Coagulated potato protein and -hydrolysates

Gecoaguleerd aardappeleiwit en -hydrolysaten

Assessment of safety for the consumer, in accordance with European Regulation 258/97 concerning novel foods and novel food ingredients

Beoordeling van de veiligheid voor de consument, volgens de Europese verordenig 258/97 betreffende nieuwe voedingsmiddelen en nieuwe voedselingrediënten

Letter to the Dutch Minister of Health, Welfare and Sport

On July 20, 2000, professor JGAJ Hautvast, Vice-president of the Health Council of the Netherlands wrote as follows to the Minister of Health, Welfare and Sport:

Herewith I present you an advisory report that is prepared in response to your request, also on behalf of the State Secretary for Agriculture, Nature Management and Fisheries regarding the safety of coagulated potato protein and hydrolysates thereof for the consumer. This advice is a so called first assessment in the context of European Regulation (EC) 258/97, concerning novel foods and novel food ingredients. The assessment is carried out by the Committee on the Safety assessment of novel foods of the Health Council of the Netherlands.

This advisory report is also presented to the State Secretary for Agriculture, Nature management and Fisheries.

signed
professor JGAJ Hautvast

Coagulated potato protein and -hydrolysates

Assessment of safety for the consumer, in accordance with European Regulation 258/97 concerning novel foods and novel food ingredients

Health Council of the Netherlands:
Committee on the Safety assessment of novel foods

to:

the Minister of Health, Welfare and Sport

the State Secretary for Agriculture, Nature management and Fisheries

No. 2000/04VNV, The Hague, July 20, 2000

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Executive summary, conclusions and recommendations

AVEBE has compiled a file in which two novel food ingredients are described, coagulated potato protein and hydrolysates thereof. The file contains chemical analyses as well as nutritional, microbiological and toxicological information. The applicant describes the nutritional value of the novel food ingredients based on their composition. Microbiological analyses show several micro-organisms originating from the soil that remains on the potatoes after harvesting. The applicant bases the toxicological safety of the novel food ingredients on the safety of cooked potatoes for the consumer. In describing the toxicological safety, the applicant pays particular attention to the naturally occurring toxins in potatoes, the glycoalkaloids.

The Committee is of the opinion that, their composition having been considered, the novel food ingredients are of a good quality. The micro-organisms which have been detected on the novel food ingredients give no cause for concern, given the stringent conditions under which the production process occurs.

The Committee believes that coagulated potato protein and the hydrolysates thereof are safe for consumption, provided that the novel food ingredients are not made available for direct consumption but are instead supplied to the food industry as a semi-processed product. The applicant must adequately inform the buyers about the sulphite level in the novel food ingredients so that the final product meet with the standards set for sulphite in the Commodities Act Decree on Food Additives. Furthermore, the Committee finds it advisable to incorporate the potato protein in the Commodities Act Decree on Protein Products.

Chapter 1

Introduction

In November 1999, the Minister of Health, Welfare and Sport requested the opinion of the Committee on the Safety assessment of novel foods, hereafter referred to as the Committee, regarding the safety of coagulated potato protein and hydrolysates thereof for the consumer. The file compiled by AVEBE, the producer and applicant for market introduction, was first considered by the Committee in March 2000.

The potato protein and the hydrolysates are produced by subjecting the potatoes to heat and enzymatic action. Initially the applicant submitted a notification request. The Committee did not concur with this viewpoint and accordingly contacted the applicant. The Committee decided to treat the application as an authorization request. The assessment was completed in July 2000. This report presents the Committee's findings.

After that the producer did apply for an authorisation on the European level.

Chapter **2**

Completeness and correctness of the file

2.1 Administrative data

Name and address of the applicant and producer of the novel food ingredients: AVEBE b.a., Prins Hendrikplein 20, 9641 GK Veendam, the Netherlands.

2.2 General description of the food

The application concerns the marketing and trading on the European market of coagulated potato protein and hydrolysates thereof.

The producer seeks the opinion of the competent Dutch authority regarding the substantial equivalence of the new food ingredients and the potato protein from cooked potatoes. In case of substantial equivalence these products may, with notification, be introduced directly to the market in accordance with Article 5 of Regulation (EC) 258/97 (EC97).

In applying the principle of substantial equivalence, there must be an existing food product that can be used as a traditional counterpart to facilitate the safety assessment of the novel food. The Committee is of the opinion that the protein from (cooked) potatoes is not the correct counterpart to the coagulated potato protein and the hydrolysates thereof, given that the two foodstuffs are not comparable with respect to composition, nutritional value, intended use and levels of anti-nutritional factors. Therefore, the principle of substantial equivalence is not applicable to this file and the Committee accordingly considers the application as an authorization request and not a notification.

2.3 Classification of the food for assessment

The file contains arguments for classification in class 2.1, one of the six main classes and sub classes of novel foods as referred to in table 1, part I of the Recommendation 97/618 of the European Commission (EC97a). This concerns a potato protein that is not derived from a genetically modified source. The source of the protein is the conventional potato, which has a history of safe use in the European Union.

The Committee concurs with this classification*.

2.4 Information about the food

The applicant specifies the information that is essential for a safety assessment of food ingredients in class 2.1 for consumption in accordance with the selection of flow charts as prescribed in the Commission Recommendation (97/618/EC).

I Specification of the novel food (NF)
II Effects of the production process applied to the NF
III History of the organism used as a source of the NF
IX Anticipated intake and extent of use of the NF
X Information from previous human exposure to the NF or its source
XI Information on the nutritional value of the NF
XII Microbiological information on the NF
XIII Toxicological information on the NF

For every subject, the applicant clearly follows each step in the flow chart and refers to the appendices or the literature for the data used. The literature referred to was supplied by the applicant.

2.5 Brief summary from the applicant

Initially the applicant has not sent a summary to the EU Member States as an notification request does not require this. Given that the Committee views the application as an authorization request, a brief summary will need to be sent, as required in accordance with Article 6(2) of Regulation (EC) 258/97.

* The novel food ingredients could also be classified in class 6. The production process is already applied to other proteins, such as soya protein, but has not been used before in the production of potato proteins and hydrolysates thereof. However, there is no difference in the selection of flow charts that need to be described for the specification of the novel food ingredients, whether the ingredients are classified in class 2.1 of class 6.

2.6 Other assessments

The food ingredients are solely assessed within the framework provided by the European Regulation for Novel Foods (258/97/EC).

2.7 Labelling proposal from the applicant

The applicant proposes to list the novel food ingredients on the packaging of the final product in which they have been used. Labelling should comply with Directive 79/112/EEC and Article 8 of Regulation (EC) 258/97 (EC79). In the Netherlands, the labelling proposal is being discussed at the Regular Consumer Goods Act Consultations and is not further assessed in this advisory report.

Chapter 3

Interpretation and evaluation of the data presented

3.1 I Specification of the novel food (NF)

The novel food ingredients are produced by processing conventional potatoes. Potato protein arises as a by-product, which is further purified, during the extraction of starch from potatoes. By further processing the potato protein with proteases, hydrolysates are obtained. The applicant specifies the novel food ingredients in terms of a guaranteed maximum level for dry weight, protein, ash, glycoalkaloids and lysinoalanin.

The coagulated potato protein and the hydrolysates are intended for use in various food systems, for example, fat or water binding, emulsifying or foaming. The novel food ingredients will not be supplied directly to the consumer but are meant for the food industry for use in consumer products.

3.2 II Effects of the production process applied to the NF

The potato is subjected to various treatments before the desired potato protein and the hydrolysates are obtained. The potatoes are first washed and ground. During the grinding, sulphite is added to avoid browning of the potatoes. The ground potatoes are then separated into fibres and starch milk. The starch milk is then separated into starch and juice. The pH of the juice is adjusted. Then the juice is heated, centrifuged and, optionally, dried. This process results in the coagulated potato protein, which can be further processed into hydrolysates. To obtain the hydrolysates, the coagulated potato protein is first washed and optionally dried to remove juice residues. It is then dissolved in water

and the pH is adjusted again. The dissolved protein is then hydrolyzed by proteases. The reaction is stopped by reducing the pH and increasing the temperature. The mixture is dried to obtain the hydrolysed potato protein. Alternatively, the mixture may be separated in a fully soluble hydrolysed potato protein and partially soluble fraction, both of which are dried.

The production procedure has not previously been applied in the production of potato proteins for consumption. According to the applicant, the production procedure is already used on a large scale for the production of other proteins and hydrolysates, for example, for soya. The applicant states that the production procedure for coagulated potato protein is comparable to cooking potatoes, which results in a physical change of the potato protein. The production process for hydrolysed protein is compared with protein digestion in the human digestive tract, which results in a comparable chemical change of the protein. The Committee finds the comparability of the production procedure with natural processes in the human body strongly dependant on the conditions under which the potato protein is produced. There are, however, no primary objections to the comparisons made. Physical and chemical changes of the potato protein, which occur as a result of the production process are described in 3.6 and 3.8.

3.3 III History of the organism used as a source of the NF

The source of the novel food ingredient is the conventional potato. Throughout the entire world, potatoes are used as a source of starch (energy) but they also contain large amounts of protein, essential amino acids, vitamins and minerals. Potatoes are thus regarded as a good nutritional source. The glycoalkaloids solanine and chaconine are the most important toxins in potatoes (Sla90). In humans, consumption of large amounts of glycoalkaloids may lead to gastrointestinal and, in serious cases, neurological problems. Potatoes of the species *Solanum tuberosum tuberosum*, which is cultivated worldwide are used for the production of the novel food ingredients (OECD97). This species of potato contains many different varieties which can vary in terms of composition and thus the quantity of toxins they contain. For the production of the novel food ingredients, potatoes with a high starch content are used. Such potatoes can be differentiated into varieties with a low glycoalkaloid content (e.g. Kartel, Kuraola, Allure, Mercury, Karnico, Krometa, Stabilo, Aurora, Kardal, Kardent and Producent) and varieties with a high glycoalkaloid content (e.g. Karakter, Elles, Elkana, Astarte, Stefano, Mercator, Karida, Kanjer, Seresta and Florijn). In practice, these starch potato varieties will be used in ratios that will differ each year.

The applicant has proposed a maximum level for glycoalkaloids in the novel food ingredients, therefore, the Committee has no objection to the use of starch potato varieties with a high glycoalkaloid content for the production of these ingredients.

3.4 IX Anticipated intake and extent of use of the NF

It is the applicant's intention to substitute a number of proteins in the food industry by the coagulated potato protein and the hydrolysates thereof. He states examples of wheat and soya proteins and hydrolysates thereof, which are already in use. The daily intake of wheat and soya proteins is estimated by the applicant to be between 25 and 30 g. The applicant states that the novel food ingredients will substitute about 6 g of these proteins. He does not expect this to lead to a change in customer's product preference.

3.5 X Information from previous human exposure to the NF or its source

Coagulated potato protein and the hydrolysates thereof are not yet used as food ingredients.

3.6 XI Information on the nutritional value of the NF

Various laboratories have analysed the composition and nutritional value of coagulated potato protein and hydrolysates thereof. In these analyses attention was focused on the amino acid composition, protein and ash content and inorganic elements.

With respect to the amino acid composition, the only differences between the coagulated potato protein and the hydrolysates were observed in the cysteine and tryptophan content. The concentrations of these two amino acids in the coagulated potato protein were twice the concentrations in hydrolysed potato protein. The amino acid and protein contents of the novel food ingredients are higher than those described in the literature for raw, unprocessed potatoes. The ash content in coagulated potato protein is virtually the same as in raw, unprocessed potatoes. In hydrolysed potato protein the ash, sodium and phosphorous content is considerably higher than that in coagulated potato protein or raw potatoes. The applicant states that the novel food ingredients are of high nutritional value, due, principally, to the high concentration of lysine and the good digestibility of the protein.

The Committee finds the potato protein and the hydrolysates thereof qualitatively good food ingredients.

3.7 XII Microbiological information on the NF

The applicant states that micro-organisms detected on the novel food ingredients originate from the soil that remains on the potatoes after harvesting. Stringent checks on the presence of micro-organisms are carried out and during the production process most of the micro-organisms are removed.

In view of the strict regulations and stringent checks currently carried out, the Committee does not expect to find other micro-organisms or microbial metabolism on the coagulated potato protein or the hydrolysates thereof than on whole potatoes.

3.8 XIII Toxicological information on the NF

The applicant has not submitted a detailed file with respect to the safety of the coagulated potato protein and the hydrolysates thereof. In case of substantial equivalence of the novel food ingredients and protein from cooked potatoes no further toxicological experiments are necessary, in accordance with Recommendation 97/618/EC. The Committee finds the principle of substantial equivalence not applicable for these novel food ingredients, however, the applicant has submitted sufficient information for a safety assessment.

The applicant has based the safety of the novel food ingredients on the safety of the potato for the consumer and accordingly describes the safety of the anti-nutritional factors in the novel food ingredients. He states that the level of the anti-nutritional factors is both checked and reduced during the production process.

Levels of the *heavy metals* cadmium, lead and mercury, in the novel food ingredients remain beneath the accepted concentrations as described in the Commodities Act Decree on Contaminants in Foodstuffs (EC) 194/97 (EC97b).

The *sulphite* level is high in the coagulated potato protein (324 mg per kg), but not in the hydrolysated potato protein. The applicant indicates that a high sulphite level is sometimes unavoidable. The Committee thinks the sulphite level will not be a problem provided that the applicant adequately informs the buyers of the novel food ingredients about this. The sulphite level of the products in which the novel food ingredients are used must remain within the standards decreed in the Commodities Act Regulation on Food Additives (War99, War00).

Glycoalkaloids, the most important toxins in potatoes, have also been detected in the novel food ingredients. Initially, the applicant guaranteed a maximum glycoalkaloid content of 750 mg per kg potato protein. The Committee found this very high and corresponded with the applicant about this. In turn, he decided to modify the production process and guaranteed a maximum glycoalkaloid level of 150 mg per kg potato protein

(Ave00a). The Committee finds this level acceptable and does not expect the glycoalkaloids in the novel food ingredients to cause any toxicological problems. However, it is desirable to keep these levels as low as possible. Composition analyses of the novel food ingredients detected a glycoalkaloid level of no more than 15 mg per kg potato protein.

Lysinoalanin is another toxin encountered in the novel food ingredients. It arises as a result of binding of certain amino acids when exposed to a high temperature or a high pH (Ano89, Pfa83). Initially, the applicant guaranteed a maximum lysinoalanin level of 500 mg per kg protein for total lysinoalanin and 50 mg per kg protein for free lysinoalanin. However, in the Commodities Act Decree on Protein Products it is stated that for soya, wheat and fungal proteins the maximum accepted level of free lysinoalanin is 10 mg per kg protein (War99, War00). The Committee is of the opinion that this Commodities Act Decree is also applicable to potato protein and corresponded with the applicant about this. By optimizing the coagulation procedure, the applicant reduced the lysinoalanin content and now guarantees a maximum level of 10 mg per kg potato protein for free lysinoalanin and 500 mg per kg protein for total lysinoalanin, in accordance with the Commodities Act Decree on Protein Products (Ave00). Total lysinoalanin levels of less than 50 mg per kg of novel food ingredient were detected in analyses. In the Commodities Act Decree on Protein Products, no standards are decreed for the level of lysinoalanin in hydrolysates. However, the maximum level of 30 mg of free lysinoalanin per kg hydrolysate guaranteed by the applicant is, in the Committee's view, acceptable. The Committee finds it advisable to incorporate the coagulated potato protein in the Commodities Act Decree on Protein Products.

The applicant concludes that the intake of novel food ingredients will scarcely effect a change in the total daily intake of glycoalkaloids, heavy metals and lysinoalanin and there is accordingly no reason to expect any toxic effects. Based on data concerning both raw and cooked potatoes, it can be concluded that the coagulated potato protein and hydrolysates thereof, will not give rise to allergic reactions. The Committee concurs with this view and considers the novel food ingredients to be safe for consumption.

The Hague, July 20, 2000,
for the committee

signed	signed
MBM van Duursen,	LM Schoonhoven,
project director	chairman

Literature

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Ave00a AVEBE b.a.. Letter. Adjustment of the specifications: lowering the maximum level of glycoalkaloid in the new food ingredients. Letter reference: PRD 00-215 [JHL 00-051]. Foxhol: AVEBE, 2000.

EG79 EG. Richtlijn 79/112/EEG van de Raad van 18 december 1978 betreffende de onderlinge aanpassing van de wetgevingen der Lid-Staten inzake etikettering en presentatie van levensmiddelen bestemd voor de eindverbruiker alsmede inzake de daarvoor gemaakte reclame. Publikatiebl Eur Gemeensch 1979; L33: 1-14

EG97 Verordening (EG) nr 258/97 van het Europees parlement en de Raad van 27 januari 1997 betreffende nieuwe voedingsmiddelen en nieuwe voedselingrediënten. Publikatieblad van de Europese Gemeenschappen 1997; L43: 1-6.

EG97a Aanbeveling (EG) nr 97/618/EC van de Commissie van 29 juli 1997 betreffende de wetenschappelijke aspecten en de presentatie van de informatie die nodig is om aanvragen voor het in de handel brengen van nieuwe voedingsmiddelen en nieuwe voedselingrediënten te ondersteunen alsmede het opstellen van de verslagen van de eerste beoordeling uit hoofde van Verordening (EG) nr. 258/97 van het Europees Parlement en de Raad 1997; L253: 1-36.

EG97b Verordening (EG) nr 194/97 van de Commissie van 31 januari 1997 tot vaststelling van maximumgehalten aan bepaalde verontreinigingen in levensmiddelen. Publikatiebl Eur Gemeensch 1997; L31.

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WHO91 WHO. Strategies for assessing the safety of foods procuced by biotechnology. Report of a joint FAO/ WHO consultation. Geneve: WHO, 1991.

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A Request for advice

B The committee

C EU-procedure

D Executive summary of the dossier

Annexes

Annex **A**

Request for advice

On 18 August 1999, the Minister of Health, Welfare and Sport wrote as follows to the President of the Health Council (under reference GZB/VVB 993428):

Since May 1977, Regulation (EC) 258/97 concerning novel foods and novel food ingredients has been in force in the European Union. Under the Regulation, the safety of novel foods has to be assessed as part of a community procedure.

Following discussions regarding the possibility of the Health Council making such assessments, the State Secretary for Agriculture, Nature Management and Fisheries and I wish the Council to take reponsibility for safety assessment for a period of several years during the fist phase of implementation of European Regulation (EC) 258/97. It is considered appropriate the the Health Council should initially take on this role because the assessment activities will be of an experimental nature, involving both a new form of assessment (i.e. pre-marketing assessment) and, in many cases, new categories of foodstuff (primarily foodstuffs with a genetically modified basis and functional foods or nutraceuticals). We also feel that if assessments are made by a body with the Council's independent scientific status, this will support the validity of the Netherlands'opinion in the eyes of the European Committee and other member states.
My wish is to make the procedure and the assessment as open and transparent as possible, so as to enhance consumer trust in the safety of novel foods. I would like the Health Council to support this objective by, for example, allowing perusal of applicants (insofar as consistent with the need to protect the

conficentiality of commercially sensitive information) and publishing the criteria upon which safety assessments are made.

The Minister of Health, Welfare and Sport,
signed Dr E. Borst-Eilers

Annex **B**

The committee

- Dr LM Schoonhoven, *chairman*
  emeritus professor of entomology; Wageningen University and Research center
- Dr JEN Bergmans, *advisor*
  COGEM, The Hague
- Dr A Brouwer
  professor of environmental toxicology; Free University, Amsterdam
- Dr CAFM Bruijnzeel-Koomen
  professor of dermatology/allergology; Academic Hospital Utrecht
- Dr EJ Kok
  toxicologist; RIKILT, Wageningen
- Dr CF van Kreijl
  molecular biologist; RIVM, Bilthoven
- Dr F Nagengast
  gastro-enterologist; Academic Hospital Nijmegen
- Dr JMA van Raaij
  food physiologist; Wageningen University and Research center
- Dr EG Schouten
  professor of epidemiology; Wageningen University and Research center
- Dr GJA Speijers
  toxicologist; RIVM, Bilthoven
- Dr WJ Stiekema
  professor of bioinformatics; Wageningen University and Research center

- Dr R Top, *advisor*
  Ministry of Health, Welfare and Sport, The Hague
- Dr WM de Vos
  professor of microbiology; Wageningen University and Research center
- Dr JAG van de Wiel, *project director*
  Health Council of the Netherlands, The Hague
- Drs MBM van Duursen, *project director*
  Health Council of the Netherlands, The Hague

Administrative assistance: C Brussee; Health Council of the Netherlands, The Hague.

Annex **C**

EU procedure

When manufacturers bring novel foodstuffs onto the market, consumer safety has to be assured. In 1997, a European Directive (EC97) came into force, laying down the procedure for approving the market introduction of novel foodstuffs. The procedure recognises various actors. The applicant must decide whether a product is a novel foodstuff, i.e. a substance that has not previously been available for human consumption to any substantial extent within the European Union and is not substiantially equivalent to any existing product. (If a foodstuff is substiantially equivalent to any existing product, it is sufficient to inform the authorities of its market introduction). Foodstuff additives, aromas and extracts are excluded from the provisions of the directive, since they fall within the scope of an established assessment regime. Before marketing a novel foodstuff, the applicant must compile a safety dossier that complies with the Recommentations of the European Commission (EG97a). These Recommendations are based on reports by a number of bodies that have studied the issue of novel foodstuffs, in particular the OECD (OECD93, OECD96) and the WHO/FAO (WHO91, FAO96). The Health Council of the Netherlands has also considered the question (GR92). Since publication of the EU recommendations, international efforts have been made to clarify and adapt the latest scientific knowledge in the field (SSC99, SCF99, OEC98).

Having compiled a dossier in line with the guidelines, the manufacturer has to submit it to the competent authority in the country where the product is to be marketed first. This dossier is assessed by the national safety assessment authority. In the Netherlands, this is the Minister of Health, Welfare and Sport, who is advised by the Health Council. The President of the Health Council has created a Committee on the

Safety assessment of novel foods (VNV) to advise the minister on behalf of the Council.

the scientific state of the art, the committee has to decide whether the information provided by the manufacturer is accurate and complete and whether the manufacturer's conclusions are sound. The committee then draws up a report on its findings for the minister; this report must also comply with the European Recommendation (EC97a, part III). After considering the report, the minister formulates the Netherlands'opinion regarding the foodstuff in question, which is discussed at European level in the Standing Committee for Food. All other European member states are invited to express a 'second opinion' regarding the dossier and the first opinion. The Permanent Committee then arrives at a final judgement. If a dossier is particularly contentious, the European Commission calls upon the Scientific Committee for Food for advice. If consensus still cannot be reached, the issue is referred to the European Council of Ministers.

Annex **D**

Executive summary of the dossier