



Technical meeting on applications for food enzymes

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EFSA info session, 24-25 October 2024

Establishment of the Union List of Food Enzymes “Article 17”

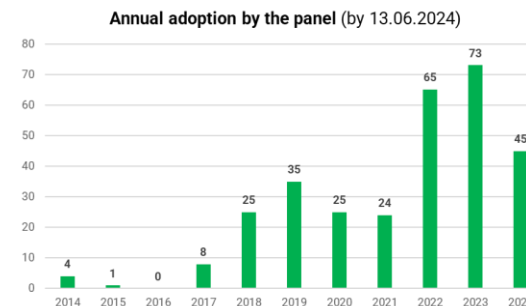
Article 17 of the Regulation (EC) No 1332/2008 lays down rules for the establishment of the Union list of food enzymes in one single step

- There is currently **no Union list** of authorized food enzymes, it will be established once the evaluations are finalized.
- **Union list** shall be drawn up on the basis of **applications submitted within the deadline**. - This period started on 11 September 2011 and finished on 11 March 2015.
- Risk assessments of EFSA for individual enzymes is published as soon as they are completed.
- **COM has established a Register** of all Food Enzymes to be considered for inclusion in the Union list and for which applications have been submitted.

Relevant link:

https://food.ec.europa.eu/system/files/2020-06/fs_food-improvement-agents_enzymes_register.pdf

Progress in the safety assessment



FE applications in the Register

Number of valid applications	282
Number of dossier (with JD packages)	373
Withdrawn	33
Negative	11
Inconclusive	15
Positive	217
Total	243
Remaining (61 from JD)	97

New FE Applications (pre and post TR)		Old and New Mid Oct-24
Number of dossiers (111 Post TR) (including 46 extension of use)	185	558
Suitability check	25	
Non valid/terminated	5	
Withdrawn	11	44
Negative	3	14
Inconclusive	3	14
Positive	53	270
Remaining	85	182

General conditions for inclusion and use of food enzymes in the Union list “Article 6”

A food enzyme may be **included in the Union list** only if it meets the following conditions and, where relevant, other legitimate factors:

- (a) it does not, on the basis of the scientific evidence available, pose a safety concern to the health of the consumer at the level of use proposed;
- (b) there is a reasonable technological need, and
- (c) its use does not mislead the consumer.

The information to be included in the opinion of EFSA is specified in **Article 13 of Regulation (EC) No 234/2011**

Establishment of the Union List of Food Enzymes

“Article 7”

Article 7 of Regulation (EC) No 1332/2008 lays down that the entry of a food enzyme in the Union list shall specify: (a) the name; (b) the specifications; (c) the foods to which the food enzyme may be added; (d) the conditions under which the food enzyme may be used;

- Until the date of application of the Union list, without prejudice to other applicable Union legislation, including Regulation (EC) No 178/2002, **national provisions in force** on food enzymes **shall continue to apply** in the Member States.

VERSION 7
DOES NOT NECESSARILY REPRESENT THE
OFFICIAL VIEWS OF THE COMMISSION

January 2023



This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission. The circumstances be regarded as stating an official position. The information transmitted is intended only for the Member State or for the discussions and may contain confidential and/or privileged information.

**Working document describing the
 which food enzymes are intended**

*The EC working document describing the food processes **is not a legally binding document***

*Version 7 has been aligned with the **categorisation of food manufacturing processes developed by EFSA for the safety assessment of food enzymes***

IMPORTANT DISCLAIMER

The descriptions of the food processes in this working document are based on the information provided by the applicants for the evaluation of food enzyme by EFSA and the drafting of the document may be reviewed in the future, taking into account the views of experts, the Commission and stakeholders.

The indication of the use of certain enzymes under the proposed food processes reflects uses proposed by the applicants and under no circumstances may it be considered as an authorization.

The working document should be read in conjunction with the appropriate legislation, especially Regulation (EC) No 1332/2008 on food enzymes which constitutes the legal basis for the placing on the market and use of food enzymes in the EU.

This working document does not represent the official position of the Commission and is not intended to produce legally binding effects. Only the European Court of Justice has jurisdiction

Other EU specific legislation describing the use of enzymes in food production

Although the Union list of enzymes is not established yet, there are some EU legal acts where the **use of enzymes is described**:

- Directive on **fruit juices** (Directive 2001/112/EC): allows the use of **pectinases, proteinases and amylases**.
- Regulation on **wine** (Regulation (EU) No 2019/934) allows the use of **urease, pectin lyases, pectin methylesterase, polygalacturonase, hemicelluase, cellulase, betaglucanase and glycosidase**.
- In the **production of organic food** (Regulation (EC) No 889/2008) preparations of micro-organisms and enzymes normally used in food processing can be used.

Example of the content of the Union List of Food Enzymes

(1) Union list number	(2) Name of the food enzyme (IUBMB name)	(3) Specifications of the food enzyme	(4) Foods/Food processing	(5) Conditions of use	(6) Restrictions on the sale of the food enzyme directly to the final consumer	(7) Specific requirements in respect of the labelling of food in which the food enzyme has been used
1	Endo-1,4- β -xylanase n°1	IUBMB No: EC 3.2.1.8 Source: A genetically modified strain of <i>Aspergillus oryzae</i> Strain: NZYM-FB	Starch processing ; Beverage alcohol processes ; Brewing processes ; Other cereal based beverage processes ; Baking processes ; Cereal based processes			
9	Beta-amylase n°4	<u>IUBMB No:</u> EC 3.2.1.2 <u>Source:</u> Soybean (<i>Glycine max</i>)	Maltose syrup production ; Manufacture of a Japanese rice cake type			The food enzyme is derived from a known allergen listed in annex II to Regulation (EU) No 1169/2011. The food enzyme should be indicated in the list ingredients of Japanese rice cake in accordance with the rules laid down in that regulation.

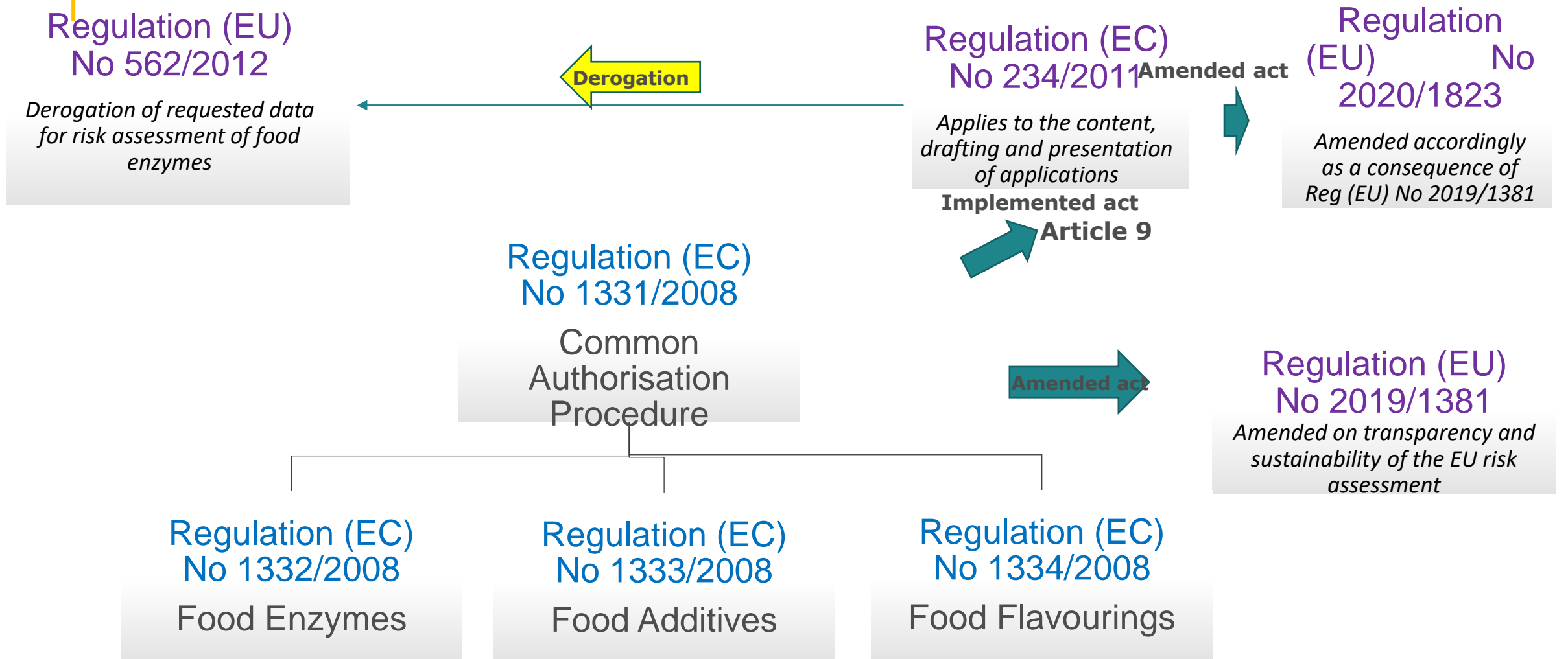
Labelling

- Food enzymes shall not be required to be included in the list of ingredients (Art.20 of Reg 1169/2011):
 - (i) in case of carry-over referred to in point (b) of Article 18(1) of Regulation (EC) No 1333/2008, provided that they serve no technological function in the finished product; or
 - (ii) when they are used as processing aids.
- Otherwise: Food enzymes must be designated in the list of ingredients by the name of their technological category, followed by their specific name (Annex VII, Part C of Reg. 1169/2011)

Relevant link:

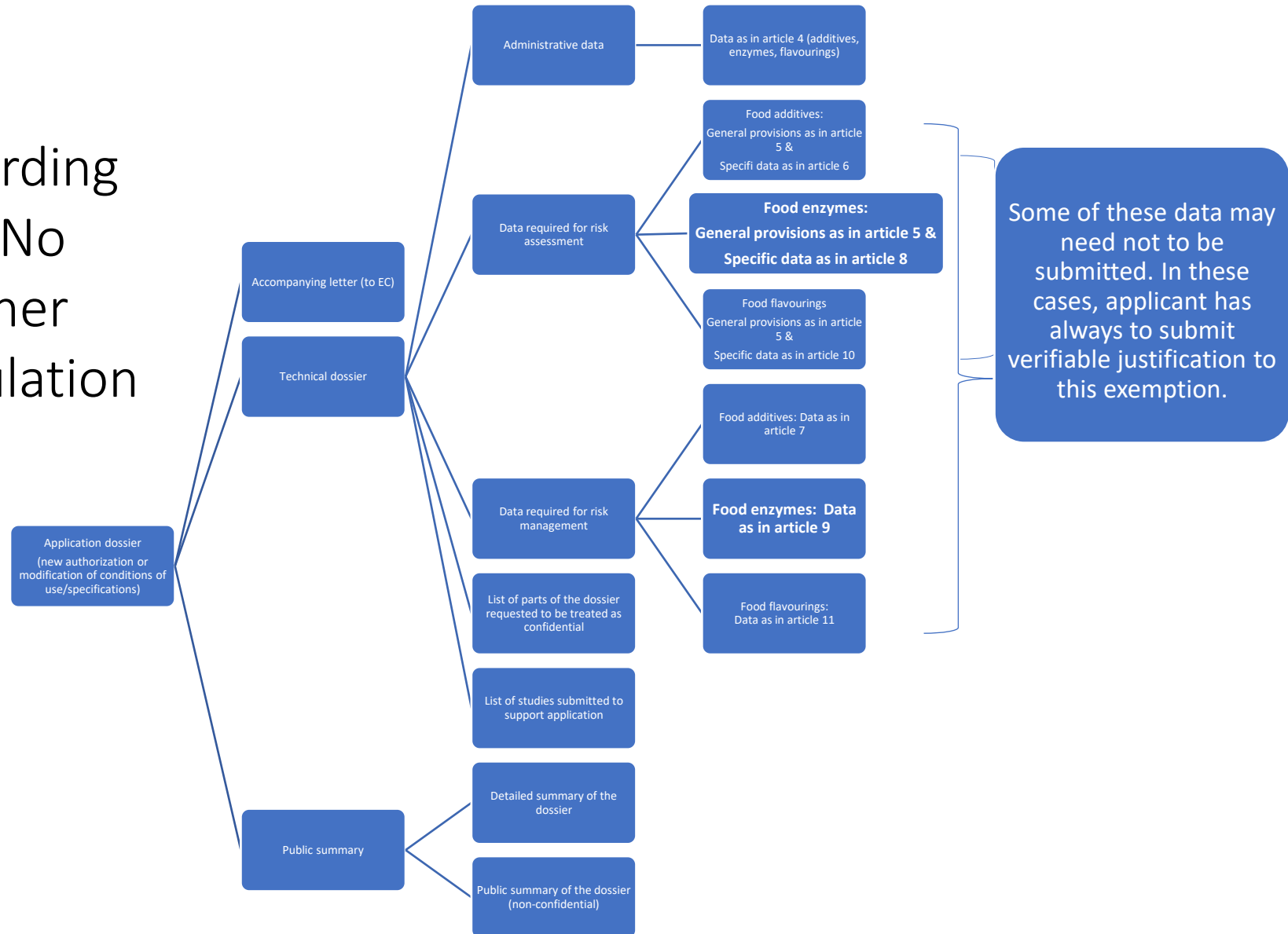
- https://ec.europa.eu/food/sites/food/files/safety/docs/fs_food-improvement-agents_enzymes-guidance-categorisation.pdf

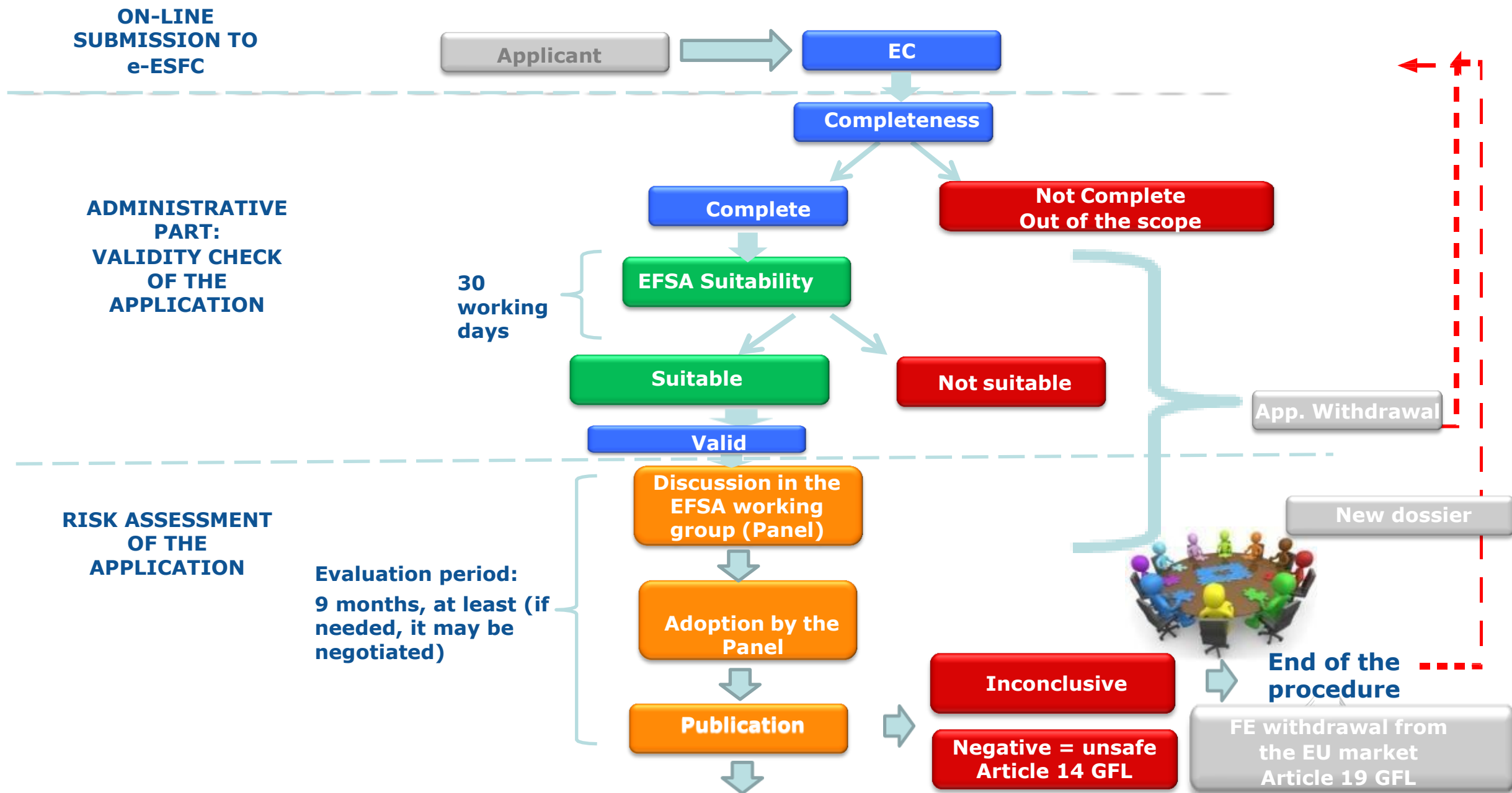
Common Authorisation Procedure



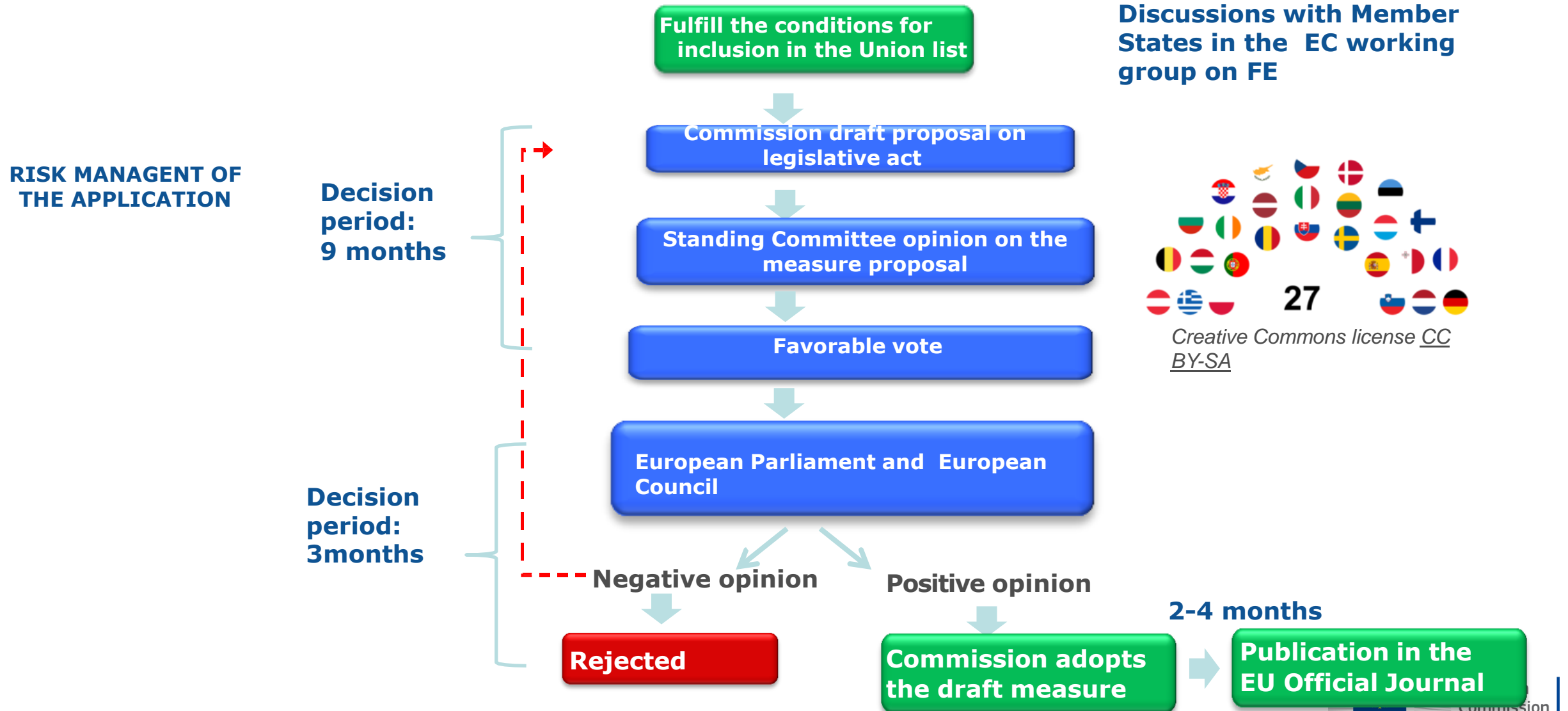
Regulation (EU) No 234/2011

General data requirements according to Regulation (EC) No 1331/2008 as further elaborated in Regulation (EU) No 234/2011





Workflow applications according to Regulations (EC) No 1331/2008 & (EU) No 234/2011 Comitology procedure



New submission - Follow up of inconclusive and negative opinions

- A new application should be submitted for the authorisation of the food enzyme under Regulation (EC) N°1332/2008
 - Reference to the initial application may be added when data are still relevant for the new enzyme
 - No need to include these data again
 - A justification should be provided why these data are still relevant

Updated administrative guidance published in July 2023: <https://www.efsa.europa.eu/en/supporting/pub/en-6509>

- Submission of partial data as a follow up of a positive opinion
 - Additional data do not form an application: CIRCA SANTE-CAD-IN Group is the relevant tool to provide these data to EC

For further instructions: https://food.ec.europa.eu/safety/food-improvement-agents/common-authorisation-procedure_en



Thank you



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