NUTREL/SIC

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

[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

The SANCO report for Hydrolysed proteins (SANCO/2615/08-rev. 3-27 October 2008) is considered to provide the relevant review information or a reference to where such information can be found. The following table provides the EU endpoints to be used in the evaluation.

Endpoints and related information (Point 5 of Final Review Report for the active substance Hydrolysed proteins; SANCO/2615/08-rev. 3 - 27 October 2008).

In order to facilitate Member States, in granting or reviewing authorisations, to apply adequately the provisions of Article 4(1) of Directive 91/414/EEC and the Uniform Principles laid down in Annex VI of that Directive, the most important endpoints were identified during the re-evaluation process. These endpoints are listed in volume 1, page 27 and at section 3 of the DAR.

Agreed EU End-points (SANCO/2615/08-rev. 3-27 October 2008)

End-Point	**Active Substance**
Acceptable Daily Intake (ADI)	Not set during EU review
Acute Reference Dose (ARfD)	Not set during EU review
Residue definition (all crops)	Hydrolysed proteins

EFSA Journal 2012; 10(2):2545, establishes these End-points.

End-Point	**Active Substance**
Acceptable Daily Intake (ADI)	No data available*
Acute Reference Dose (ARfD)	No data available*
Residue definition (all crops)	No residue definition

Hydrolysed protein produced by SICIT 2000 is obtained by hydrolysis of animal tissues. Hydrolysed protein is used also as a foliar fertiliser and does not cause negative transformations in the environment, if it is used following the suggested conditions. The product is constituted by natural substances and consequently is completely biodegradable. Reasonably there are not negative effects on the environment.

Stability of Residues

The stability of residues for the active substance(s) not is applicable.

Supplementary studies on metabolism in plants or livestock

Based on the intended uses supported in the context of inclusion of Hydrolysed protein in Annex I of Directive 91/414/EEC, no potential feedingstuffs are expected to result and be fed to

livestock. Furthermore, it would not be possible to distinguish the proteins brought in an artificial way from the ones already existing in the same animal tissues. Therefore, it is not expected that livestock will be exposed to significant hydrolysed protein residues through diet. Consequently, metabolism studies are not considered necessary.

Supplementary residue trials (supervised field trials)

Metabolism studies in plants are not considered necessary and a residue definition of Hydrolysed protein for plants is not considered relevant for the uses intended in EU.

Supplementary Livestock Feeding Studies

Metabolism studies in livestock are not considered necessary and a residue definition of Hydrolysed protein for products of animal origin is not considered relevant for the uses intended in EU.

Supplementary Studies on Industrial Processing and/or Household Preparation

Data/information on processing studies were reviewed during the Annex I inclusion of Hydrolysed protein and were considered acceptable. Such a study is not required as residue in plants or plant products which would be processed are not significant and the total TMDI (%ADI) according to WHO European Diet not is required, TMDI (%ADI) according to EFSA PRIMO Model rev. 2A not is required, TMDI (%ADI) according to National (to be specified) diets not is required

Supplementary Studies for Residues in Representative Succeeding Crops

Data/information on residues in succeeding crops were reviewed during the Annex I inclusion process and were considered to be acceptable and no further data have been generated.
There is no risk for significant residues of Hydrolysed proteins in succeeding crops given the rapid degradation of this substance in soil. Therefore no studies are required for this Annex point.

Proposed Residue Definition and Maximum Residue Levels

The EU Agreed residue definition for monitoring and risk assessment is Hydrolysed proteins only.

Proposed Pre-Harvest Intervals, Re-Entry or Withholding Periods

Setting of a PHI is not relevant as the application moment is fixed to a specific growth stage interval. This issue was already raised in the DAR. PHI (days) depends on the insecticide to be mixed with the attractant.
Re-entry period (in days) for livestock, to areas to be grazed: Not relevant, no applications are made to areas to be grazed.

Re-entry period for man to crops, buildings or spaces treated: Not relevant, NUTREL is only applied to orchards.
Withholding period (in days) for animal feedingstuffs: Not relevant, NUTREL is only applied to orchards.
Waiting period before sowing or planting crop to be protected:Not relevant, NUTREL is applied to orchards to already established trees.
Waiting period between application and handling treated products:Not relevant, NUTREL is only applied to orchards during the growth season. There are no treated products to be handled. At harvest, there is no residue in the fruits.
Waiting period (in days) before sowing or planting succeeding crops:Not relevant, NUTREL is only applied to orchards so the succeeding crop will be the same orchard.

Estimation of Exposure Through Diet and Other Means

The ADI and ARfD for the active substance(s) contained in NUTREL are summarised in the table below.

End-Point	Value	Study	Safety factor	Reference
Acceptable Daily Intake (ADI)	- mg/kg bw/d	No data avaiòable*	/	EFSA Scientific Report 2012
Acute Reference Dose (ARfD)	- mg/kg bw/d	No data avaiòable*	/	EFSA Scientific Report 2012

*Hydrolysed proteins *per se* are considered of low toxicological concern and no risks to human health are expected from its use as a plant protection product. However due to the fact that a specification to include the main components in the active substances is still outstanding a final conclusion cannot be drawn whether the technical specification is of toxicological concern leading to a data gap and issue that cannot be finalized.

TMDI calculations

It is unclear whether TMDI calculations have to be presented as Hydrolysed proteins is a naturally occurring compound in plants and thus already present in our daily diet as discussed in the DAR. Based on this, an proposal was made to include NUTREL on the list of substances which are exempt of MRL requirement. If this is confirmed, TDMI calculations are not required.

NEDI calculations

The ADI for Hydrolysed proteins is not available during the EU review.The above mentioned calculations show that in none of the situations, the TMDI value exceeds the ADI value. Hence it is not required to perform NEDI calculations

NESTI calculations

No ARfD was set for Hydrolysed proteins during the EU review. Therefore NESTI calculations are not required.

Summary and Evaluation of Residue Behaviour

This dossier is presented to support the product NUTREL for the use on Olive trees, Pome fruits, Stone fruits, Walnut, Citrus, Fig, Kiwi and Blueberries. During the EU review, a proposal was made to add Hydrolysed proteins to Appendix VI of the residue Regulation 396/2005/EC due to its natural occurrence in plants. This Appendix lists all compounds which are exempt of MRL setting.

The EU Agreed residue definition for monitoring and risk assessment is Hydrolysed proteins only.

New dietary risk assessments for the active substance were carried out and the results are presented in this section.

The results of the TMDI calculations (% ADI) according to WHO European Diet, according to National Diet and with the EFSA Model are summarized in the paragraph *TDMI calculation* and show that there is no chronic risk for consumer for the active substance:
The TMDI (% ADI) estimation according to the EU calculations is not required.

As no acute reference has been set for the active substance(s), there is no need to evaluate the acute risk for this active substance.

Based on the different calculations made to estimate the risk for consumer though diet and other mean it can be concluded that the use of product NUTREL does not lead to unacceptable risk for consumer when applied according to the recommendations.