

Ministerio de Agricultura, Ganadería y Alimentación - Guatemala

stakeholder group: Competent Authority (CA)

1. General questions

1.1 Market size and value?

<u>Novel food as total</u>	Significant
<u>Traditional food from 3rd countries (outside the EU)</u>	Significant
<u>R&D based novel foods</u>	Significant

1.2 Import value?

<u>Novel food as total</u>	Significant
<u>Traditional food from 3rd countries (outside the EU)</u>	Significant
<u>R&D based novel foods</u>	Significant

1.3 Staff 15

1.4 Innovation cost 85000

1.5 Time taken

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

1.6 Costs of administrative burden

<u>novel food as tota</u>	Significant
<u>Traditional food from 3rd countries (outside the EU)</u>	Significant
<u>R&D based novel foods</u>	Significant
<u>1.6 Specify</u>	\$ 100,000.00

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>	Not relevant
<u>Impact on consumer rights</u>	Not relevant
<u>Impact on competitiveness, markets and trade (including 3rd countries)</u>	Fairly beneficial
<u>Impact on the administrative burden imposed on business</u>	Fairly beneficial
<u>Impact on innovation and research</u>	Very beneficial
<u>Impact on employment and jobs</u>	Very beneficial
<u>Environmental impact (EU and 3rd countries)</u>	Very beneficial
<u>Socio-economic impact (3rd countries in particular)</u>	Very beneficial

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

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

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

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

2.1.5 Preference: Option 1: No changes ‘One size fits all’

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>	Not relevant
<u>Impact on consumer rights</u>	Not relevant
<u>Impact on competitiveness, markets and trade (including 3rd countries)</u>	Fairly beneficial
<u>Impact on the administrative burden imposed on business</u>	Fairly beneficial
<u>Impact on innovation and research</u>	Very beneficial
<u>Impact on employment and jobs</u>	Very beneficial
<u>Environmental impact (EU and 3rd countries)</u>	Very beneficial
<u>Socio-economic impact (3rd countries in particular)</u>	Very beneficial

Opt 2: Centralised risk assessment and authorisation procedure

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

2.2.3 Preference: Option 1: No changes (decentralised assessment and authorisation procedure)

2.3 Authorisation decision?

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

<u>Impact on public health and food safety</u>	Not relevant
<u>Impact on consumer rights</u>	Not relevant
<u>Impact on competitiveness, markets and trade (including 3rd countries)</u>	Fairly beneficial
<u>Impact on the administrative burden imposed on business</u>	Fairly beneficial
<u>Impact on innovation and research</u>	Very beneficial
<u>Impact on employment and jobs</u>	Very beneficial
<u>Environmental impact (EU and 3rd countries)</u>	Very beneficial

Socio-economic impact (3rd countries in particular) Very beneficial

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

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

Opt 3: Generic authorisation + data protection for certain foods

Impact on public health and food safety Not relevant
Impact on consumer rights Not very beneficial
Impact on competitiveness, markets and trade (including 3rd countries) Fairly beneficial
Impact on the administrative burden imposed on business Fairly beneficial
Impact on innovation and research Not very beneficial
Impact on employment and jobs Not very beneficial
Environmental impact (EU and 3rd countries) Very beneficial
Socio-economic impact (3rd countries in particular) Very beneficial

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

Impact on public health and food safety Not relevant
Impact on consumer rights Very beneficial
Impact on competitiveness, markets and trade (including 3rd countries) Fairly beneficial
Impact on the administrative burden imposed on business Fairly beneficial
Impact on innovation and research Very beneficial
Impact on employment and jobs Very beneficial
Environmental impact (EU and 3rd countries) Very beneficial
Socio-economic impact (3rd countries in particular) Very beneficial

2.3.5 Preference: Option 1: No changes: Authorisation linked to the applicant (only applicant able to market)

2.4 Submission of application for several food uses

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

Impact on public health and food safety Not relevant
Impact on consumer rights Not relevant
Impact on competitiveness, markets and trade (including 3rd countries) Fairly beneficial
Impact on the administrative burden imposed on business Fairly beneficial
Impact on innovation and research Neutral
Impact on employment and jobs Not very beneficial
Environmental impact (EU and 3rd countries) Very beneficial
Socio-economic impact (3rd countries in particular) Very beneficial

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

Impact on public health and food safety Not relevant
Impact on consumer rights Not relevant
Impact on competitiveness, markets and trade (including 3rd countries) Fairly beneficial
Impact on the administrative burden imposed on business Fairly beneficial
Impact on innovation and research Neutral

<u>Impact on employment and jobs</u>	Very beneficial
<u>Environmental impact (EU and 3rd countries)</u>	Very beneficial
<u>Socio-economic impact (3rd countries in particular)</u>	Very beneficial

2.4.3 Preference: Option 1: No changes: Separate applications for different food uses

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>	Not relevant
<u>Impact on consumer rights</u>	Neutral
<u>Impact on competitiveness, markets and trade (including 3rd countries)</u>	Fairly beneficial
<u>Impact on the administrative burden imposed on business</u>	Fairly beneficial
<u>Impact on innovation and research</u>	Very beneficial
<u>Impact on employment and jobs</u>	Very beneficial
<u>Environmental impact (EU and 3rd countries)</u>	Very beneficial
<u>Socio-economic impact (3rd countries in particular)</u>	Very beneficial

2.5.3 References : UNIDAD DE NORMAS Y REGULACIONES MINISTERIO DE AGRICULTURA DE GUATEMALA. www.unr.gob.gt