« Human Consumption to a Significant Degree »

Information and Guidance Document

The producer, importer or any other person responsible for the placing of a product on the EU market is primarily responsible for complying with the relevant legislation. Therefore, if necessary they should provide to the competent authorities the necessary information to substantiate that the product would not fall within the scope of Regulation (EC) No 258/97.

In case of doubt, food business operators may consult the relevant competent authority for novel foods on the status of this food.

According to Article 1 (2) of Regulation (EC) No 258/97 novel foods and novel food ingredients are foods which have **not been used for human consumption to a significant degree** within the Community before the entry into force of the Regulation (15 May 1997). The determination whether this particular provision is fulfilled may be in certain cases difficult. This document therefore aims to assist the competent authorities and interested stakeholders to better understand it and to apply it correctly and in a uniform way.

This document does not provide an exhaustive list of relevant criteria to be considered for determination of the novel food status. Furthermore, the order of the criteria listed should not be taken as a ranking. In fact, each product has to be evaluated on a case by case basis. A specific criterion might be not applicable in one case but of significant value for another product.

1. Criteria to be considered when establishing whether a food has been used for human consumption to a significant degree

1.1 Information

In addition to general information about the composition of the product, at least the following information is needed in order to ensure that the available documentation about the use of the food prior to 15 May 1997 relates to the product in question.

The enquirer should therefore provide at least the following information for:

organisms (plants, micro-organisms, fungi, algae, animals etc.) and ingredients produced from organisms:

1) taxonomic name of the organism (full Latin name with author name), also other names, synonyms etc, where applicable
2) specification of which part of the organism the use before 15 May 1997 refers to
3) the form and/or concentration of the product (fluid, extract etc.), and
4) if ingredient in a food supplement, possible indication of the quantity/amount

chemical substances:

5) CAS[1] name according to IUPAC[2], also other product names (e. g. trade name, common name), where applicable, and specification about purity
6) description/specification of production process, and
7) if ingredient in a food supplement, possible indication of the quantity/amount.

The main points that have to be taken into account, when considering the novel food status are described below. Whilst there may be occasions when a history of consumption to a significant degree for a product is unequivocal (e.g. by provision of extensive sales data), given the timescales since the entry into force of Regulation (EC) No 258/97, it should be emphasised that as it is as such evidence would now be 12-15 years old this will not always be the case and the "whole picture" needs to be examined. This document therefore also details possible alternative sources of information which could be used to determine "consumption to a significant degree".

[1] CAS = Chemical Abstracts Service
[2] IUPAC = International Union of Pure and Applied Chemistry

1.2 Documentation

The fact finding process whether a food has already been used for human consumption to a significant degree within the European Union before 15 May 1997 should be based on robust, reliable information and data taken from referenced sources and relate to foods which have been legally on the Community market.

It is recognised that individual pieces of information provided may not, in isolation, reliably indicate that a product was on the market to a significant degree in the EU before 15 May 1997. For example import or distribution lists may not accurately describe the purpose for which the specific product has been sold/imported (food, cosmetics, medicinal products, animal feed…). It is therefore reasonable that all available data and information should be taken into account in establishing whether the food in question falls within the scope of Regulation (EC) No 258/97. These could include for example, invoices, recipes, cookbooks, catalogues etc.

Relevant national and Community legislation also needs to be taken into account to determine whether a food would fall under the scope of Regulation (EC) No 258/97. For instance, certain fruit may be used for the production of fruit nectar is listed in Annex IV of Council Directive 2001/112/EC of 20 December 2001 relating to fruit juices and certain similar products intended for human consumption (and were already listed in the previous Directive 93/77/EWG). In such cases, Regulation (EC) No 258/97 would not be applicable, unless the food/food ingredient in question does not correspond to the form or type of food/food ingredient covered by the legislation in question (e. g. a new extract from a fruit).

1.3 Geographical aspects

Foodstuffs commonly used and known in different EU Member States and in specific regions of some Member States, vary greatly.

Therefore the first step is to provide information whether a specific food was used for human consumption to a significant degree before 15 May 1997 widely and commonly within an EU country or whether the use as food was only on local or regional scale.

However, food use on local or regional scale does not necessarily mean that such a food requires authorisation under Regulation (EC) No 258/97. The respective Member State's authorities have to see in each case whether such local use could be considered as “significant degree” or not. The authorities will take into account criteria as, whether operators were con-

tinuously on the market, whether the use of the food is linked to local or regional traditions etc.
An established history of food use to a significant degree in at least one EU Member State is sufficient to exclude the food from the scope of Regulation (EC) No 258/97.

The deadline 15 May 1997 is applicable to all Member States, irrespective from the date of accession to the EU.

A use of a food in third countries only is not acceptable to demonstrate a history of food use according to Regulation (EC) No 258/97.

1.4 Quantity of use

Generally, the more a food has been used the easier it should be to demonstrate a significant degree. However, the quantities consumed may vary significantly dependent on the type of food, e. g. spices, herbs or some berries may be used in smaller amounts than bread, cereals or flour. The assessment as to whether a food has been used for human consumption to a significant degree before May 1997 should therefore be based on typical levels of consumption for specific product categories.

In addition to the information about quantities (weight) consumed also the number of units (packages) sold, the availability on the market (only in a very limited number of shops or widely available) and the nature of these "shops" (if they were only home-sales or sales to a limited group of consumers) are sometimes important (see also the section "Availability").

In certain cases, Member States have to determine for a food that was used in apparently small quantities, whether such a food requires authorisation under the Novel Food Regulation.

1.5 Intended purpose

Regulation (EC) No 258/97 exclusively covers foods and food ingredients. Therefore, only food uses can be taken into account in establishing whether a specific product has been used for human consumption to a significant degree within the Community before 15 May 1997 or not. Furthermore, the demonstrated use should relate to the specific food in question.

Products that have been used for their medicinal effects/as a drug or as cosmetics (for example, traditional restorative remedies, plant based medicinal products, traditional Chinese medicine, toothpaste) do not indicate that this product was used as food. It should be kept in mind that the classification of products as medicinal product or a food may differ across the EU and

independent of the classification under Regulation (EC) No 258/97, a product might be classified as a medicinal product in one or several Member States. Furthermore, the placing on the market of a product might be restricted by other specific national legislation.

When a food has been exclusively used as food belonging to one of the categories mentioned in Article 2.1 of Regulation (EC) No 258/97 (food additives, flavourings, extraction solvents), such a use cannot be taken into account as "food use" in the sense of Regulation (EC) No 258/97.

1.6 Specific population groups/context of use

The assessment whether a specific food has been used for human consumption to a significant degree before 15 May 1997 should also take into consideration if the product in question is part of a normal diet by the average population or has been used by specific population groups only, or whether it is used in a specific and limited food category only.

The Standing Committee on the Food Chain and Animal Health agreed in its meeting of 14 February 2005, that a use exclusively in food supplements before 15 May 1997 would not be considered as “human consumption to a significant degree” according to Article 1 of Regulation (EC) No 258/97. Therefore, authorisation under Regulation (EC) No 258/97 would be necessary if the food/food ingredient should be used in other foodstuffs than food supplements.

Food used at specific occasions like particular ceremonies, festivities etc., might be significant use in the sense of the Novel Food regulation. However, products on the market only in emergency situations, but not regularly and in a commercially sustainable way, could require an authorisation under the Novel Food Regulation.

1.7 Use of other forms/parts of a food/new technologies

It is also important to note that the use to a significant degree within the EU before 15 May 1997 of a particular food or food ingredient does not automatically apply if the product in question has been subject to additional processing. If this processing alters the composition of the food, or the food is produced from a new source material or by a new production process (Article 1(2)(f)) then the resultant product could fall under the scope of Regulation (EC) No 258/97.

For example, specific selective extracts of a plant, fungus, algae or microorganism could fall within the scope of Regulation (EC) No 258/97 if they have not been used for human con-

sumption as such and this may be the case even if the source material is widely consumed. Consideration should also be given to the type of the extracts. For instance, an aqueous extract might be classified quite differently from an extract obtained by using another solvent. In such cases the safety of the particular product needs to be demonstrated due to a lack of experience with and knowledge about the safe use of such ingredients an authorisation under Regulation (EC) No 258/97 would be required. In this context the following aspects should be considered what are the normal quantities consumed, whether the new purpose would correspond to such quantities or would lead to significantly higher intakes or whether the amounts that are intended to be used would deviate extensively to those normally consumed with common food.

This also applies to other parts of a plant that have so far not been used for human consumption. A specific part of a plant, e.g. a fruit may be an established food, but if the leaves, bark or the rind have not been consumed as food, authorisation under Regulation (EC) No 258/97 would be required.

The use of new technologies in food production might in some cases also lead to a significantly different product with new desirable and/or also undesirable properties. In such cases a safety assessment under Regulation (EC) would be required since knowledge about the safety of the commonly produced product cannot be applied equally to the product produced by a new production process, e. g. food ingredients used in significantly different forms than commonly known, like nano-particles.

Consequently, the conclusion that a specific form or part of a food has been used to a significant degree should not be applied to all other forms/parts of that particular food in general. In fact, applicability of Regulation (EC) No 258/97 should be carefully checked on a case by case basis.

1.8 Availability

a) Locality

Another criterion for consideration whether a food has been used to a significant degree is the question how and where the food has been available. Only foods that have legally been placed on the respective Member State's market can be taken into account.

If a product has only limited availability e.g. in pharmacies, health shops or specific restaurants, a significant use could be questionable. However, if a food has been widely available to consumers in common food stores/supermarkets a significant use could normally be assumed.

In the context of Regulation (EC) No 258/97, foods that have been commercially placed on the market of at least one EU Member State have to be taken into account rather than a use in the private domain only (e. g. mushrooms that have only been used as food by some people, berries that have been picked from the forest by individuals). However, such foods may be on the market in certain geographical areas, e.g. in local farmers markets. Therefore they may be included e.g. in official and qualified Member States documentation for edible mushrooms/berries/herbs, and may be regarded by the Member States authorities as consumed to a significant degree, even if the commercial value is limited.

b) Timeframe

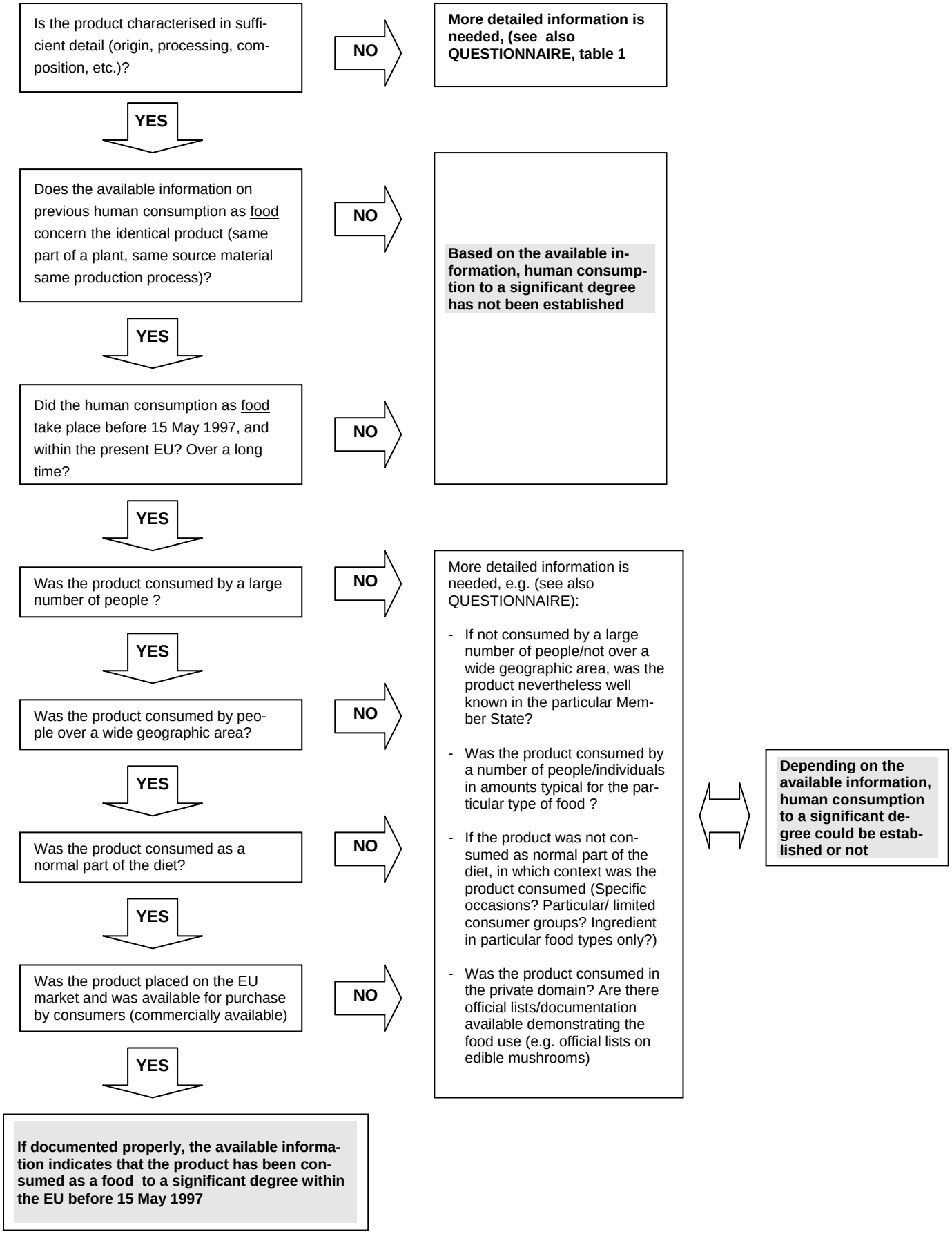
The availability over the years should also be considered. It is of interest, whether the food has been available regularly e.g. for dozens of years, or only once in a while. For instance, if a product had only been presented once at a trade fair before 15 May 1997, this does not demonstrate significant use. Also foods that were used a long time/many years ago only but not in recent times a history of food use relevant for the Novel Food Regulation has not been established.

2. Decision tree/Questionnaire

In order to assist interested parties to assess the novel food status of a particular product and, if necessary, to ensure that all relevant information is made available to Competent Authorities the attached decision tree and questionnaire should be followed. The use of the decision tree and questionnaire should also indicate to interested parties when the evidence that they have available is unlikely to be sufficient to demonstrate that the produce has been consumed to a significant degree prior to 15 May 1997.

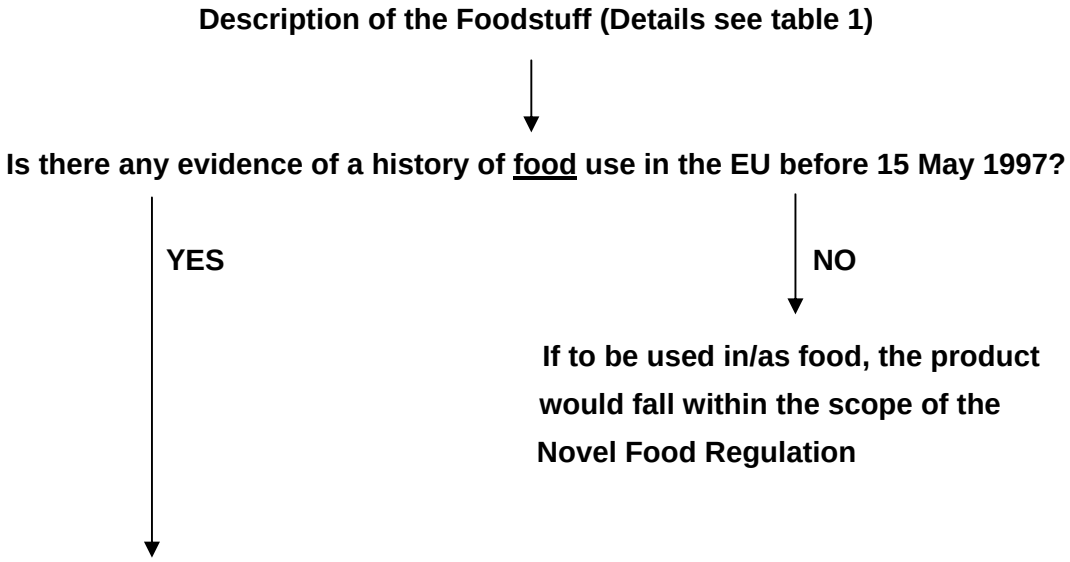
The decision tree is intended as a guidance and to give an initial indication whether or not a product in question would fall within the scope of Regulation (EC) No 258/97. Due to the diversity of possible novel foods, it may in many cases not be possible to determine whether a certain food was on the market on simple "**yes or no**" answers. Therefore, several sub-criteria need to be considered. In view of this the questionnaire, which requires the provision of more detailed information, will facilitate the answer.

2.1 DECISION TREE



2.2 Q E S T I O N A I R E

I. Initial Step:



II. Main part:

How much information is known about the product?
Complete following Table(s)

Explanatory note:

1. In order to assist interested parties as regards the conclusion on the novel food status of a particular product, it is recommended to fill in the table(s) below, which aim to most adequately describe the foodstuff and, where appropriate, include additional confirmatory information.
2. Interested parties should use Table 3 (below) to detail the nature of evidence provided to support evidence of a history of consumption.
3. In case of doubt about the novel food status, interested parties may send the information to a relevant Member State's Novel Food Competent Authority for review.

I. Initial step

Table 1 Description of food or food ingredient:

(1) Composition of the food or food ingredient	
In addition:	
(2) For organisms (plants, micro-organisms, fungi, algae, animals etc.) and ingredients produced from organisms:	
(a)	Taxonomic name of the organism (full Latin name with author name) , and other names, synonyms etc, where applicable
(b)	Specification of which part of the organism the History of food consumption refers to
(c)	The form and/or concentration of the product (fluid, extract etc.), and
(d)	If ingredient in a food supplement, possible indication of the quantity/amount
(3) For chemical substances:	
(a)	CAS name according to IUPAC, also other product names (e. g. trade name, common name), where applicable, and specification about purity
(b)	Description/specification of production process, and
(c)	If ingredient in a food supplement, possible indication of the quantity/amount

II. Main part

Table 2 Information for the determination whether a product requires authorisation under the Novel Food Regulation

1	It was consumed by a large number of people as a food or food ingredient throughout in the EU prior to 15 May 1997 [Example a kiwi fruit] not relevant: uses exclusively e.g. as food additive, flavouring, other than as food uses like medicinal products, cosmetics	☐ yes ☐ no ☐ information not available		
	Supplementary Information		**Evidence?**	**Brief Summary**
A	It was consumed as a normal part of the diet.			
B	It was placed on the EU market and was available for purchase by consumers (e.g. not only in pharmacies, healthshops or specific restaurants).			
C	It has been consumed for a long period of time.			

D	It has been consumed in quantities typical for similar products of the specific food category.			

2	It was consumed by a large number of people as a food or food ingredient in one Member State prior to 15 May 1997 [Example Frogs legs] not relevant: uses exclusively e.g. as food additive, flavouring, other than food uses like medicinal products, cosmetics	☐ yes ☐ no ☐ information not available		
	Supplementary Information		**Evidence?**	**Brief Summary**
A	It was consumed as a normal part of the diet.			
B	It was placed on the EU market and was available for purchase by consumers (e.g. not only in pharmacies, healthshops or specific restaurants)			
C	It has been consumed for a long period of time.			
D	It has been consumed in quantities typical for similar products of the specific food category.			

3	It was consumed only regionally/on a small local scale. [Example a regional seaweed – e.g. Laver Bread in South Wales]	☐ yes ☐ no ☐ information not available		
	Supplementary Information		**Evidence?**	**Brief Summary**
A	It was consumed as a normal part of the diet.			
B	It was placed on the EU market and available for purchase by consumers (e.g. <u>not</u> only in pharmacies, healthshops or specific restaurants).			
C	It has been consumed for a long period of time.			
D	It has been consumed in quantities typical for similar products of the specific food category.			

4	It was used in the private domain only. [Example a supplement from a third country]	☐ yes ☐ no ☐ information not available		
	Supplementary Information		**Evidence?**	**Brief Summary**
A	Imported for personal consumption. (If yes: Not relevant)			
B	There was a similar food product on the market in the EU. (If yes: Information Table 1 or 2).			
C	It was harvested from the wild.			

5	Was it available as an ingredient designed for a specific target population ? (Example a Food for Special Medical Purpose)	☐ yes ☐ no ☐ information not available		
	Supplementary Information		**Evidence?**	**Brief Summary**
A	Target population group.			
B	It was placed on the EU-market/was widely available for purchase by consumers suitable for use.			
C	It's use was restricted to individuals with an underlying medical condition.			
D	It was used in food supplements only. (If yes: Only relevant for use in food supplements. Authorisation for use in other foods required)			

Table 3 Evidence of a history of consumption

Type of Evidence*	Type of evidence	Possible Weighting
Comprehensive Sales Information	Invoices etc detailing sale of food, including evidence of large quantities of sale in the EU	Very Good Evidence, if purpose (food use) is indicated
Sales Information	Invoices etc detailing sale of food	Good Evidence, if purpose (food use) is indicated
Government Import/Export Information	Official documents	Supporting Evidence, if purpose (food use) is indicated
Sales Information	Catalogues, Sales Brochures	Supporting Evidence, if purpose (food use) is indicated
Listed in recognised catalogues/documents		Supporting Evidence
Expert knowledge	Personal Testimonies	Supporting Evidence
Supporting Information	Magazine articles, Recipe Books etc.	Supporting Evidence
Other	Please Specify	