



## The European Commission published the Register of food enzymes to be considered for inclusion in the Union List

The food enzyme Regulation<sup>1</sup> stipulates that only food enzymes included in the future Union list may be placed on the market as such and used in food for technological needs during manufacturing and subsequent steps.

The first publication of the Union list will be based on the evaluation of the dossiers submitted before 11<sup>th</sup> March 2015. There is no formal deadline for this publication, and Amfep does not expect it to take place before 2023.

Pending this first Union List, the European Commission published the Register<sup>2</sup> of all applications considered valid according to the Regulation on a common authorization procedure<sup>3</sup> in June 2020.

For an application to be considered valid, the product must be in scope of the food enzyme regulation, and the dossier should contain all information and data required for the risk assessment and risk management of the food enzyme<sup>4</sup>.

The Register of food enzymes to be considered for inclusion in the Union List can be found [here](#).

The Register is not a list of authorized food enzymes.

Until the first publication of the Union List<sup>5</sup>, all food enzymes that comply with existing legislation at Member State level can be placed on the market and used in such Member States.

The Register contains the following information on each food enzyme:

- Commission ID number: reflecting the year of submission and subsequent submission number
- Enzyme nomenclature: IUBMB number and name, usual name (the one under which the enzyme is placed on the market).
- Production organism: the name of the microorganism, plant or animal source of the food enzyme is mentioned at the genus and species levels. When appropriate, the reference of the microorganism strain used to produce the enzyme is also mentioned.
- EFSA question number: each food enzyme dossier is assigned a reference by EFSA, for the purpose of transparency on the progress of the safety evaluation.

Amfep welcomes the publication of the Register. Further information can be found in our FAQ, as well as on the European Commission's web site.

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<sup>1</sup> Regulation (EC) 1332/2008.

<sup>2</sup> Pursuant to Art. 17.3 of above regulation.

<sup>3</sup> Regulation (EC) 1331/2008, Art. 9.

<sup>4</sup> Regulation (EU) 234/2011 implementing Regulation (EC) 1331/2008, art 8 and 9.

<sup>5</sup> Pursuant to Art. 24 of Regulation 1332/2008.

## FAQ

### **1. Is the Register the EU positive list of enzymes which are currently permitted within the EU?**

The Commission Register is not a positive list of currently permitted enzymes. It is the list of food enzymes for which a dossier was submitted to the Commission by March 2015, and was declared valid following the validity criteria laid down in Article 12 of Regulation (EC) N°234/2011. These dossiers are being assessed by EFSA and the Member States for future inclusion in the Union List. Also see 3. below.

### **2. What is the difference between the list of submitted dossiers and the Register?**

The list of submitted dossiers, published on July, 25<sup>th</sup> 2016 by the European Commission, contains all the dossiers which have been submitted to the Commission before the deadline of 11 March 2015. As explained above, the Register contains only food enzymes whose dossiers have been declared valid according to the criteria laid down in Article 12 of Regulation (EC) N°234/2011 and that will subsequently undergo the EFSA and Member States evaluation.

### **3. What is the Union list ?**

The Union List of food enzymes is a list of food enzymes that have been authorised to be placed on the EU market and will be adopted by the EU Commission and the Member states. It will list all food enzymes for which EFSA has issued a positive opinion (according to the requirements in Art. 6a of Regulation 1332/2008), and the Commission and Member States have concluded that they comply with the requirements in Art. 6b and 6c of Regulation 1332/2008. These evaluations are conducted on each food enzyme included in the Register in accordance with the procedure laid down in article 3 of regulation (EC) N°1331/2008.

A valid application qualifies for EFSA and Member States evaluation but it does not automatically mean that the evaluation will lead to an entry in the future Union List

### **4. Will all the enzymes that are listed on the Register be included in the Union list?** (see previous question)

### **5. Why is the enzyme my company uses not on the Register? Can my company still use an enzyme which is not listed in the Register?**

There can be various reasons why an enzyme is not on the Register.

- A food enzyme dossier has been submitted to the Commission by the deadline of March 2015, but the data contained in the dossier did not comply with the validity criteria of the Regulation (EU) N°234/2011 which would enable EFSA to conduct a valuable scientific assessment. In this case the enzyme can be placed on the market at national level according to local rules (cf. article 24 of Regulation (EC) N°1332/2008)
- A food enzyme dossier may not have been submitted to the Commission. In this case the enzyme can be placed on the market at national level according to local rules (cf. article 24 of Regulation (EC) N°1332/2008).
- It is a new enzyme developed by the enzyme industry after the deadline for dossiers submission (March 2015): being a new enzyme, it is not listed in the Register. In this

case the enzyme can be placed on the market at national level according to local rules (cf. article 24 of Regulation (EC) N°1332/2008).

**6. Why does the Register not specify the food applications in which the enzyme is intended to be approved?**

According to the EFSA guidelines<sup>6</sup> the submitted dossiers describe the specific applications in which the enzyme is specifically intended to be used. However, as described processes were not always named in a consistent way it was agreed that pending the publication of the Union list the detailed applications will not be specifically mentioned in the Register, but only at the time when the Union list will be published.

**7. Does this mean that enzymes can be used in any application pending the publication of the Union list?**

Food enzymes which are or are not listed in the Register can still legally be marketed within the EU, in accordance with existing EU and national provisions, until the publication of the Union List (article 24 of Regulation N°1332/2008). So far, only France and Denmark (and Spain to some extent) have a national regulatory framework for enzymes which rely on application specific approvals.

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<sup>6</sup> <https://www.efsa.europa.eu/en/efsajournal/pub/4581>