Network on Novel Foods
Minutes of the 1st meeting

Held on 8-9 November 2017, Parma

(Agreed on 7 December 2017)

Participants

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

Country	Name
Austria	Klaus RIEDIGER
Belgium	N/A
Bulgaria	Svetlana TCHERKEZOVA
Cyprus	N/A
Croatia	Lea POLLAK
Czech Republic	Anna HOSTALKOVA / Karolina MIKANOVA
Denmark	Heddie MEJBORN
Estonia	Ivi JOUDU
Finland	Tero HIRVONEN
France	Irini MARGARITIS
Germany	Regina SCHUMANN
Greece	Dimitra PAPADIMITRIOU
Hungary	Anita MACZO
Ireland	Patrick O'MAHONY
Italy	Valeria DI GIORGI GEREVINI
Latvia	Elina CIEKURE
Lithuania	N/A
Luxembourg	N/A
Malta	N/A
Netherlands	Marja RUTGERS / Clemens VAN ROSSUM
Poland	N/A
Portugal	N/A
Romania	Daniela NUTA
Slovakia	Alzbeta MEDVEDOVA
Slovenia	Pavel POLLAK
Spain	Vicente CALDERÓN PASCUAL
Sweden	Bettina JULIN
United Kingdom	Ruth WILLIS
Iceland	N/A
Liechtenstein	N/A

Country	Name
Norway	Bente MANGSCHOU[1]
Switzerland (Observer)	Barbara ENGELI

- **Hearing Experts**

None

- **European Commission:**

Rafael Pérez Berbejal (EC representative)

- **EFSA:**

Nutrition Unit: Valeriu Curtui (Chair), Reinhard Ackerl, Agnès De Sesmaisons-Lecarré, Wolfgang Gelbmann, Andrea Germini, Leng Heng, Leonard Matijevic, Emanuela Turla, Mathias Amundsen and Ermolaos Ververis

Henk van Loveren (Chair of WG on Novel Foods)

1. Welcome and apologies for absence

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

25 participants from 23 Member States (MS) attended the meeting.

2. Tour de table

All participants presented themselves during a tour de table.

3. Adoption of agenda

The agenda was adopted without changes.

4. The scope of the Novel Food (NF) Network and the role of members

The Chair explained the background and presented the Terms of Reference[2], as endorsed by EFSA's Advisory Forum during its 64th meeting, establishing the NF Network. The objectives and the expected role of members were highlighted.

Specifically, the NF network aims: to facilitate exchange of information and collaboration in the area of NF; to discuss and harmonise a methodology for searching for information and the approach to streamline submission of "duly reasoned safety objections" for traditional foods (TF) from third countries in accordance with Article 15 of Regulation (EU) 2015/2283; and to avoid duplication.

Members/Alternates are required to act as a communication point for relevant organisations and stakeholders within their MS, ensuring the timely exchange of

[1] Participated on 8 November.

[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

scientific information between these national organisations and EFSA. Members/Alternates are also required to comply with the rules of confidentiality.

The Chair also addressed some administrative issues pertinent to the working methods of the NF Network, including the confidentiality rules and the reimbursement rules in accordance with EFSA's experts compensation guide.

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

The EC representative provided an update concerning the legislative framework, particularly the status of the draft implementing acts laying down administrative and scientific requirements for NF applications and TF from third countries, transition measures and measures concerning the Union list of NF.

In view of the coming into force of Regulation (EU) 2015/2283 as of 1 January 2018, an e-submission system for NF applications and TF notifications was presented, with an outline on the system features, the workflows, the request for information option, and the roles of MS and EFSA.

Member States will have read-only access to NF applications (when acknowledged). Regarding TF notifications, MS may consult with other MS and EFSA, and may submit to EC duly reasoned safety objections.

EFSA will have access to perform suitability (completeness) checks and safety assessments of NF applications, including the option of requesting information to the applicant. For TF notifications, EFSA may consult with MS and may submit to EC duly reasoned safety objections.

It was emphasised that the e-tool is a pilot version. The initial implementation will have the minimum elements of the workflow to make the system useful. The workflow may be refined in later versions based on user experience.

For some MS, where risk assessment is separated from risk management and especially in countries where the national internal structure allocates the two bodies in different organisations, there was a concern that there is too little time to consult with other MS and EFSA, particularly when notifications will be directed first to the risk manager, and if the risk assessors need approval from their risk managers before they can provide their input to the consultation. *The EC representative emphasised that the possibility for consultation has been introduced as a platform to facilitate exchange of information and scientific considerations between MS and EFSA, but participation in such consultation with other MS and EFSA is optional, comments made in this consultation have no legal meaning, and any comments made in such consultation cannot be binding for the decision on whether or not to raise "duly reasoned safety objections". The consultation option and the possibility of raising objections are two different features of this e-tool and independent from each other.*

A question was posed with regards to the handling of a possibly high number of notifications received within a short period of time. *The EC pointed out that prioritisation will have to be carried out for their validation.*

Regarding user access to the e-submission system, there were questions about the number of licences available and whether the experts (Working Group/Panel) could have access. *The EC representative clarified that users must have a valid*

EU login to access the systems (EU login Authentication), that export application in zip is feasible for EC/EFSA/MS, and that there is no limitation to the number of licences. However, the latter will be further checked by the EC.

There were comments about the procedure for determination of NF status/scope. *It was clarified that the check on whether the NF falls under the scope of NF Regulation is outside the remit of EFSA, and that the e-submission system does not apply to Article 4 of Regulation (EU) 2015/2283 (i.e. Procedure for determination of novel food status).*

6. Questionnaire: Discussion & feedback from Member States

In order to prepare for the coming into force of Regulation (EU) 2015/2283, members were asked to complete a questionnaire ahead of the network meeting.

One objective was to collect information on how NF applications have been assessed so far by MS when preparing the initial assessment report and when providing comments by day 60; the second objective was to gather information/ideas on the approach and methodologies MS intend to apply for the assessment of TF notifications within the 4 months.

6.1. Assessment of NF applications: approach/methodologies applied by Member States for the initial assessment report and for the commenting phase

The survey outcome was summarised and the following was noted:

- The assessment of NF dossiers was performed either by scientific staff in the organisation, by a scientific committee, was contracted to external experts (in combination with scientific staff/committee), or was performed by scientific staff in combination with Federal States/Academia (University).
- When preparing the initial assessment report, most MS did not limit the assessment only to the data in the dossier, but looked for additional information on a case-by-case basis.
- When commenting by day 60, some MS limited their assessment only to the data in the dossier, while other MS looked for additional information on a case-by-case basis.
- When looking for additional information, the approach applied by MS includes: expert knowledge/experience, data from comprehensive/ literature search, previous evaluations of related substances in other fields (e.g. as food additives), national guidelines/databases, and additional data requested from applicants. In this context, a number of databases were identified by MS as relevant to the Network.

Representatives from Ireland, Germany and the Netherlands presented their experience gained from NF assessments and from the 60-day commenting phase. Other Member States reflected on their experience, challenges, and provided additional considerations.

While the importance of expertise was highlighted, limitation of resources is an issue. NF assessments require multidisciplinary experts, and pending on the type of NF a case-by-case approach is needed.

6.2. Assessment of Traditional Food (TF) notifications: approach/methodologies Member States intend to apply

The second objective of the survey launched by EFSA was to gather the view of MS on how they will approach the assessment of TF notifications under Article 14 of Regulation (EU) 2015/2283. Most MS indicated that the decision whether or not to look for additional data (not contained in the dossier) will be based on case-by-case considerations. Others indicated that they will limit their assessment to the data provided in the notification dossiers, while another MS may look for additional data by default. MS stressed that definitive decisions on their approach have not been made yet.

The representative from Austria presented his remarks on the assessment of TF notifications, outlining the importance of looking for data and using networks (including opinions) from other regions. A MS pointed out that owing to a lack of resources, evaluation of TF notifications will not be feasible.

6.3. Proposed approach for the assessment of Article 14 (traditional foods from third countries) notifications

A presentation was given by staff from EFSA's Nutrition Unit proposing that EFSA's considerations on whether or not raising "duly reasoned safety objections" to Article 14 notifications should be based on a risk-based approach (i.e. taking into account also available information on hazard identification and characterisation, health-based guidance values and exposure) rather than only on the basis of a possible or actual presence of a hazard. It was also communicated by EFSA that the proposal foresees that EFSA would not limit its assessment to the information provided in the dossiers. It was noted that applying a risk-based approach and looking for additional data which were not provided by the applicant will be a challenging task given the legal time limit of 4 months given by the Regulation. Taking into account this time constraint, the EFSA proposal suggests not to perform a full risk characterisation, but to 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 for whole foods and other complex foods which cannot be fully characterised, a risk-based approach may often not provide meaningful results owing to incomplete compositional data (i.e. it is not possible to identify all components) or owing to lack of information to perform hazard characterisation of identified substances. In this case, the decision (whether or not to raise "duly reasoned safety objections") may rely less or not completely on a risk-based approach, but more or exclusively on the substantiation of the claimed history of safe food use.

There was discussion as to whether risk assessors should undertake the task of looking for additional data which were not provided in the dossiers, considering

that it is the applicants' responsibility to provide all relevant data. EFSA noted that this is indeed a requirement spelled out in the EFSA Guidance for TF. EFSA also indicated that it was not its intention to look for additional data to demonstrate that the TF is safe, but to undertake some efforts to look for relevant data which were not provided by the applicant and which may help to identify and characterise potential hazards which may pose a risk when considering also the uses and use levels (exposure).

Discussion was made in relation if the identification of allergenicity of a traditional food would only be enough by itself to raise "duly reasoned safety objections" for the safety. EFSA clarified that the relevant information will be communicated to risk managers but will not be a factor to reject the dossier for the safety. EC representative emphasized that the relevant information will be reflected in a specific reference in the labelling of the food prior its release to the market.

EFSA's approach will be further discussed and elaborated by the Working Group on Novel Foods and the NDA Panel, and EFSA will further consult with the NF Network. It is anticipated that the approach may require adaption with the experience gained next year in 2018.

7. Prepare for break-out session: Towards Harmonisation of the assessment of TF notifications

EFSA presented the questions and topics which should be discussed and elaborated in a break out session (agenda item 9).

8. Draft EFSA output on a mock-up notification

In preparation for this network meeting, a mock-up notification was presented as a case study. It had been adapted based on the EFSA approach (outlined under item 6.3) in order to reflect on the efforts and challenges regarding hazard identification, hazard characterisation and exposure assessment. The lessons learned from this exercise were that: attention should be given to scientific and non-scientific synonyms of a food item, including the Latin name, when searching for relevant data; that several databases and sources, taking into account the nature of the TF, should be consulted in order to collect comprehensive information; that the amount of information gathered depends highly on the efforts and number of consulted databases and sources; and that expertise in the relevant field is required to perform a targeted search.

9. Break-out session

The questions discussed in the break-out sessions concerned requirements regarding the compositional characterisation of the traditional food (e.g. number of batches, sources of the batches, geographical, seasonal origin), and number of samples. It was also discussed how risk assessors would deal with incomplete compositional data, and when information is lacking on potential effects of identified substances.

It was also asked whether there are minimum requirements to show that the food has been consumed at a sufficient level in the population group in order to support the safety of the TF, and under which circumstances the history of use could compensate for incomplete compositional data for whole/complex foods.

Finally, the level of detail was discussed at which data on the macronutrients and micronutrients should be documented and what kind of data (or lack of data) would result in "duly reasoned safety objections", because potentially nutritionally disadvantageous for the consumer.

It was highlighted that safety assessment of Article 14 TF notifications will be challenging for all, and it should be a learning process for applicants, MS and EFSA, and the importance of communication was emphasised.

The EC representative pointed out that no clock-stop procedure is foreseen in the NF Regulation to go back to applicants in order to request information during the 4 months TF notifications.

During the discussion, it was stressed that the validity check performed by the EC is critical for the screening of "incomplete" notifications. Some MS questioned the possibility to improve the e-submission system (e.g. by requiring a mandatory field for the applicant to provide the information using the example of plants). In this context, it was pointed out that the duty should be on the applicant to provide the complete information, but the burden should not be on the risk assessors. The EC took note of the issues and clarified that the e-submission system has been developed following EFSA guidance, and that it may be further refined in later versions based on user experience/lessons learned.

10. Any Other Business

- EFSA provided clarifications about *Article 36 tasking Grant* "GP/EFSA/NUTRI/2017/01-Entrusting preparatory work for the safety assessment on Novel Foods and Traditional Foods from third countries" published on the EFSA website: https://www.efsa.europa.eu/en/art36grants/article36/170714. The Network was informed about the extension of the deadline until 17 November.
- Several MS raised the issues faced with the classification of *borderline products*, medicines versus foods/novel foods. However, the classification of products is outside the remit of EFSA but under the responsibility of MS, and therefore it should be addressed in another context, and not in the NF Network.
- With respect to NF applications, EFSA discussed with MS and explored the possibility of a 2 month consultation with MS upon receipt of a valid NF application. EFSA encouraged the risk assessors to get permission from their risk managers (access permission to e-submission tool).

11. Summary of the chair/Conclusions

The audience highly appreciated the EC effort to set up the e-submission tool.

Participants shared the expectation that assessing Article 14 notifications on traditional foods from third countries will be a challenging task when considering

the time constraints, the fact that communication between the applicant and risk assessors is not feasible, and that the required data will be limited to compositional information and data on the history of consumption. It was indicated that EFSA will further elaborate on its approach to assessing TF notifications, and that EFSA invites MS to provide further input and comments.

Considering that the provisions for Article 14 (TF) notifications will introduce a new procedure differing from all other procedures with EFSA involvement, it was generally acknowledged that the exercise will also include "learning by doing" and that it is expected that the applied approach will require adaption and refinement in the course of 2018 and possibly beyond. EFSA also indicated that it intends to make use of the consultation option during the 4 months by providing its preliminary findings and considerations. EFSA emphasised that it would highly appreciate it if also MS would share their findings and preliminary thoughts. EFSA encouraged the risk assessors to get permission from their risk managers (access permission to e-submission tool) to join this consultation while stressing again that any comment made in the consultation would have no legal meaning, and that comments and considerations made in the consultation were not binding for the final outcome.

The EC stressed that the e-submission tool provides two clearly separated features for (1) the consultation, which will have no legal meaning for the EC, and (2) for submitting "duly reasoned safety objections" in accordance with Article 15 of Regulation (EU) 2015/2283.

EFSA thanked all participants for the fruitful discussions.