

# Agence française de sécurité sanitaire des aliments - France

*stakeholder group:* Competent Authority (CA)

## **2.1 Adjusted safety assessment and management for traditional food from 3rd countries**

Opt 1: No changes 'One size fits all'

Opt 2: Adjusted safety assessment for traditional food from 3rd countries

Opt 3: Adjusted safety assessment and management for traditional food from 3rd countries

Opt 4: No pre-market safety assessment and authorisation for traditional food from 3rd countries

**2.1.5 Preference:** Option 2: Adjusted safety assessment for traditional food from 3rd countries

**2.1.6 Explanation of choice:** First of all, although the Commission is right in considering all possible impacts of the regulatory provisions governing Novel Foods (NF), it is surprising (§ 1.2-2 of the Explanatory document) that the effect of novel foods on health and their safety for the consumer are seen as secondary factors in terms of social impact. The safety of use of a novel food in the EU is in itself a key responsibility for the Commission. The AFSSA's responses focus on issues relating to risk assessment and food safety for consumers. The questions concerning the economic aspects will therefore be disregarded. The issue raised is ambiguous in that the concept of traditional foods from third countries is not defined and could refer to various situations when it comes to demonstrating harmlessness. It appears legitimate for the Commission to guarantee consumer safety through a health assessment of the product before authorising NF (this rules out option 4), particularly since experts generally do not have sufficient knowledge of NF, whether derived from animals or plants, on which there is little documentation in scientific literature, and also since the drop in food consumption is difficult to verify. There have, for instance, been regular reports of pharmacovigilance problems concerning plants with a traditional use in third countries. We consider that plant-based foodstuffs which are not traditionally consumed as part of a normal diet but are used because they contain pharmacologically active substances cannot be described as novel foods (c.f. AFSSA opinion of 10 January 2006 concerning the assessment of the use of *Scutellaria baicalensis* and *Acacia catechu* extracts in the form of a food supplement pursuant to Regulation (EC) No 258/97 concerning novel foods and novel food ingredients, [www.afssa.fr](http://www.afssa.fr)). In the case of a documented food tradition backed by methods for ascertaining possible undesirable effects, there should be specific guidelines on how to carry out risk assessments of novel foods which are traditional in third countries. We are therefore in favour of option 2.

## **2.2 Safety assessment and Authorization procedure?**

Opt 1: No changes (decentralised assessment and authorisation procedure)

Opt 2: Centralised risk assessment and authorisation procedure

**2.2.4 Explanation of choice:** With a view to cooperation between the national agencies and the EFSA (European Food Safety Authority), we propose a third option: novel food referrals would be registered by the EFSA and their assessment entrusted to a Member State on a random basis. When consulting the Member States, and in order to complete the assessment properly, the manufacturer's file must be available in its entirety.

## **2.3 Authorisation decision?**

Opt 1: No changes: Authorisation linked to the applicant (only applicant able to market)

Opt 2: Generic authorisation (all companies able to market in EU and abolishment of simplified procedure)

Opt 3: Generic authorisation + data protection for certain foods

Opt 4: Different types of authorisations (generic and for certain foods, applicant linked)

2.3.5 Preference: Option 4: Different types of authorisations (generic and for certain foods, applicant linked)

2.3.6 Explanation of choice: The conditions for generic authorisation must be in keeping with the type of assessment carried out. In the case of a novel ingredient, consideration should be given to: composition; the choice of vector(s) (impact of the matrix, consumption patterns, how the food is perceived, etc.); the blend level in view of the ingredient's importance and the risk of dose build-up; how the product is consumed (e.g. after heating). In the case of a novel food, consideration should be given to: the organism or part of the organism (animal or plant) used to produce the novel food (e.g. from a fruit juice with or without pulp/seeds/husks, or a new food derived from the fruit or leaf of the plant); composition; the production process; how the product is consumed (e.g. whether the food must be heated to guarantee product safety). If any changes are made to one of these parameters, a new file should be submitted for assessment and possible approval. We are therefore in favour of option 4.

## **2.4 Submission of application for several food uses**

Opt 1: No changes: Separate applications for different food uses

Opt 2: One application for all new foods for different uses

2.4.3 Preference: Option 2: One application for all new foods for different uses

2.4.4 Explanation of choice: No objection to option 2, provided that the common core requirements for the different uses are sufficiently detailed. Such an approach must not conceal the specific safety aspects related to any particular use – these should continue to be indicated in addition to the common requirements.

## **2.5 Legal act**

2.5.3 References: Avis de l' Afssa du 10 janvier 2006 relatif à l'évaluation de l'emploi d'extraits de *Scutellaria baicalensis* et d'*Acacia catechu* sous forme de complément alimentaire d'après le règlement CE n 258/97 relatif aux nouveaux aliments et nouveaux ingrédients alimentaires, disponible sur le site [www.afssa.fr](http://www.afssa.fr).