



# UPDATE ON FOOD ENZYME DOSSIERS

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*Health and  
Consumers*

# Content of the presentation

- 1. Type of food enzyme applications*
- 2. Update on the food enzyme dossiers*
- 3. Applicability checks: Main issues*
- 4. Confidentiality: Main issues*

# 1-Type of applications

## Generic (joint) dossiers: Non-GM microorganisms

- *Enzymes produced by QPS microorganisms*
- *Enzymes already evaluated in FR/DK*
- *Enzymes obtained from animal-plant sources*

## Producer-specific dossiers

- *Enzymes produced by GM microorganisms*
- *Enzymes for which no joint dossier is possible*

# **FOOD ENZYMES FALLING UNDER ARTICLE 8(5)(c) OF REGULATION (EU) No 234/2011**

IUB No.	Principal Enzyme Activity	Production microorganism	Full evaluation according to SCF guidelines
			Enzymes evaluated after 1992 in France/Denmark
3.4.11.xx (CA)	Aminopeptidase	<i>Aspergillus niger</i>	yes
3.4.11.2	Aminopeptidase (leucyl)	<i>Aspergillus oryzae</i>	yes
3.5.4.6	AMP deaminase	<i>Aspergillus melleus</i>	yes
3.2.1.55	Arabinofuranosidase	<i>Aspergillus niger</i>	yes
1.11.1.6	Catalase	<i>Aspergillus niger</i>	Yes* (as complex)
3.2.1.4	Cellulase	<i>Aspergillus niger</i>	Yes** (as complex)
3.2.1.4	Cellulase	<i>Penicillium funiculosum</i>	yes
3.2.1.4	Cellulase	<i>Trichoderma reesei</i> or <i>longibrachiatum</i>	Yes***** (as complex)
3.2.1.11	Dextranase	<i>Chaetomium erraticum</i> or <i>gracile</i>	yes
3.2.1.73	Glucanase (endo-beta)	<i>Aspergillus niger</i>	Yes** (as complex)
3.2.1.74	Glucanase (exo-beta)	<i>Aspergillus niger</i>	Yes** (as complex)
3.2.1.74	Glucanase (exo-beta)	<i>Trichoderma reesei</i> or <i>longibrachiatum</i>	yes
3.2.1.6	Glucanase (beta)	<i>Aspergillus niger</i>	yes
3.2.1.6	Glucanase (beta)	<i>Penicillium</i> or <i>Talaromyces emersonii</i>	yes
3.2.1.3	Glucoamylase or Amyloglucosidase	<i>Aspergillus niger</i>	yes
1.1.3.4	Glucose oxidase	<i>Aspergillus niger</i>	Yes* (as complex)
3.2.1.68	Isoamylase	<i>Pseudomonas amyloclavata</i>	yes
3.2.1.23	Lactase or Galactosidase (beta)	<i>Aspergillus niger</i>	yes
3.1.1.3	Lipase triacylglycerol	<i>Candida rugosa</i>	yes
3.1.1.3	Lipase triacylglycerol	<i>Rhizopus niveus</i>	yes
3.1.1.3	Lipase triacylglycerol	<i>Rhizopus oryzae</i>	yes
3.1.1.5	Lysophospholipase	<i>Aspergillus niger</i>	yes
3.2.1.1	Alpha amylase	<i>Microbacterium imperiale</i>	yes
	Pectinase	<i>Aspergillus niger</i>	Yes*** (as complex)
3.1.1.4	Phospholipase A	<i>Streptomyces vialoecoruber</i>	yes
3.4.2x.xx	Protease (exopeptidase)	<i>Aspergillus melleus</i>	yes
3.4.24.39	Protease	<i>Aspergillus oryzae</i>	yes
3.4.23.23	Protease (mucorpepsin)	<i>Rhizomucor miehei</i>	yes
3.5.1.xx	Protein glutaminase	<i>Chryseobacterium proteolyticum</i>	yes
3.1.26.5	Ribonuclease	<i>Penicillium citrinum</i>	yes
3.1.1.20	Tannase	<i>Aspergillus oryzae</i>	yes
2.3.2.13	Transglutaminase	<i>Streptomyces mobaraense</i>	yes
3.2.1.8	Xylanase	<i>Aspergillus niger</i>	Yes***** (as complex)
3.2.1.6	Glucanase (beta)	<i>Humicola insolens</i>	Yes***** (as complex)
3.2.1.8	Xylanase	<i>Humicola insolens</i>	Yes***** (as complex)
3.2.1.41	Pullulanase	<i>Pullulanibacillus spp</i>	yes
3.2.1.41	Pullulanase	<i>Klebsiella planticola</i>	yes
3.2.1.8	Xylanase	<i>Trichoderma reesei</i> or <i>longibrachiatum</i>	yes

## 2-Update on the food enzyme dossiers

Year	Number of dossiers submitted	GMM	Valid dossiers
2012	5	4	5
2013	28	19	18 7 more info are requested 3 in process
2014	13 (26 May 2014)	10	7 in process

## 2-Update on the food enzyme dossiers

***46 enzymes:** 43 obtained by microorganisms and 6 of them are QPS*

***29 enzymes** are authorised either in DK, FR or both*

***The remaining 17** have not yet been evaluated in the EU*

## 2-Update on the food enzyme dossiers: Forecast of applications

Year	Number of expected dossiers	Number of received dossiers	Discrepancy
2012	4	5	+1
2013	53	28	-25
2014	199	13 (until 26 May)	-
March 2015	26	-	-

### 3- Applicability checks: Main issues

*Very few dossiers have been sent back to the applicant as some data were missing:*

- *Description of the different food processing. No information on the key steps and on the time and temperatures used.*
- *Dietary exposure assessment. No data provided*
- *Why the use would not mislead the consumer. Not enough information supporting this point.*

## 4-Confidentiality

Regulated by Article 12 of CAP Regulation

*Information that cannot be regarded as confidential:*

- *The name and address of the applicant*
- *The name and a clear description of the substance*
- *The justification of the use of the substance in or on specific foodstuffs or food categories*
- *Information that is relevant to the assessment of the safety of the substance*
- *Where applicable, the analysis method(s)*

## 4-Confidentiality

### Article 12 of CAP Regulation

➤ *Art 12.2. Applicants shall indicate which of the info provided should be treated as confidential. **Verifiable justification must be given***

➤ *Art. 12.3. The COM shall decide after consulting with the applicants which info can remain confidential and shall notify applicants and the MS accordingly*

## 4-Confidentiality

*By means of a Commission Decision, the COM has delegated to the Director-General of DG SANCO the adoption, on its behalf of*

- *Decisions determining, in accordance with Article 12(3) of Reg 1331/2008*

## 4-Confidentiality

*Examples of information claimed as confidential which are not in line with Art 12 of CAP*

- *The properties of the food enzyme*
- *Measured enzymatic activity (e.g. activity of the enzyme/mg TOS)*
- *Reaction and Fate in Food*
- *Case of need and proposed conditions of use*
- *Proposed normal, recommended and maximum use levels*
- *Dietary exposure assessment*
- *Characterisation of the batch used for toxicity tests*

## 4-Confidentiality

*Examples of information claimed as confidential  
which may be in line with Art 12 of CAP*

- *Amino-acid sequence of enzymes produced by GMMs*
- *Genetic stability of the production strain*
- *The GMM dossier*
- *Manufacturing process*

***Confidential treatment will be given on a case-by-case basis***



## *QUESTIONS?*

European Commission, DG Health and Consumers Website  
[http://ec.europa.eu/food/food/fAEF/index\\_en.htm](http://ec.europa.eu/food/food/fAEF/index_en.htm)

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