COUNCIL DIRECTIVE
of 18 April 1983
on the fixing of guidelines for the assessment of certain products used in animal nutrition

(83/228/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition (1), and in particular Article 7 thereof,

Having regard to the proposal from the Commission,

Whereas Directive 82/471/EEC provides that the products belonging to certain groups must be examined on the basis of a dossier forwarded officially to the Member States and the Commission;

Whereas such dossiers must make it possible to verify that the products in question comply with the general principles laid down in the Directive in respect of the inclusion of new products in the Annex;

Whereas it has been found necessary to provide for the dossiers to be compiled in accordance with common guidelines defining, for each principle, the scientific data which make it possible to identify and characterize the products concerned and the studies necessary in order to evaluate their nutritional properties and biological effects; whereas these guidelines must be applicable on the date on which Directive 82/471/EEC itself enters into force;

Whereas the guidelines are intended primarily as a general guide; whereas, depending on the nature of the product or its conditions of use, the extent of the studies necessary in order to evaluate its properties or its effects may vary;

Whereas the guidelines have been drawn up on the basis of present scientific and technical knowledge and they may be adapted if necessary to any developments in this sphere,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Member States shall prescribe that the dossiers on the products listed in points 1.1 and 1.2 of the Annex to Directive 82/471/EEC are to be compiled in accordance with the guidelines set out in the Annex hereto.

Article 2

Member States shall bring into force the laws, regulations or administrative provisions necessary in order to comply with this Directive by 13 July 1984 at the latest. They shall forthwith inform the Commission thereof.

Article 3

This Directive is addressed to the Member States.

Done at Luxembourg, 18 April 1983.

For the Council

The President

I. KIECHLE

(1) OJ No L 213, 21. 7. 1982, p. 8.

ANNEX

GUIDELINES FOR THE ASSESSMENT OF CERTAIN PRODUCTS USED IN ANIMAL NUTRITION

General aspects

These 'guidelines' constitute a guide intended to establish dossiers on products listed in items 1.1 and 1.2 of the Annex to Directive 82/471/EEC, which have been obtained from culturing micro-organisms and which are likely to be admitted as a new source of proteins in animal nutrition. These dossiers should enable an assessment of such products based on the present state of knowledge and should ensure their compliance with the fundamental principles laid down for permitting their use, which are the subject of Article 6 (2) of the abovementioned Directive.

All the studies outlined in this document may be required and, if necessary, additional information may be requested. As a general rule, all the information necessary to establish the identity of the micro-organism and the composition of the culture medium, and also the manufacturing process, characteristics, presentation, conditions of use, methods of determination and nutritional properties of the product must be provided. The same applies to the information necessary to assess the tolerance of the product by the target species and the risks for man and the environment, which could result directly or indirectly from the use of the product. The toxicological studies required for this purpose will depend on the nature of the product, the animal species concerned and the metabolism of the product in laboratory animals.

The documentation to be provided should include detailed reports, presented in the order and with the numbering proposed in these guidelines and should be accompanied by a summary. The omission of any proposed studies should be justified. The publications quoted as references should be attached.

Observations

The term 'product', as used in these guidelines, refers to any proteinaceous product in the state in which it will be presented as feedingstuff or component of a feedingstuff.

Any modification in the manufacturing process or in the conditions of use of a product will require notification and, if necessary, additional documentation for a new assessment.

Presentation of studies

I. Micro-organism, culture medium and manufacturing process, characteristics of product, presentation and conditions of use, methods of determination

II. Studies on the nutritional properties of the product

III. Studies on the biological consequences of the use of the product in animal nutrition

IV. Other relevant studies

SECTION I

MICRO-ORGANISM CULTURE MEDIUM AND MANUFACTURING PROCESS, CHARACTERISTICS OF PRODUCT, PRESENTATION AND CONDITIONS OF USE, METHODS OF DETERMINATION

1. MICRO-ORGANISM

1.1. Classification, provenance, morphology, biological properties, any genetic manipulation.

1.2. Innocuity, possible survival outside the fermenter and any environmental consequences.

1.3. Constancy and purity of strains cultivated. Methods used to check these criteria.

2. CULTURE MEDIUM AND MANUFACTURING PROCESS

2.1. Composition of substrate, added substances, etc.

2.2. Manufacturing, dessication and purification processes. Devitalizing process for micro-organisms. Methods used to check the constancy of composition of the culture product and the detection of any chemical, physical and biological contamination during production.

2.3. Technical processes of preparation for use.