PROCEDURE FOR SUBMITTING AN APPLICATION FOR FOOD ENZYMES

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Content of the presentation

1. *Food enzyme legislation*
2. *Guidance on food enzymes*
3. *Submission of applications: Procedure*
4. *Applications after the submission period*

1-Food Enzymes Legislation (1)

1. *Regulation (EC) No 1332/2008 (enzyme Regulation) as amended by Comm. Reg. No 1056/2012.*
2. *Regulation (EC) No 1331/2008 establishing a CAP for FA, FE and FF.*
3. *Commission Regulation (EC) No 234/2011 implementing CAP Reg. as amended by Comm. Regulation (EC) No 562/2012.*

1-Food Enzymes Legislation (2)

Scope of Reg 1332/2008

Food enzymes that are added to food to perform a technological function in the manufacture, processing, preparation, treatment, packaging, transport or storage of food, including enzymes used as processing aids.

1-Food Enzymes Legislation (3)

Reg 1332/2008 does not apply to

- *Enzymes used exclusively in the production of FAs and PAs.*
- *Enzymes intended for human consumption, such as enzymes for nutritional purposes.*
- *Microbial cultures that are traditionally used in the production of food, such as cheese and wine, which may contain enzymes but are not specifically used to produced them.*

1-Food Enzymes Legislation (4)

Reg No 234/2011 concerns:

a) *the content, drafting and presentation of the application;*

b) *the arrangements for checking the validity of applications;*

c) *the type of information that must be included in the opinion of EFSA.*

1-Food Enzymes Legislation (5)

Reg No 562/2012 provides for:

- *Derogation from submitting toxicological data in specific cases;*
- *Possibility of grouping FE dossiers under one application in specific cases.*

This amendment does not apply to:

- *GMM derived enzymes*

2-Guidance

- *The applicant shall take into account the practical guidance on the submission of applications made available by DG SANCO's website (Article 3 of Reg 234/2011)*

- *The applicant shall take into account the latest guidance documents adopted or endorsed by EFSA (Article 5 of Reg 234/2011)*
  - *GMM derived enzymes*
  - *Conventional food enzymes*

3-SUBMISSION OF FOOD ENZYME APPLICATIONS: Procedure (1)

WHO: Interested parties

WHEN: It started from 11 September 2011

Deadline: 42 months after the date of application of Reg 234/2011 as amended by Reg No 1056/2012 (11 March 2015 at midnight).

WHY: The COM shall submit the applications to EFSA for its opinion (Art 17.3 of Reg 1332/2008)

3-SUBMISSION OF FOOD ENZYME APPLICATIONS: Procedure (2)

An application shall consist of:

- ✓ *An accompanying letter*
- ✓ *A technical dossier*
- ✓ *A summary of the dossier*
- ✓ *A public summary of the dossier*
- ✓ *A checklist*
- ✓ *CD rom/paper version*
- ✓ *List of the parts of the dossier requested to be treated as confidential*

3-SUBMISSION OF FOOD ENZYME APPLICATIONS: Procedure (3)

Initiating the procedure

COM shall acknowledge receipt of the application within 14 working days.

Validity check by both COM and EFSA

COM's task:

1. *Verification that the application falls within the FE legislation*
2. *Verification that the application contains all the elements required under Chapter II*

3-SUBMISSION OF FOOD ENZYME APPLICATIONS: Procedure (4)

Validity check-EFSA's task.

If application contains all the required elements COM shall:

- *Request EFSA to verify the suitability of the data for risk assessment (30 working days to inform COM by letter).*

***If not suitable**, COM will inform the applicant and ask for additional info (COM shall determine the period together with the applicant)*

3-SUBMISSION OF FOOD ENZYME APPLICATIONS: Procedure (5)

Validity check.

*If additional data are not provided within the set time limit, the application shall be considered **as not valid**. COM shall inform the applicant, MS and EFSA indicating the reasons.*

***If suitable**, the evaluation period shall begin from the date when EFSA's letter is received by COM. No deadline for EFSA for giving its opinion*

3-SUBMISSION OF FOOD ENZYME APPLICATIONS: Procedure (6)

Validity check.

Valid applications will go to a "Register" which will be established by COM

Derogation: An application may be considered as valid even if it does not contain all the required elements provided that the applicant has submitted verifiable justification for each missing element.

3-SUBMISSION OF FOOD ENZYME APPLICATIONS: Procedure (7)

- *Risk assessments of EFSA for individual enzymes should be published as soon as they are completed.*
- *Procedure will end with the adoption of the Union list in one single step once EFSA has delivered its opinion on all the FE listed in the Register.*
- *Until the date of application of the Union list, national provisions in force on food enzymes shall continue to apply in the MS.*

4-If a new enzyme is developed after March 2015. What happens?

- *An application shall be submitted for a safety evaluation. It will not be included in the Register.*
- *The enzyme will not be listed on the first Union list. However, it may be in the updated list.*
- *Until the updated list is established, the enzyme concerned may be marketed under current national laws. If needed, transitional arrangements can be made.*

4-If an enzyme is developed after the establishment of the Union list.

- *An application shall be submitted for a safety evaluation. It will not be included in the Register.*
- *EFSA has 9 months to make the opinion.*
- *COM has to submit the draft Regulation to the Committee within 9 months*
- *The new enzyme cannot be marketed until the updated Union list is adopted.*

THANK YOU FOR YOUR KIND ATTENTION

QUESTIONS?

European Commission, DG Health and Consumers Website
http://ec.europa.eu/food/food/fAEF/index_en.htm

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