



# EFSA's risk assessment methodology for the evaluation of food enzymes - Structure of EFSA opinions

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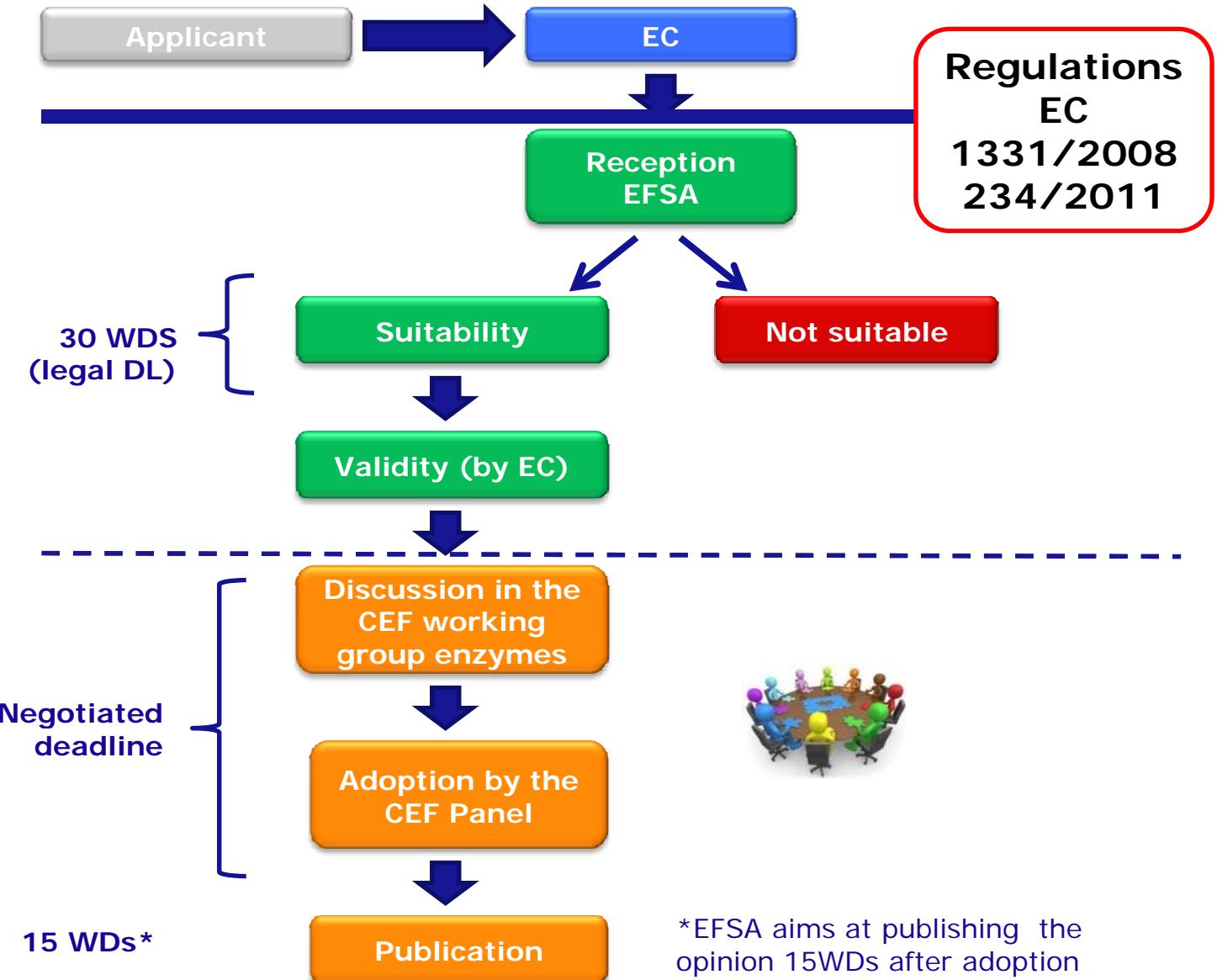
## This presentation will deal with

- EFSA's application workflow and risk assessment for food enzymes
- The elements of an opinion
- The conclusion of an opinion





## FOOD ENZYMES – WORKFLOW APPLICATIONS



FIP



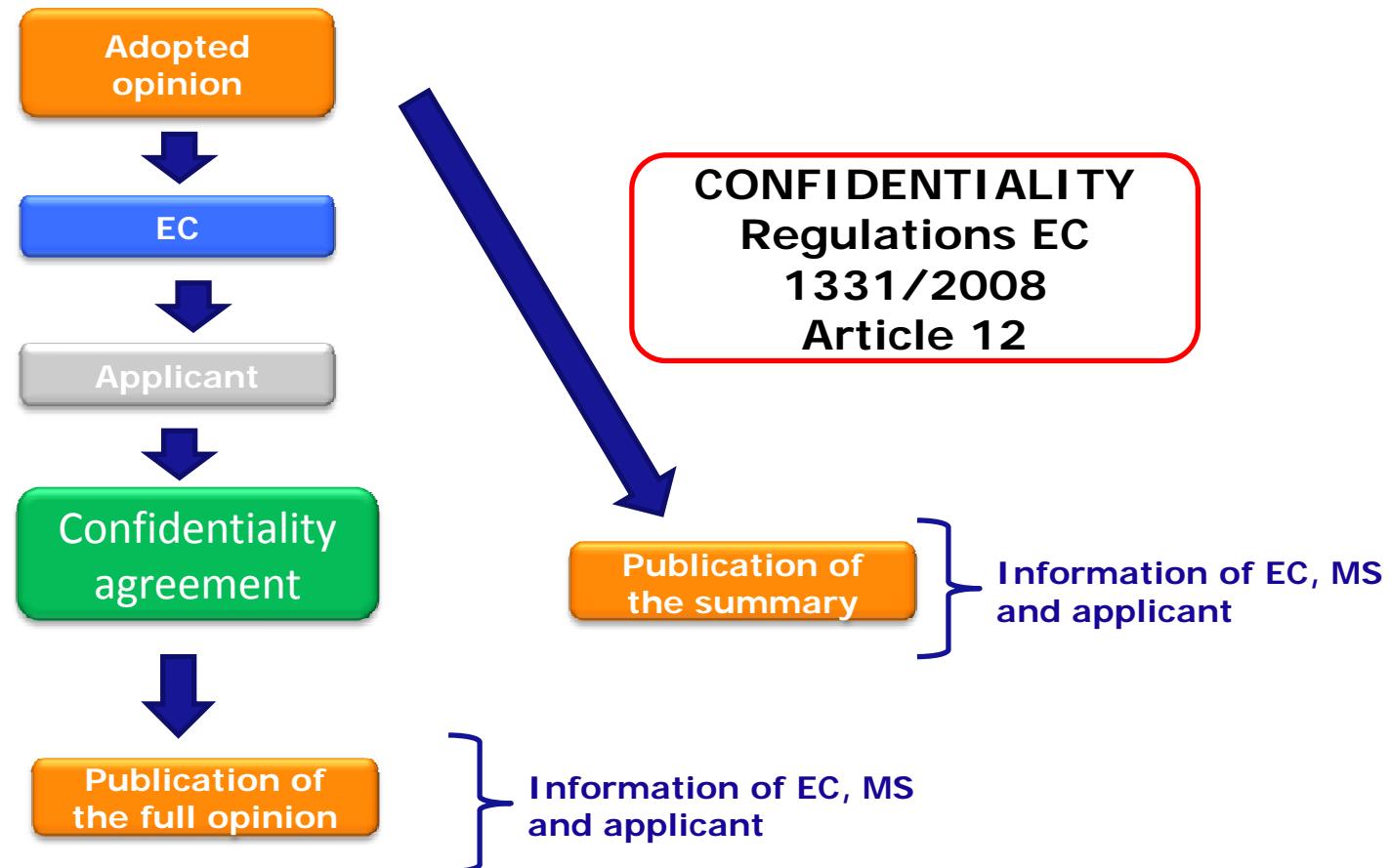


## FIRST OPINION ON FOOD ENZYMES

- The CEF Panel has adopted its first opinion on a food enzyme on the 22 April
- During the 47th CEF Plenary meeting 2 more opinions were discussed and prepared for adoption by written procedure
- The summary of the first opinion has been published in the EFSA journal on 14 May:  
<http://www.efsa.europa.eu/en/efsajournal/pub/3645.htm>



## FOOD ENZYMES – PUBLICATION OF AN OPINION





## EFSA JOURNAL

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### Scientific Opinion on xylanase from a genetically modified strain of *Aspergillus oryzae* (strain NZYM-FB)

EFSA Journal 2014;12(5):3645 [2 pp.] doi:10.2903/j.efsa.2014.3645

EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF)



**Note:** The full opinion will be published in accordance with article 11 of Regulation (EC) No 1331/2009 once the decision on confidentiality, in line with article 12(3) of the Regulation, will be received from the European Commission





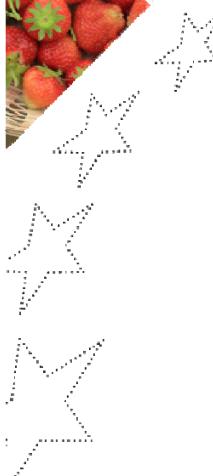
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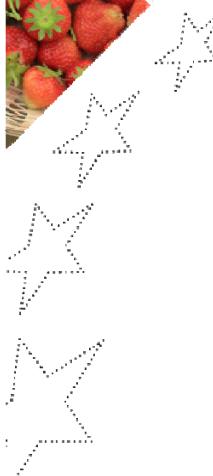
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# DATA REQUIREMENTS FROM CEF GUIDANCE

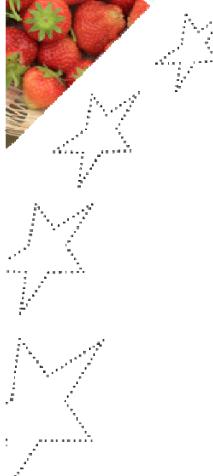
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## Conclusion of an opinion are...

- ...Based on information on
  - the genetic modifications performed,
  - the manufacturing process,
  - the compositional and biochemical data provided and
  - the findings in the toxicological studies,
- the food enzyme "XXX from a genetically modified strain of YYY (strain ZZZ)" does not raise safety concerns
  - under the intended conditions of use.





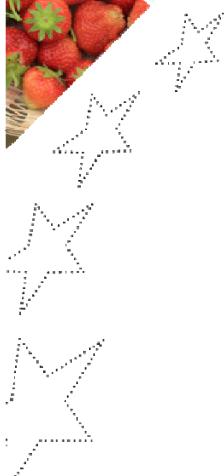
## MARGIN OF EXPOSURE (MOE)

$$\text{MOE} = \text{NOAEL} / \text{TDI}$$



No Observed Adverse Effect Level from the 90-day study as agreed by the CEF Panel

Theoretical Maximum Daily Intake





## CEF GUIDANCE DOCUMENT

A conservative technique such as the “budget method” should be used to assess potential dietary exposure in a standard adult of 60 kg body weight consuming large amounts of the categories of foods and beverages for which use levels have been proposed, assuming that they always contain the food enzyme at its proposed upper use level.



## INFORMATION NEEDED FOR THE BUDGET METHOD

- The level of consumption of foods and of non-milk beverages
- The level of presence of the food enzyme in foods and in non-milk beverages (expressed on TOS basis)
- The proportion of foods and of non-milk beverages that may contain the food enzyme





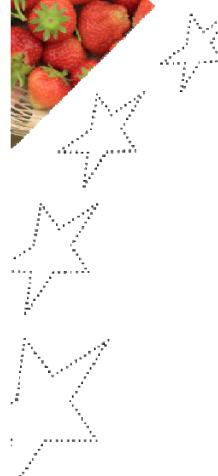
## THE BUDGET METHOD

### Pros

- + Easy to perform
- + No specific food and beverage consumption data needed
- + Based on the assumptions, it can be very conservative

### Cons

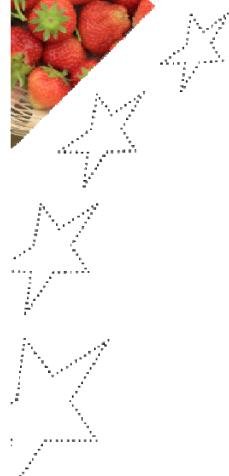
- Assumptions made for use made by expert judgement
- Only adults are considered, a standard version for children does not exist
- Based on the assumptions, it can be very conservative





## NEED FOR REFINEMENT

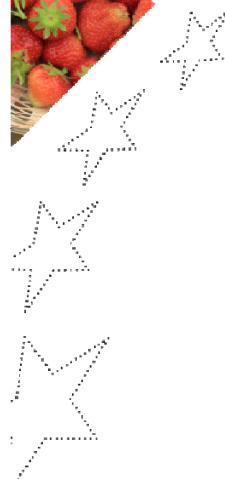
“A more refined exposure assessment should be performed if the use calculated according to the method described in the FAO/WHO report (s. also “Budget Method”) indicates potential concern with high consumers.”

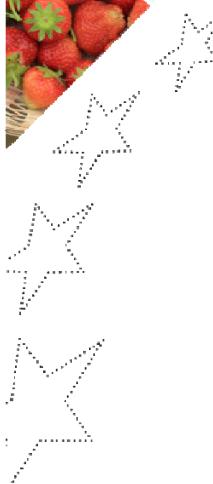




## NEED FOR REFINEMENT

“All assumptions and data used for the dietary exposure assessment should be clearly described and justified.”





■ Thank you for your interest!