ACNFP
THE ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

ACNFP guidelines for the presentation of data to demonstrate substantial equivalence between a novel food or food ingredient and an existing counterpart

Introduction

Regulation (EC) No 258/97 on novel foods and novel food ingredients provides a simplified route for manufacturers to bring certain novel products to the market, by making a notification in accordance with Article 5.

This procedure applies only to:

- foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae; and

- foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals (except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use)

and the product in question must be shown to be “substantially equivalent” to an existing food or food ingredient as regards:[1]

- its composition,

- its nutritional value,

- its metabolism,

- its intended use and

- the level of undesirable substances.

In practice each notification requires a suitable opinion from a competent authority in one of the member states that confirms that the product meets these criteria. The competent authority in the UK is the Food Standards Agency, which draws on the expert advice of the ACNFP.

This document provides guidance on the data that should be submitted when a request for such an opinion is submitted for consideration by the ACNFP.

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[1] Article 3(4) of regulation 258/97.

Contents of the application dossier

The dossier should contain basic administrative information, data addressing each of the 5 criteria mentioned above and any other relevant information on the novel product.

(a) *administrative information*

Name of the applicant; contact information (postal and email addresses, telephone and fax); name of the novel food or food ingredient; date of the application.

(b) *composition*

The application should contain a specification of the novel product, including information on the source organism, methods used for preparation of the novel product, the composition of the final product and maximum limits for the presence of known or potential contaminants. Comparisons should be drawn with only one existing product, which should be described in the same level of detail. Compositional analyses should be reported for a number of representative batches of each product and the results should be analysed by appropriate statistical methods, including information on the power of the study. The ACNFP Secretariat can advise on the range of analyses that should be carried out for each specific product.

If the applicant is not the manufacturer of the novel product, the application should indicate the intended supplier(s).

The novel and existing products should be derived from the same or very similar species, grown and harvested under similar conditions. This requirement may be relaxed if the products are refined extracts that contain only a limited number of defined chemical components.

The novel product should not contain significant levels of substances that are not present in the existing counterpart – the presence of such substances requires a fuller evaluation that is not compatible with the simplified procedure.

(c) *nutritional value*

(d) *metabolism*

If the composition of the product does not differ from its existing counterpart, it is unlikely that there will be significant differences in its nutritional value or metabolism. Nevertheless, the application should consider this possibility and provide results of any relevant studies. These might include the results of stability tests to show that the novel product does not degenerate during storage or use, or bioavailability studies.

(e) *intended use*

The application should describe the uses of the existing product and explain which of those are relevant to the novel product. This may include use in food supplements, use as a food, and use as a food ingredient in a list of specified food categories. The levels of use should be specified.

Where the application covers use in food supplements, it should include information on the recommended dosage of the new and existing products.

In general applications cannot include new uses, particularly if they are likely to result in consumption of the product by a wider range of the population or at higher levels, compared with the existing product. In particular, the novel product cannot be assessed as “substantially equivalent” if it is intended for use as an ingredient in foods and the existing counterpart is only consumed in the form of food supplements.

(f) *level of undesirable substances*

The application should consider the potential presence of undesirable substances, such as environmental contaminants, mycotoxins, allergens, naturally occurring toxins and anti-nutrients, and undesirable microorganisms. Evidence should be provided that the levels of these substances are comparable between the new and existing products. Analytical data that are provided should be for a number of representative batches of the new and existing products.

The applicant should undertake a detailed literature search to identify any undesirable substances that could be associated with the novel product and its source and, where necessary, should provide analytical data to show that such substances are not present.

The new product should obviously comply with existing EU legislation on contaminants, pesticides etc.

(g) *other relevant data*

The application should also include any other relevant data on the novel product, including the reports of any safety studies that have been conducted on it.

It should also include a proposal for labelling, to demonstrate that consumers will be adequately informed of the nature of the novel ingredient, its intended use and any restrictions that may need to be respected.

The application should include details of any monitoring that will be undertaken to provide ongoing assurance that the product is of appropriate quality with regard to its composition and the presence of undesirable substances.

These guidelines have been developed by the Committee based on its experience with the range of products that have been assessed under this procedure. The document will be revised from time to time in response to any comments from interested parties or to take account of new information and further experience gained under the procedure.

The Committee welcomes comments and suggestions, which can be sent to:

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