

DGCCRF - Bureau C2 - Nouveaux Aliments et Ingrédients A - France

Stakeholder group: Competent Authority (CA)

1. General questions

1.1 Market size and value?

<u>Novel food as total</u>	Not applicable
<u>Traditional food from 3rd countries (outside the EU)</u>	Not applicable
<u>R&D based novel foods</u>	Not applicable

1.2 Import value?

<u>Novel food as total</u>	Not applicable
<u>Traditional food from 3rd countries (outside the EU)</u>	Not applicable
<u>R&D based novel foods</u>	Not applicable

1.5 Time taken

<u>Safety assessment of novel foods</u>	Long
<u>Authorization decision on novel foods</u>	Long
<u>Authorization procedure as a whole</u>	Long

1.6 Costs of administrative burden

<u>Novel food as total</u>	Not applicable
<u>Traditional food from 3rd countries (outside the EU)</u>	Not applicable
<u>R&D based novel foods</u>	Not applicable

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

Opt 1: No changes 'One size fits all'

<u>Impact on public health and food safety</u>	Neutral
<u>Impact on consumer rights</u>	Don't know
<u>Impact on competitiveness, markets and trade (including 3rd countries)</u>	Not at all beneficial
<u>Impact on the administrative burden imposed on business</u>	Don't know
<u>Impact on innovation and research</u>	Don't know
<u>Impact on employment and jobs</u>	Don't know
<u>Environmental impact (EU and 3rd countries)</u>	Don't know
<u>Socio-economic impact (3rd countries in particular)</u>	Not at all beneficial

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

<u>Impact on public health and food safety</u>	Neutral
<u>Impact on consumer rights</u>	Don't know
<u>Impact on competitiveness, markets and trade (including 3rd countries)</u>	Not at all beneficial
<u>Impact on the administrative burden imposed on business</u>	Don't know
<u>Impact on innovation and research</u>	Don't know
<u>Impact on employment and jobs</u>	Don't know
<u>Environmental impact (EU and 3rd countries)</u>	Don't know
<u>Socio-economic impact (3rd countries in particular)</u>	Not at all beneficial

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

<u>Impact on public health and food safety</u>	Neutral
<u>Impact on consumer rights</u>	Don't know
<u>Impact on competitiveness, markets and trade (including 3rd countries)</u>	Not at all beneficial
<u>Impact on the administrative burden imposed on business</u>	Don't know

<u>Impact on innovation and research</u>	Fairly beneficial
<u>Impact on employment and jobs</u>	Don't know
<u>Environmental impact (EU and 3rd countries)</u>	Don't know
<u>Socio-economic impact (3rd countries in particular)</u>	Not at all beneficial

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

<u>Impact on public health and food safety</u>	Neutral
<u>Impact on consumer rights</u>	Don't know
<u>Impact on competitiveness, markets and trade (including 3rd countries)</u>	Not at all beneficial
<u>Impact on the administrative burden imposed on business</u>	Don't know
<u>Impact on innovation and research</u>	Don't know
<u>Impact on employment and jobs</u>	Don't know
<u>Environmental impact (EU and 3rd countries)</u>	Don't know
<u>Socio-economic impact (3rd countries in particular)</u>	Not at all beneficial

2.1.5 Preference: Option 3: Adjusted safety assessment and management for traditional food from 3rd countries

2.1.6 Explanation of choice: France would prefer at the very least option 2, based on an appropriate risk assessment which takes better account of the antecedents and consumption methods relating to products traditionally consumed in third countries. However, it is vital that: 1/ this procedure is not limited only to foods traditionally consumed in third countries, but that it is also extended to use as an ingredient in substances authorised for other purposes (for example, an additive used as an ingredient); 2/ guidelines for the assessment of these products are drafted in order to better define the conditions in which assessments must be made of the antecedents and consumption methods and/or of the data available on the safe use of these substances/ingredients/foods known elsewhere or in other uses. Furthermore, the French authorities consider that the establishment of a streamlined management procedure (option 3) for these substances/ingredients/foods known elsewhere or in other uses could be envisaged, provided that the steps in this procedure are clearly defined, with a view to consultation of the Member States and the publication of decisions.

2.2 Safety assessment and Authorization procedure?

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

<u>Impact on public health and food safety</u>	Neutral
<u>Impact on consumer rights</u>	Don't know
<u>Impact on competitiveness, markets and trade (including 3rd countries)</u>	Not at all beneficial
<u>Impact on the administrative burden imposed on business</u>	Don't know
<u>Impact on innovation and research</u>	Neutral
<u>Impact on employment and jobs</u>	Don't know
<u>Environmental impact (EU and 3rd countries)</u>	Don't know
<u>Socio-economic impact (3rd countries in particular)</u>	Not at all beneficial

Opt 2: Centralised risk assessment and authorisation procedure

<u>Impact on public health and food safety</u>	Neutral
<u>Impact on consumer rights</u>	Don't know
<u>Impact on competitiveness, markets and trade (including 3rd countries)</u>	Not at all beneficial
<u>Impact on the administrative burden imposed on business</u>	Don't know
<u>Impact on innovation and research</u>	Fairly beneficial
<u>Impact on employment and jobs</u>	Don't know
<u>Environmental impact (EU and 3rd countries)</u>	Don't know
<u>Socio-economic impact (3rd countries in particular)</u>	Not at all beneficial

2.2.3 Preference: Option 2: Centralised risk assessment and authorisation procedure

2.2.4 Explanation of choice: France is in favour of centralising procedures. This would lighten the workload of the national institutions, shorten deadlines and thereby encourage innovation. However, the centralisation of risk assessments must not imply an end to the participation of the existing national assessment authorities.

2.3 Authorisation decision?

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

<i>Impact on public health and food safety</i>	Neutral
<i>Impact on consumer rights</i>	Don't know
<i>Impact on competitiveness, markets and trade (including 3rd countries)</i>	Not at all beneficial
<i>Impact on the administrative burden imposed on business</i>	Don't know
<i>Impact on innovation and research</i>	Not very beneficial
<i>Impact on employment and jobs</i>	Don't know
<i>Environmental impact (EU and 3rd countries)</i>	Don't know
<i>Socio-economic impact (3rd countries in particular)</i>	Not at all beneficial

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

<i>Impact on public health and food safety</i>	Neutral
<i>Impact on consumer rights</i>	Don't know
<i>Impact on competitiveness, markets and trade (including 3rd countries)</i>	Not at all beneficial
<i>Impact on the administrative burden imposed on business</i>	Don't know
<i>Impact on innovation and research</i>	Fairly beneficial
<i>Impact on employment and jobs</i>	Don't know
<i>Environmental impact (EU and 3rd countries)</i>	Don't know
<i>Socio-economic impact (3rd countries in particular)</i>	Not at all beneficial

Opt 3: Generic authorisation + data protection for certain foods

<i>Impact on public health and food safety</i>	Neutral
<i>Impact on consumer rights</i>	Don't know
<i>Impact on competitiveness, markets and trade (including 3rd countries)</i>	Not at all beneficial
<i>Impact on the administrative burden imposed on business</i>	Don't know
<i>Impact on innovation and research</i>	Fairly beneficial
<i>Impact on employment and jobs</i>	Don't know
<i>Environmental impact (EU and 3rd countries)</i>	Don't know
<i>Socio-economic impact (3rd countries in particular)</i>	Not at all beneficial

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

<i>Impact on public health and food safety</i>	Neutral
<i>Impact on consumer rights</i>	Don't know
<i>Impact on competitiveness, markets and trade (including 3rd countries)</i>	Not at all beneficial
<i>Impact on the administrative burden imposed on business</i>	Don't know
<i>Impact on innovation and research</i>	Fairly beneficial
<i>Impact on employment and jobs</i>	Don't know
<i>Environmental impact (EU and 3rd countries)</i>	Don't know
<i>Socio-economic impact (3rd countries in particular)</i>	Not at all beneficial

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

2.3.6 Explanation of choice: [Options 3 and 4 both possible] France prefers the idea of favouring decisions of general effect as far as possible. If clear definitions of their field of application and the particular authorisation conditions are given, namely in the form of precise specifications for ingredients, these decisions would offer the advantage of setting the same

conditions for all operators wishing to benefit from authorisation, without requiring each operator to submit a file, while maintaining a high level of food safety. The consequent reduction in the workload of the national and Community institutions is another advantage to be considered. However, in some specific scenarios (a very advanced degree of innovation, the need for a precise evaluation of expected consumption levels, etc.), it could be necessary in one way or another to ensure a degree of exclusivity for the operator who first applied for marketing authorisation. On the other hand, given the information available to the French authorities concerning how to implement options 3 and 4, it is still difficult for them to make a final choice.

2.4 Submission of application for several food uses

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

<u>Impact on public health and food safety</u>	Neutral
<u>Impact on consumer rights</u>	Don't know
<u>Impact on competitiveness, markets and trade (including 3rd countries)</u>	Not at all beneficial
<u>Impact on the administrative burden imposed on business</u>	Don't know
<u>Impact on innovation and research</u>	Neutral
<u>Impact on employment and jobs</u>	Don't know
<u>Environmental impact (EU and 3rd countries)</u>	Don't know
<u>Socio-economic impact (3rd countries in particular)</u>	Not at all beneficial

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

<u>Impact on public health and food safety</u>	Neutral
<u>Impact on consumer rights</u>	Don't know
<u>Impact on competitiveness, markets and trade (including 3rd countries)</u>	Not at all beneficial
<u>Impact on the administrative burden imposed on business</u>	Don't know
<u>Impact on innovation and research</u>	Neutral
<u>Impact on employment and jobs</u>	Don't know
<u>Environmental impact (EU and 3rd countries)</u>	Don't know
<u>Socio-economic impact (3rd countries in particular)</u>	Not at all beneficial

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

2.4.4 Explanation of choice: We would choose option 2 in the case of new substances for which the assessment could be conducted jointly for various types of application: this would on the one hand help to reduce processing time, and on the other ensure greater consideration of overall exposure at any given time. However, a new assessment should be carried out when substances are intended for uses other than those which have already been authorised (e.g. a substance authorised as an additive to be used as an ingredient, or vice versa).

2.5 Legal act

2.5.1 What would be the impact of the revision for your organisation?

<u>Impact on public health and food safety</u>	Neutral
<u>Impact on consumer rights</u>	Don't know
<u>Impact on competitiveness, markets and trade (including 3rd countries)</u>	Not at all beneficial
<u>Impact on the administrative burden imposed on business</u>	Don't know
<u>Impact on innovation and research</u>	Fairly beneficial
<u>Impact on employment and jobs</u>	Don't know
<u>Environmental impact (EU and 3rd countries)</u>	Don't know
<u>Socio-economic impact (3rd countries in particular)</u>	Not at all beneficial

2.5.2 Explanation: France is in favour of revising Regulation (EC) No 258/97 because, like other Member States, it is experiencing difficulties in applying these provisions and the related

decisions. The present situation is creating legal uncertainty, and undermines consumer protection and the monitoring of fair trade in conditions which are identical for all Member States. The Commission will in any case have to ensure a certain level of consistency between all assessment and authorisation procedures under review.

2.5.3 References: Note of the French authority to the Commission.