

NUTRITION UNIT

NETWORK ON NOVEL FOODS

MINUTES OF THE 3RD MEETING

**Held on 14 November 2019, Parma
(Agreed by written procedure on 28 November 2019)**

Participants

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

Country	Name
Austria	Klaus RIEDIGER
Belgium	Jean POTTIER ¹ and Isabelle LAQUIERE ¹
Bulgaria	Svetlana TCHERKEZOVA
Cyprus	-
Croatia	-
Czech Republic	Anna HOSTALKOVA ¹
Denmark	Hanne BOSKOV HANSEN
Estonia	-
Finland	-
France	Sabine HOUDART ¹
Germany	Marcel DUHS ¹
Greece	Dimitra PAPADIMITRIOU
Hungary	Anita MACZO
Ireland	Patrick O'MAHONY
Italy	Valeria DI GIORGI GEREVINI ¹
Latvia	Inese SIKSNA
Lithuania	-
Luxembourg	-
Malta	-
Netherlands	Clemens VAN ROSSUM
Poland	Justyna CIEŚLAK
Portugal	-
Romania	Daniela NUTA
Slovakia	Alzbeta MEDVEDOVA
Slovenia	Urska BLAZNIK
Spain	Ricardo LOPEZ RODRIGUEZ
Sweden	Bettina JULIN ¹ and Mia KRISTERSSON ¹
United Kingdom	-
Iceland	-
Liechtenstein	-
Norway	Bente MANGSCHOU ¹
Switzerland	Barbara ENGELI

¹ Participated via web-meeting

- Hearing Experts²:
Not applicable
- European Commission (EC) representatives:
Rafael Perez Berbejal (DG SANTE)
- EFSA:
Nutrition Unit: Valeriu Curtui, Lucien Ferreira, Wolfgang Gelbmann and Emanuela Turla (Chair)
SCER Unit: Bernard Bottex (agenda item 8)

1. Welcome and apologies for absence

The Chair welcomed the participants and opened the meeting.

14 participants from 13 Member States (MS) and Switzerland attended the meeting. Nine participants from 6 MS (Belgium, Czech Republic, France, Germany, Italy, Sweden) and Norway were connected via web-conference. Apologies were received from 9 MS (Cyprus, Croatia, Estonia, Finland, Lithuania, Luxembourg, Malta, Portugal, UK), Iceland and Liechtenstein.

The Chair reminded participants of the [Terms of Reference](#)³ of the novel food (NF) Network, highlighting the objectives and the expected role of members.

2. Declaration of interests and statement of confidentiality

The Network representatives signed a statement of confidentiality through the submission of their Annual Declaration of Interests.

3. Adoption of agenda

The [agenda](#) was adopted without changes.

4. Agreement of the minutes of the 2nd meeting of the Novel Foods Network, held on 19-20 November 2018 in Parma

The [minutes](#) of the 2nd Novel Foods Network meeting held on 19-20 November 2018 were agreed by written procedure on 13 December 2018 and published on the EFSA web-site.

5. Re-cap on action points from the 2nd meeting

The Chair summarised the main points which were raised at the previous meeting.

² As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>

³ 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>

- The validation of traditional (TF) notifications was considered an important step, in particular in relation to the completeness and quality of the data in the TF notifications.
- Prior to submitting 'duly reasoned safety objections', MS were invited to pro-actively discuss and exchange the relevant issues with other MS and\or EFSA through the EC e-submission tool.
- EFSA shared with MS its approach and methodologies applied for assessing TF notifications.
- EFSA was welcome to continue sharing with MS its preliminary assessment on TF notifications ('preliminary Technical Report') both via the EC e-submission tool and via the Network. EFSA also committed to share with MS the results of the literature search performed on TF.

6. 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 the EC through the e-submission tool and their status (156 NF applications and 44 TF notifications).

An update of new functionalities and features, which were introduced into the e-submission tool, were presented. The User Guide on the e-submission tool will be updated to reflect the changes introduced in the e-submission tool.

The EC representative informed that under the Commission initiative 'Better Training for Safer Food (BTSF)' specific training on how to prepare TF notifications will be offered to officials from Competent Authorities in the beneficiary third countries involved in the training programme.

7. Assessment of TF notifications: shared experience; approach and methodologies

7.1. Approach and methodologies applied by MS

MS were invited to share their experience in assessing TF notifications.

MS acknowledged the importance of the 'history of use' of TF in a third country, which represents one of the two key legal requirements for TF either during validation or during the 4-month assessment period. MS noted that for some recent TF notifications the intended uses of the TF in EU 'deviated' from the traditional uses of the TF in the third country. It was acknowledged that modern technologies used for producing the TF may lead to compositional differences in the TF intended to be put in the EU market as compared to the TF traditionally produced and consumed in a third country.

MS acknowledged that the 'specifications' of TF represent a challenge, in particular in consideration of the 'generic' nature of the authorisation of TF in EU. Concerns were expressed on how to deal with compounds (such as contaminants when they are not regulated by cross-cutting Regulations) or substance of potential concern. EFSA highlighted that it would propose to include additional parameters in the specifications proposed by the applicant, owing to safety concerns.

MS expressed their appreciation in receiving the EFSA 'preliminary Technical Report' in advance from the end of the 4-month assessing period for TF notifications. Appreciation was also expressed towards EFSA for promptly sharing with MS its literature search on TF at the very beginning of the 4-month assessing period.

7.2. Approach and methodologies applied by EFSA

EFSA presented the approach and methodologies applied in the assessment of TF notifications. In particular EFSA indicated that hazard identification and characterisation are based on the data provided in the notification and on additional publications which are retrieved through a dedicated literature search applied for TFs.

EFSA presented the steps in the 4-month assessing period of TF notifications, which have been consolidated in the last year and consisted in sharing with MS the literature search performed by EFSA, as well as the 'preliminary' and 'final' Technical Reports of TFs.

EFSA presented practical examples of TF notifications that have been recently assessed and for which duly reasoned safety objections were raised by EFSA (Moringa stenopetala leaf powder; powder and concentrated juice of Maqui berries). EFSA outlined the critical issues encountered for these two TF notifications and highlighted the importance to integrate the data provided by applicants with publications retrieved through a dedicated literature search to identify hazards potentially present in the TF. EFSA noted the lack of qualitative and quantitative information of undesirable substances potentially present in these TFs. The expected uses and use levels of these TFs in EU 'deviated' from the historical uses and use levels of the TFs in the third country. In this respect, EFSA noted the uncertainty regarding the potential exposure of the TFs if marketed in the EU at proposed uses and use levels, as the exposure levels in EU may exceed historical intakes in the third country.

EFSA also presented the assessment of other two TF notifications on cocoa pulp for which no duly reasoned safety objections were identified by EFSA. EFSA also provided an update on on-going TF notifications.

EFSA highlighted some elements from the experience gained in the assessment of TFs, which may serve as a basis to update the EFSA Guidance on the preparation of TF notifications. EFSA invited the Network to share ideas and proposals for the future update of the EFSA Guidance on the preparation of TF notification.

8. Update on the EFSA Compendium of Botanicals

EFSA provided an overview on the work done on the Compendium of Botanicals from 2004 to 2019. A web-based database containing approximately 2,700 plants will be released in 2020. Plants will be searchable via plant names, groups of chemicals or substances of possible concern. EFSA presented the development of the Compendium of Botanicals for 2019-2023, which consists in characterising in a systematic manner the toxicity of approximately 2,500 specific substances, which are listed in the EFSA Compendium of Botanicals and are of possible concern for human health.

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

EFSA highlighted the importance for MS (and Norway) to have access to the EC e-submission tool for both NF applications and TF notifications.

EFSA highlighted that the Network is a dedicated forum for discussion of issues related to the safety assessment of NF and TF.

With respect to Article 10 NF applications, EFSA acknowledged that at the last Network MS highlighted the limitation in resources to provide their contribution in the first 2-months of the assessment of NF applications. EFSA reiterated the invitation to MS to contribute during the initial phase of the assessment of NF applications.

10. Ways forward for the Network on NF

The Chair reminded participants that the 'Terms of Reference' of the Network on NF, which was approved by the Advisory Forum in 2017, has a 3-year duration. The Chair indicated that there is the possibility to renew the Network on NF.

MS acknowledged the importance of the Network on NF as a platform for exchanging information on the assessment of NF and TF and expressed their view to renew the Network NF. Thus, a request to renew the Mandate of the Network on NF will be presented to the Advisory Forum.

11. Any Other Business

Upon a request from a MS, EFSA provided an update on an electronic tool, which is currently under development by EFSA, on the exposure assessment of NF and TF. The electronic tool is based on the EFSA FoodEX2 classification system.

12. Summary of the Chair/Conclusions

- The improvement of functionalities in the EC e-submission tool was highly appreciated.
- The Network acknowledged the importance of the validation phase of TF notifications, particularly in relation to the completeness and quality of data in the TF notifications.
- The Network acknowledged the importance of pro-actively discussing and exchanging relevant issues on TF notifications through the EC e-submission tool, prior to submitting 'duly reasoned safety objections'.
- EFSA will continue sharing with MS the literature search as well as its preliminary and final assessment on TF.
- Based on the experience gained in the evaluation of TF notifications and NF applications, EFSA will update the EFSA guidance on the preparation of TF notifications and NF applications.
- EFSA will provide updates on the developments of the EFSA's Compendium of Botanicals.
- EFSA will submit to the Advisory Forum the request to renew the Network on NF.

13. Closing of the meeting

The Chair thanked all participants for the fruitful discussion.