

Ad hoc meeting with industry representatives – Joint dossiers on food enzymes produced from animal and plant sources

Rennet: data gaps and proposals

EFSA FIP Unit – food enzyme team

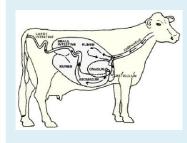




EFSA-Q-2015-00237 Animal rennet

Source material Abomasum of:

- cattle
- buffalo
- goat
- sheep



Methods used to ensure the absence of any risk of infectivity

Available data

- The risk of the possibility that Transmissible spongiform encephalopathy (TSE) infectivity might be associated with the abomasum and rennet could be considered negligible (Scientific Steering Committee, 2002). In WHO (2003), the absence of BSE infectivity in stomachs of cattle was reiterated.
- Human health problems associated with other infective agents originating from rennet have not been reported.
- Rennet preparations are often sterile filtered.
- The microbiological quality of rennet is subject to strict analytical control.

Product specific data

- Documented compliance with meat inspection requirements and in accordance with good hygienic practice.
- Data on the absence of infectious agents in the source tissue and methods to ensure the absence of any risk of infectivity.



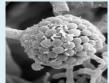
EFSA-Q-2015-00237 Animal rennet

FOOD ENZYME Available data

Animal rennet pepsin A)







Physical state (liquid, powder or paste) of rennet

may be marketed as a liquid food rennet*. enzyme preparation, or it may be dried to a granulate or powder.

Product specific data

(chymosin and The food enzyme preparation Specification of physical state of

*EFSA (2014): different types of rennet commercially available which may differ in their origin (e.g. animal, vegetable, microbial or recombinant rennet) or physical state (liquid, powder or paste).



EFSA-Q-2015-00237 Animal rennet

FOOD ENZYME

Animal rennet (chymosin and pepsin A)

Manufacturing process, raw materials

Available data

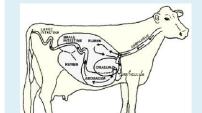
There are many producers, and some variation in the processing. The steps may be undertaken in a different sequence, or combined, e.g.

- Concentration (in some cases)
- Separation of chymosin and pepsin (in some cases)
- Formulation/standardisation of strength and (in some cases) composition
- Drying to powder or granulate (*if needed*)

Raw materials

Product specific data

 Detailed description of the concrete manufacturing process actually used.



- An updated list of all raw materials that are actually used in the course of the food enzyme production.
- Clear indication at which step of the manufacturing process each raw material is used, as well as information on their functions.



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The ratio between chymosin and pepsin activity

FOOD ENZYME

Animal rennet (chymosin and pepsin A)

Available data

Animal rennet varies with respect to the Characterization of the rennet with ratio between activity, but that variation depends on the individual dossiers and description of age and feeding of the source animals the standard methods used for more than on the source species.

Product specific data

chymosin and pepsin the ratio chymosin:pepsin in an determining the two enzymes:

- IDF 110/ISO 15163 (2012) or
- IDF 110A/1987 **IDF** and 110B/1987



Chymosin dominates in extracts from stomachs of young animals, pepsin in from stomachs extracts of mature animals.



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Chemical composition of batches

FOOD ENZYME

Animal rennet (chymosin and pepsin A)

Available data

The batches were selected as technically typical examples of animal rennet, extracted from slightly variable source materials (stomachs of different age) by a typical process. Analyses of samples from 8 other producers confirm that these batches are indeed typical.

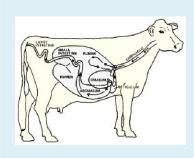
3 batches representative* for the product from manufacturers in general and the analyses of 27 batches, 3 from each of 9 producers are presented in the dossier, however, 10 manufactures are mentioned in the list

- Enzyme activity: 79–2,543 IMCU/mL
- Protein: 0.2–6.2%
- Ash: 7.05–19.4%
- TOS: 0.48-7.2%
- Activity/mg TOS: 3.0-54.8 IMCU/mg TOS

*REPRESENTATIVITY: the batch data can be regarded as representative for the product from manufacturers in general, from the point of view that 1) the production method is the same (extraction of the same source material, namely ruminant stomachs), and 2) that the specifications are the same, including the purity criteria.

Product specific data

 Chemical composition, including TOS

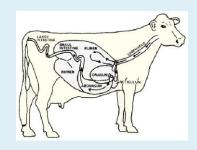




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FOOD ENZYME

Animal rennet (chymosin and pepsin A)



Analytical methods for the determination of milk-clotting activity

Available data

(IDF) has developed the Relative method used: Clotting Activity Milk Test (REMCAT), standard assay • IDF 157/ISO 11815 (2007) method and the International Milk Clotting Unit (IMCU) is therefore • IDF 157A (1997) widely known and accepted.

Product specific data

The International Dairy Federation Information about standard assay

- or



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FOOD ENZYME

Animal rennet (chymosin and pepsin A)

Available data

Toxicological data

Referring to Article 8.5 of the Implementing Measures, Reg. 234/2011, as amended by Reg. 562/2012, Art. 8.3, the dossier does not need to include toxicological data if the food enzyme is obtained from edible parts of plants or animals intended to be or reasonably expected to be ingested by humans. Accordingly, this dossier does not provide any toxicological documentation of animal rennet.

Product specific data

Any existing toxicological studies (EFSA, 2009)





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FOOD ENZYME

Animal rennet (chymosin and pepsin A)

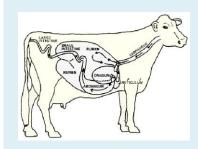
Allergenicity

Available data

chymosin and pepsin have not been determined. Therefore, the homology search could not be performed.

Product specific data

The amino-acid sequences for • A comprehensive literature search for possible adverse reactions, allergy after consumption of source material, published in the last 10 years





EFSA-Q-2015-00237 Animal rennet

FOOD ENZYME

Animal rennet (chymosin and pepsin A)

Intended uses and exposure

Available data

cheese manufacturing, and there are some minor uses such as *quarg*).

Animal rennet is used to a limited extent in the manufacturing of other milk products, *yoghurt, kefir* and *cumus*, where benefits include improved texture during processing.

Yield in cheese production and whey from milk

Budget method, the Theoretical Maximum Daily Intake (TMDI) calculation (cheese, whey)

The food enzyme may be denatured by heat in cheese types which are heat treated, and in whey which is normally heat treated.

Product specific data

Uses: dairy processing (typically used in Intended uses of the food enzyme aligned with the 'EC working document describing the food processes in which food enzymes are intended to be used'

- Specify the intended uses
- Use levels to be expressed as mg TOS/kg raw material

Flowcharts for each intended food process and indication at which step(s) the food enzyme is added and yield factor

Specific tissues/organs used as a source of the food enzyme

Quantity of consumption in the EU or elsewhere

The estimation of dietary exposure, if deemed necessary, will be carried by EFSA.

