Association of Manufacturers and Formulators of Enzyme Products

Submission

Proposal P1025 – Code Revision

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The present submission is authorised by the Amfep Executive Committee

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Background

Amfep – the European Association of Manufacturers and Formulators of Enzyme Products – submits this document as a response to the call for submissions on Proposal P1025 published by FSANZ on 10 July 2014.

Amfep appreciates the opportunity to comment on P1025 and in particular on the draft Food Standards Code — Standard 1.5.2, section 4 Requirement to label food as 'genetically modified'. For the definition of 'novel protein' described in this section, Amfep respectfully requests FSANZ to change it to what is described in Amfep's request below.

Amfep request and justification

Amfep requests that the definition of 'novel protein' described in section 4 (6) of draft Standard 1.5.2 be changed to read:

> *"**novel protein** means a protein encoded from novel DNA, except where the protein:*
> *(a) is used as a processing aid or used as a food additive; and*
> *(b) has an amino acid sequence that is within the variation found in nature."*

This is justifiable because the change in amino acid sequence in connection with protein engineering in order to optimize enzymes for their industrial use is typically considerably lower or, at least, within the same range compared to the variation found in nature. From the wealth of DNA and protein sequences in public databases, it is known that such sequence variation is a fundamental phenomenon in nature; at the same time, the sequence variation already known from databases likely underestimates the true natural variability, because only a fraction of nature's diversity has been characterized thus far.

Enzymes are proteins with catalytic activity and they exist in all living matter. While the enzymatic activity is classified according to the Nomenclature Committee of the International Union of Biochemistry and Molecular Biology (IUBMB), it is important to note that each enzyme activity can be found in many different organisms with a wide variety in amino acid sequence and still exerting the same enzymatic activity.

Therefore, as a result of the diversity of living organisms caused by adaptations to their environment, an enzyme's protein sequence can vary widely in nature. Whilst enzymes with different protein sequence can still exert the same enzymatic activity, such differences in sequence may have an influence on other physico-chemical properties of the enzyme, such as temperature and pH stability.

For certain applications it may be optimal to have an enzyme with specific physico-chemical properties; to obtain such an enzyme, several techniques could be used:

a) screen (endlessly) in nature for an organism which makes an enzyme with the desired properties
b) conduct classical mutation rounds of an organism until selection allows isolation of a mutant producing the wanted enzyme
c) use post-translational modification to optimize the characteristics of the enzyme; however, this is not always feasible
d) modify the amino acid sequence of an existing enzyme via genetic modification of the coding DNA, known as protein engineering

Regardless of the technique used, the resulting enzyme protein sequence (and structure) may turn out to be the same, and thus should not be classified as 'novel protein' *per se*.

We acknowledge that the next step needs to be to reach a common understanding of what is to be considered "within the variation found in nature". Different concepts are conceivable to come to a practicable, straightforward and operational handling that both:

- establishes regulatory criteria for 'novel' proteins; and
- provides an impetus for industry to apply protein engineering to come up with superior technical solutions for established activities and applications.

We, as Amfep, would appreciate continuing the dialogue with FSANZ, with the aim to set up such mutually agreed criteria.

On behalf of the Amfep Executive Committee,

Pia Skaerbak – Amfep Secretary General