

## Regulation on Food Enzymes and Submission of Dossiers Outreach to suppliers for Dossier Preparation

- Industry has until March 2015 for submitting dossiers for food enzymes. Flavouring Manufacturers should contact their enzyme suppliers to make sure that the relevant dossiers are prepared and submitted with the template for the *Risk Management* part of the dossier.
- AMFEP and EFA have now finalised this *Risk Management Template* for flavouring uses, which will have to be subsequently shared with the enzyme suppliers by flavouring manufacturers.
- An update of the *EFA survey* on the use of enzymes has been completed and shared with AMFEP.

### Introduction

Through **EFA Information Letter 13/20** we informed you about the need to ask the enzyme suppliers to prepare enzyme dossiers. With the current Information Letter we would like to provide some further advice and recommendation and share the final **Template for the Risk Management** part of the Enzyme dossiers (i.e. “*RM Template*”), which has been completed and reviewed by AMFEP.

#### 1. Contacting suppliers

EFA already circulated two different types of *supplier query letters* in the context of the establishment of the Union List of enzymes. The letters were developed for the EFA membership to contact their respective enzyme & ingredient suppliers and to make sure that the enzymes supplied (case a) and/or the enzymes contained in other purchased ingredients (case b) are identified and notified in due time. These letters were recirculated with the previous EFA IL 13/20.

EFA now recommends **pursuing the supplier outreach only** (case a) with the attached updated supplier query letter including the *RM Template* (see Enclosures 1 and 2) in order to prepare the subsequent steps for the identified materials. It is highly recommended to request your supplier to incorporate the relevant risk management aspects (cfr the *RM Template*) in their dossiers.

#### 2. Dossier preparation and submission

In the **EFA Information Letter 13/20** we explained the difference between the two scenarios for dossier preparation: “**joint dossiers**” versus “**individual dossiers**”.

The “**joint dossiers**” are taken care of by AMFEP Consortia (i.e., Active working groups for joint submissions) and EFA together with AMFEP is monitoring the actions. For an overview of **Active Working Groups for joint submission of Food Enzymes Dossiers** and the enzymes covered: see link below under point 5.

The “**individual dossiers**” have to be prepared and submitted by the suppliers and for enzymes used for the production of flavourings, it is the responsibility of the flavour manufacturers to outreach to their enzyme suppliers. Hence, follow-up action is required at B2B-level.

This Information Letter is thus specifically addressing the scenario of “individual dossiers”.

### 3. Risk management template (See [Enclosure 2](#))

The dossiers to be submitted by the enzymes producers consist of a **risk assessment** part which will be put together by the enzyme industry and a **risk management** section.

The framework for the **risk management section** has been written by AMFEP and discussed with the EU-Commission. Whilst some of it is common to many enzymes / sectors some sections require input by the users of the enzymes (e.g. flavouring manufacturers). The various user sector groups including EFFA have been contacted and asked to fill this risk management section in and a task force at EFFA has worked on this. The result of this work is the attached **RM Template** which has been reviewed by AMFEP and which can now be used by the suppliers as part of all Enzyme dossiers dealing with flavourings.

In the case of joint dossiers as described above (Scenario 1), the AMFEP working groups (consortia) will incorporate the template. For all other enzymes (not subject to joint dossiers) (Scenario 2) each flavouring manufacturer should send the template to its enzyme supplier and ask for it to be included in their dossier. Unless flavouring manufacturers are certain that their supplier is a member of a consortium covering the enzyme in question (from that particular source (micro-organism) as listed in the AMFEP list: see link below) they are recommended to send the template to all their suppliers.

### 4. Deadline for dossier submission

The **deadline** for dossier submission as set in the Enzyme regulation is **March 2015**; however, it is highly recommended to request your suppliers to start preparing and submitting the dossiers **as soon as possible**.

### 5. Legal implications and set-up of Positive List

At this stage it is far from certain how enzymes will be entered in the final positive list of Enzymes. Where single company submissions are made the entry may be specific but for joint dossiers it is still uncertain how this will be handled. It is also uncertain how specific the permitted applications will be but it is hoped that there will be generic entries such as baking rather than listing all uses – bread cakes cookies etc. For flavour use the generic wording “Flavour Production” has been proposed to refer to the application. The overview of **Active Working Groups for joint submission of Food Enzymes Dossiers** is available on the [Amfep website](http://www.amfep.org/content/active-working-groups-joint-submission-food-enzymes-dossiers) via the following link: <http://www.amfep.org/content/active-working-groups-joint-submission-food-enzymes-dossiers>

It should be noted that discussions between Amfep and the EU-Commission are still ongoing.

### 6. Update of EFFA survey on the use of enzymes

An **updated survey** with the complete list of enzymes, reported to be used by the EFFA membership, can be found in [Enclosure 3](#). This list has been shared with AMFEP and is also part of the *RM Template*.

### 7. Additional guidance documents

**Additional guidance documents** can be found under [Enclosures 4-6](#):

- [Encl 4: COM Practical guidance for applicants on the submission of applications \(FL/11/69-vs 5\)](#)
- [Encl 5: EFSA Scientific Opinion: Guidance of the CEF Panel on the submission of a dossier on food enzymes](#)
- [Encl 6: EFSA Technical Report for the Guidance of the CEF Panel on the submission of a dossier on food enzymes](#)

If you have further questions, please do not hesitate to contact EFFA at [info@effa.eu](mailto:info@effa.eu).