 6.

CA 6.7 Proposed Residue Definitions and Maximum Residue Levels

CA 6.7.1 Proposed residue definitions

No residue definition is recommended. Please refer to the argumentation presented under Point B 6.

CA 6.7.2 Proposed maximum residue levels (MRLs) and justification of the acceptability of the levels proposed

According to the argumentation presented under Point B.6, Hydrolysed proteins should be exempted from the requirements of residues data and thus included in Annex IV of the Regulation (EC) No 396/2005. No maximum residue levels (MRLs) should be required for Hydrolysed proteins.

CA 6.7.3 Proposed maximum residue levels (MRLs) and justification of the acceptability of the levels proposed for imported products (import tolerance)

According to the argumentation presented under Point B.6, Hydrolysed proteins should be exempted from the requirements of residues data and thus included in Annex IV of the Regulation (EC) No 396/2005. No maximum residue levels (MRLs) should be required for Hydrolysed proteins.

CA 6.8 Proposed Safety Intervals

Pre-harvest interval:

Not required. Please refer to the argumentation presented under Point B 6.

Re-entry period for livestock to areas to be grazed:

Not required. Please refer to the argumentation presented under Point B 6.

Re-entry period for man to treated crops:

Not required. Please refer to the argumentation presented under Point B 6.

Withholding period for animal feed stuffs:

Not required. Please refer to the argumentation presented under Point B 6.

Waiting period between application and handling treated produce:

Not required. Please refer to the argumentation presented under Point B 6.

Waiting period between last application and sowing or planting succeeding crops:

Not required. Please refer to the argumentation presented under Point B 6.

CA 6.9 Estimation of the Potential and Actual Exposure through Diet and other Sources

Acceptable Daily Intake (ADI) and Dietary Exposure Calculation

No ADI available, dietary exposure calculation not required. Please refer to the argumentation presented under Point B 6.

Acute Reference Dose (ARfD) and Dietary Exposure Calculation

No ARfD available, dietary exposure calculation not required. Please refer to the argumentation presented under Point B 6.

CA 6.10 Other Studies

No data submitted, not required.

CA 6.10.1 Effect on the residue level in pollen and bee products

No data submitted, not required. Please refer to the argumentation presented under Point B 6.