Network on Novel Foods
Minutes of the 2nd meeting

Held on 19-20 November 2018, Parma

(Agreed on 13 December 2018)

Participants

- **Network Representatives of Member States (including EFTA Countries):**

Country	Name
Austria	Klaus RIEDIGER
Belgium	Thibault FIOLET
Bulgaria	Svetlana TCHERKEZOVA
Cyprus	N/A
Croatia	Lea POLLAK
Czech Republic	Anna HOSTALKOVA
Denmark	Hanne BOSKOV HANSEN and Heddie MEJBORN[1]
Finland	N/A
France	Sabine HOUDART[1]
Germany	Regina SCHUMANN and Marcel DUHS[1]
Greece	Dimitra PAPADIMITRIOU
Hungary	Anita MACZO
Ireland	Patrick O'MAHONY
Italy	Valeria DI GIORGI GEREVINI
Latvia	Inese SIKSNA
Lithuania	Zygimantas JANELIUNAS
Luxembourg	N/A
Malta	N/A
Netherlands	Clemens VAN ROSSUM and Marja RUTGERS[1]
Poland	Justyna CIEŚLAK
Portugal	N/A
Romania	Daniela NUTA
Slovakia	Alzbeta MEDVEDOVA and Petra VANKOVÁ[1]
Slovenia	Urska BLAZNIK
Spain	Vicente CALDERÓN PASCUAL
Sweden	Bettina JULIN
United Kingdom	Ruth WILLIS
Iceland	N/A
Liechtenstein	N/A

[1] Participated via web-meeting (P. Vankova only on 20/11)

Norway	Gro MATHISEN
Switzerland (Observer)	Barbara ENGELI

- **Hearing Experts**

None

- **European Commission:**

Rafael Perez Berbejal (EC representative)

- **EFSA:**

Nutrition Unit: Valeriu Curtui (Chair), Reinhard Ackerl, Paolo Colombo, Wolfgang Gelbmann, Tilemachos Goumperis, Leng Heng, Annamaria Rossi, Emanuela Turla and Ermolaos Ververis.

SCER Unit: Bernard Bottex (item 6)

1. Welcome and apologies for absence

Valeriu Curtui (head of the EFSA Nutrition Unit, and Chair of the meeting), welcomed participants and opened the meeting.

28 participants from 24 Member States (MS) attended the meeting. Apologies were received from Estonia.

The Chair reminded participants of the Terms of Reference[2] of the NF Network, highlighting the objectives and the expected role of members.

2. Adoption of agenda

The agenda was adopted without changes.

3. Re-cap on action points from 1st meeting

- A draft document on "the approach and methodologies for assessing traditional foods from third countries" was emailed by EFSA to members of the NF Network to receive further input and comments *(see item 5.2).*
- EFSA, during the four-month assessment period established by Article 15 of the novel food regulation, has shared preliminary findings and considerations on the Traditional Food (TF) from third countries concerned with the MS and explained the rational before deciding whether duly reasoned safety objections should be raised. EFSA has shared with MS (between days 70-90) its draft assessment, i.e. "Preliminary Technical Report", for the first three TF notifications assessed (i.e. Haskap berries, Fonio grains, Sorghum syrup) via EC e-submission platform.

The possibility to share preliminary assessment on the TF was in principle welcomed by the members of the network. However, some MS were careful on the approach during the assessment of the first three TF notifications, pointing to the need for gaining more experiences with assessment of TF.

[2] The Terms of Reference of the EFSA Scientific Network on Novel Foods were endorsed at the 64th meeting of the EFSA Advisory Forum which was held on 8-9 June 2017: https://www.efsa.europa.eu/en/events/event/170608

For MS who do not have yet access to the e-submission tool, EC representative encouraged members/the risk assessors to contact their risk managers for granting them access to join this consultation.

4. Feedback from the European Commission (EC) on the implementation of Regulation (EU) 2015/2283

The EC representative provided an update concerning the number of TF notifications and NF applications received so far by EC (*85 NF applications and 25 TF notifications*) through the e-submission tool and their status, showing the magnitude of the expected increase in workload.

An update of new features, the role and functions, introduced into the e-submission tool were presented. Attention has been drawn to how the "identity" of a TF/NF is described. Feedback by MS on the e-submission tool was positive, and some ideas for improvement have been suggested by MS and EFSA (*e.g. a calendar giving an overview of TF notifications and consultation timing*).

The procedure through which a TF notification is validated by the EC was also presented.

Key elements drawn from experience in using the EC e-submission tool for consultation purposes were outlined. Criteria for raising "duly reasoned safety objections" to a TF notification have been further explained by the EC representative, emphasising that objections should be substantiated. In this context, EC encouraged MS to make more use of the e-submission tool for consultation purposes: to bring the attention of other MS and EFSA on potential issues before making a decision whether duly reasoned safety objections should be raised.

5. Assessment of TF notifications: Approach and methodologies

5.1. Approach and methodologies applied by MS

Representatives from Belgium, the Netherlands, Ireland, Germany, Austria, Sweden and the United Kingdom presented the process, their approaches and methodologies for assessment of TF notifications. MS shared their insights and reflected on their experiences during the initial learning phase with assessment of TF notifications, the use of e-submission tool for consultation purposes, and the challenges faced.

It has been generally concurred that poor quality of data received in the notifications is of concerns. Non-adherence to EFSA guidance was specifically pointed out. While some MS indicated that a scientific assessment cannot be performed owing to the "deficit" of the notification received, other performed additional literature search.

Acknowledging that no consultation with applicants is foreseen by the Regulation once the notification is declared valid, the validation phase carried out by EC was considered an important step.

Need to instruct applicants how to prepare notifications has been underlined by some MS, in order to increase the quality of received notifications. EFSA cannot provide pre-submission consultation to

individual applicants, but contributes by replying to questions for clarifications related to the EFSA guidance documents.

In addition to the overall quality/completeness of notifications and the lack of consultation with applicants, the other challenges pointed out by MS included: lack of clarity regarding the "identity" of TF, documented history of use (reliability of data, extent/type of use), use of batch testing for hazard identification and characterisation, specifications, production of a TF in other areas than the traditional ones, and difficulties with the extrapolation of a TF into the diet of a new population group.

With regard to potential residues/contaminants and the specifications of TF, the EC representative pointed out that in principles contaminants should comply with the existing EU regulations in force unless there are some safety driven elements which are not covered by the existing EU regulations.

Some MS asked EFSA whether it could also share with MS other information in addition to the "Preliminary Technical Report", such as the results of the literature search performed. It was agreed *EFSA will be sharing with MS its preliminary results of the literature search performed on the TF notifications*. Similarly, EFSA emphasised its appreciation if also MS would share their preliminary findings on the TF.

5.2. Approach and methodologies applied by EFSA

EFSA presented an updated draft document on the approach and methodology applied for the assessment of a TF notification. In this context, EFSA clarified that hazard identification and characterisation are performed based on the data provided in the notification, and also on additional systematic search of literature to retrieve information, taking into account health-based guidance values if available and exposure. EFSA will not perform a full risk characterisation, but will raise "duly reasoned safety objections" in case the applied approach indicated that the consumption of the TF under the proposed conditions of use may pose a risk to the EU consumer.

It was noted that looking for additional data which were not provided by the applicant is challenging owing to the 4-month time period.

EFSA presented three practical examples of TF notifications that have been assessed so far to depict the process, data sources, the approach for assessing TF, and the issues encountered.

Some MS pointed out that it is unclear how the history of safe use in a non-EU country is demonstrated by the applicant, and its importance for the safety evaluation.

6. Systematic literature search – example of plants (COMPENDIUM)

EFSA gave an insight on the systematic literature search performed for plant-based NF/TF, in particular the methodology and the contribution from the Scientific Committee Working Group Compendium.

In order to identify and characterise potential hazards of plant-based NF/TF, the literature search, which is carried out by a contractor, has been based on the methodology defined for the Compendium of Botanicals and include an additional search to retrieve information related to "Allergic reactions".

An overview of EFSA's Compendium of Botanicals was given. It is a hazard database of plants reported to contain naturally occurring substances of possible concern for human health when present in food. It contains about 2,700 plant species listed in and outside of Europe by Competent Authorities or professional organisations, and includes information related to the botanical family/species/plant parts, toxicity information (oral intake only) and relevant composition data (qualitative and quantitative if available). The criteria and approach used for the searching/screening of scientific literature, and for how the data collected are reviewed and validated for transferring to the database, were outlined.

7. Systematic literature search – example of non-plants

EFSA gave a presentation on the systematic literature search that will be conducted for NF/TF of non-plant origin, e.g. insects, fungi (mushrooms, yeast, molds), algae and chemically defined substances. In this context, EFSA will be adapting the methodology used for the Compendium of Botanicals and extending the systematic literature search to other non-plant based NF/TF.

EFSA updated the MS on the number and the status of NF applications/TF notifications related to insects received (see EFSA Register of Questions for information). EFSA drawn members' attention to the Scientific Committee opinion on the risk profile related to production and consumption of insects as food and feed (published in 2015), and national reports and guidelines on insects published by EU Member States.

8. Ways for improvement - communication with MS for advance sharing of information/comments:

It was stressed again the importance that all members of the network have access to the e-submission tool for NF applications/TF notifications.

MS expressed appreciation in EFSA's commitment of sharing its draft preliminary technical report on TF notification in advance from the end of the 4-month time period.

With respect to Article 10 NF applications, EFSA discussed with MS the usefulness of a 2-month consultation with MS upon receipt of a valid NF application. MS with experiences in safety assessment of NFs could raise specific issues to EFSA. MS highlighted the limited resources available for such activity.

There was a question whether correspondences with applicants related to stop-the-clock letters for requesting additional information for NF applications are accessible. The EC representative clarified the information related to stop-the–clock letters are available in the e-submission tool, and the new features introduced will highlight the new information.

9. Ways forward for the Network on Novel Foods

The Chair reminded participants that the mandate of the EFSA Scientific Network on Novel Food was approved by the Advisory Forum, and it will be subject to evaluation after 3-years of its existence. Collaboration will be one of the key elements for the evaluation of this Network. Participation to the Network is not mandatory, but is open to all EU MS and should serve as a platform for collaboration.

MS, which identified specific questions of scientific nature relevant to NF/TF that require scientific discussions under the framework of the NF Network, are invited to frame the question and provide the background information, and make a proposal to EC. The EC may decide on the appropriateness to bring the issues to the EFSA Network on NF. In this context, tele-meetings can be organised to serve that specific purpose.

10. Any Other Business

None.

11. Summary of the chair/Conclusions

- The **e-submission tool** was highly appreciated.
- **Quality** of data/notifications of TF received was highlighted as the main concern by MS, during the validation phase. Non-adherence to EFSA Guidance was pointed out.
- Acknowledging **the lack of a consultation** phase with applicants once the notification is declared valid, **the validation** phase is a very important step.
- Criteria for raising "**duly reasoned safety objections**" to a TF have been further explained by the EC representative, emphasising that Objections should be substantiated. EC invited MS to make use of consultation phase" for pro-active/discussion before making objection.
- Need to instruct applicants to increase quality of submitted dossiers. **EFSA cannot provide pre-submission meetings** to individual applicants, but contributes by replying to questions for clarifications related to the guidance documents.
- **EFSA will share with MS its updated draft document** on the approach and methodologies applied for assessing TF. The document is not for publication, but will be revised with additional experiences gained.
- **EFSA will continue sharing with MS its preliminary assessment on TF** (draft Technical Report).

12. Closure of the meeting

The Chair thanked all participants for the fruitful discussions.