BIOCEBO/BIO

DOCUMENT M-CP, Section 8

RESIDUES IN OR ON TREATED PRODUCTS, FOOD OR FEED

Version history[1]

Date	Data points containing amendments or additions and brief description	Document identifier and version number
2005-26-06	Initial Document M version, submitted for application of approval of the active substance.	M-Hydr.Protein-AnnexIII IIIA.8. Metabolism and residues data
2018-01-09	Added the conclusions from Peer Review (EFSA Journal 2012).	DOCUMENT M-CP, Section 8

[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

CP 8 RESIDUES IN OR ON TREATED PRODUCTS, FOOD AND FEED

No plant metabolism or residues studies were performed during the process of inclusion in Annex I and no definition of residues were established for either monitoring and control, or risk assessment purposes.

No trials were presented either in support of the requested uses, taking into consideration:

- Hydrolysed proteins mainly originate from the hydrolysis of natural proteins, and mostly consist of amino acids and small peptides, undistinguishable from those present naturally in the crop, whether originating in the actual plant or having an exogenous origin in other organisms.
- They are used as attractant substance and have no insecticide capacity per se
- Hydrolysed Proteins derive from hydrolytic cleavage of natural proteins, and are mainly composed by amino acids and small peptides. Because of that, there is no way to distinguish between the hydrolysed proteins coming from the active substance and those formed by field degradation of proteins from living organisms.
- Hydrolysed Proteins are used as an attractant substance. It doesn't have any pesticide effect by itself, thus, it has to be mixed with properly authorized insecticides.

In addition, in the Peer Review (EFSA Journal 2012; 10 (2): 2545) it was noted that hydrolysed proteins are of low toxicity (following pages).

Taking these arguments into account, the expert panel of Spanish Ministry or Residues area agreed with these arguments and proposed to authorise the requested uses of BIOCEBO (citrus, olive and deciduous fruit trees), also taking into consideration the composition of the plant protection product.

The following pages are a summary of the main aspects assessed in the residues section during the process for inclusion in Annex I of hydrolysed proteins, and the EU-wide agricultural practices evaluated and authorised and the results of the residues testing supported by those practices.

Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	No study provided. Not required according to the representative uses(1).
Rotational crops	No study provided. Not required according to the representative uses(1).
Metabolism in rotational crops similar to metabolism in primary crops?	Not relevant.
Processed commodities	No study provided. Not required according to the representative uses(1).
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Not relevant.
Plant residue definition for monitoring	Not required(1).
Plant residue definition for risk assessment	Not required(1).
Conversion factor (monitoring to risk assessment)	Not applicable

Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered	No study provided. Not required according to the representative uses(1).
Time needed to reach a plateau concentration in milk and eggs	Not relevant
Animal residue definition for monitoring	Not required(1).
Animal residue definition for risk assessment	Not required(1).
Conversion factor (monitoring to risk assessment)	Not relevant
Metabolism in rat and ruminant similar (yes/no)	Not relevant
Fat soluble residue: (yes/no)	Not relevant

Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

Not relevant(1)

Stability of residues (Annex IIA, point 6 introduction, Annex IIIA, point 8 Introduction)

Not relevant(1)

Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

No study provided. Not required according to the representative uses(1).

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	Not Required	Not Required	Not Required

Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	Not Required	Not Required	Not Required
	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Residue levels in matrices: Mean (max) mg/kg		
Muscle	-	-	-
Liver	-	-	-
Kidney	-	-	-
Fat	-	-	-
Milk	-		
Eggs		-	

Summary of residues data according to the representative uses on raw agricultural commodities and feedingstuffs (Annex IIA, point 6.3, Annex IIIA, point 8.2)

No supervised trials were conducted since hydrolysed protein is exempted from the requirement of residues data.

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
No study provided. Not required according to the representative uses[1].						

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17
(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the representative use
(c) Highest residue

Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	No data available[1]
TMDI (% ADI) according to WHO European diet	Not required[1]
TMDI (% ADI) according to EFSA PRIMo Model rev.2A	Not required[1]
TMDI (% ADI) according to national (to be specified) diets	Not required[1]
IEDI (WHO European Diet) (% ADI)	Not required[1]
NEDI (specify diet) (% ADI)	Not required[1]
Factors included in IEDI and NEDI	None
ARfD	No data available[1]
IESTI (% ARfD) according to EFSA PRIMo Model rev.2A	Not required[1]
NESTI (% ARfD) according to national (to be specified) large portion consumption data	Not required[1]
Factors included in IESTI and NESTI	None

[1] 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 (see section 1). A data gap may be required to reconsider the consumer risk assessment through dietary intake and drinking water pending the outcome of the outstanding data on the specification and on the groundwater exposure assessment.

Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%) (Optional)
		Transfer factor	Yield factor	
No study provided. Not required according to the representative uses[1].				