

**GOVERNMENT OF PAKISTAN  
MINISTRY OF COMMERCE**

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No. 5(1)/2023-Admn-I/HR-I

Islamabad, the 22<sup>nd</sup> May, 2023

**CIRCULAR**

**SUBJECT: - INVITATION PAKISTAN TO BTSE TRAINING SESSION ON NOVEL FOODS-INDIA-31ST OCTOBER-3<sup>RD</sup> NOVEMBER 2023**

Please find enclosed herewith a copy of self explanatory email along with its enclosure, received from Permanent Mission of Pakistan to the WTO Geneva on the above mentioned subject for placing on the website of the Ministry of Commerce.

2. Interested officers, who fulfill the eligibility criteria may send their nominations, duly approved by their respective Head(s) of the Wing(s) to HR-I Section (along with their C.V and details of availed Foreign Training/Workshops etc), latest by 02-06-2023 positively. Nominations received after the deadline will not be entertained.

Encl: As Above



(Aamir Waheed)  
Section Officer (HR-I)

**Database Administrator,  
Ministry of Commerce  
Islamabad**

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**Invitation PAKISTAN to BTSF training session on Novel Foods – India – 31st October – 3rd November 2023**

1 message

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**haja.ranaivo@wto-pakistan.org** <haja.ranaivo@wto-pakistan.org>

Fri, May 12, 2023 at 1:56 PM

Reply-To: **haja.ranaivo@wto-pakistan.org**

To: Deputy Director MoC Ministry of Commerce &lt;ddcommercedivision@gmail.com&gt;

Cc: "ashfaqdcwto@gmail.com" &lt;ashfaqdcwto@gmail.com&gt;, Sadia Sultan &lt;sowto2.moc@gmail.com&gt;, "fahad.raza@wto-pakistan.org" &lt;fahad.raza@wto-pakistan.org&gt;

Dear Sir,

In continuation with my previous message on the captioned subject, please find attached the following documents:

- • an official invitation letter,
- • an information package on the training course and the session in India
- • a blank registration form to be filled in by your selected participants and returned by 19<sup>th</sup> June 2023.

The list of official nominees may please be shared with this Mission.

Best regards,

Haja

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**Haja Ranaivo**  
**Trade Development Officer**  
**Delegation Coordinator**Permanent Mission of Pakistan to the WTO  
37-39 Rue de Vermont. 1211 Genève  
Tel 022 748 70 25 - Fax 022 748 70 29

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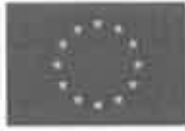
*Save Trees - Think Before Print. Do not print this email unless necessary!*

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**3 attachments** **20189607 - Information to NCPs-1.pdf**  
1204K

 **20189607 - Invitation letter - Pakistan.pdf**  
367K

 **20189607 - Registration form(1).xlsx**  
57K



Funded by the  
Better Training for Safer Food Initiative  
of the European Union

# Better Training for Safer Food

ORGANISATION AND IMPLEMENTATION OF TRAINING ACTIVITIES ON

**EU RULES APPLICABLE TO THE AUTHORIZATION AND PLACING ON  
THE MARKET OF NOVEL FOODS AND TRADITIONAL FOODS COMING  
FROM NON-EU COUNTRIES**

UNDER THE "BETTER TRAINING FOR SAFER FOOD" INITIATIVE

**INFORMATION PACKAGE TO NATIONAL CONTACT POINTS**

**TRAINING SESSION 8**

**DELHI, INDIA, 31 OCTOBER – 3 NOVEMBER 2023**

Project implemented by:



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## 1. The “Better Training for Safer Food” Initiative

Better Training for Safer Food (BTSF) is a Commission training Initiative covering food and feed law, animal health and welfare and plant health rules.

Article 51 of Regulation (EC) No 882/2004 on official controls on food and feed, animal health and animal welfare rules, and Article 2 of Council Directive 2000/29 on protective measures on plants or plant products provide the legal basis for this initiative. They empower the Commission to develop training for competent authority staff in EU countries and non-EU countries responsible for controls in the covered areas.

### 1.1 Main objectives of BTSF

The main objectives of the Initiative "Better Training for Safer Food" are the organisation and development of an EU training strategy with a view:

- To ensure and maintain a high level of consumer protection and of animal health, animal welfare and plant health;
- To improve and harmonise Community and national control procedures;
- To create an equal level playing field for all food businesses;
- To safeguard the safety of food imports from third countries on the EU market, and to reduce risks for EU consumers;
- To boost trade of safe food;
- To ensure fair trade with third countries and in particular developing countries.

## 2. Information on the project

### 2.1. Context

The European Union has developed a strong body of regulations to ensure the protection of its citizens. This is particularly relevant to food safety and innovation. Food and agriculture is a major business in Europe, and facilitating innovation while maintaining safety is a priority. The European Commission has developed a **comprehensive set of laws** that govern the **authorization of Novel Foods**. Novel Foods are defined as those which have not been consumed to any significant extent within Europe prior to May 15th 1997, the date of the first Novel Food legislation (Regulation (EC) No 258/97).



The revised novel food Regulation (EU) 2015/2283 (NFR) covers an increased number of food categories (10 compared to 4 in the old Regulation). New categories specified under Article 3 of the NFR include, foods containing or consisting of animals or their parts (e.g. insects) material of mineral origin, cell or tissue culture microorganisms, animals or plants and engineered nanoparticles... Another new feature of the NFR is the procedure set out in Article 4 whereby a food business can request a determination from a Member State on the novel food status of a food or ingredient. This process is set out in detail in Commission Implementing Regulation (EU) 2018/456.

The NFR has moved the novel food authorisation process to a centralised procedure which allows for a more streamlined process that is more user-friendly for food businesses and regulatory authorities alike. The scientific and administrative requirements for a novel food application are set out in Commission Implementing Regulation (EU) 2017/2469. In brief, an applicant submits a dossier through the Commission's electronic submission system, including relevant technical, scientific and safety information. The Commission then manages all aspects of the submission to its final conclusion. If requested by the Commission, the European Food Safety Authority (EFSA) conducts a rigorous scientific assessment of the evidence provided. EFSA has developed administrative and scientific guidance to assist applicants in compiling an application dossier. The EFSA safety assessment forms the basis for a proposal by the Commission which is voted upon by the Member States. Data protection provisions in the NFR ensure confidentiality of certain information where appropriate. Under normal circumstances, novel food authorisations are generic rather than applicant-specific which they were under the original Regulation. However, where an applicant can demonstrate that proprietary scientific data or information has been critical to the safety assessment and authorisation of a novel food, that data or information may not be used to benefit a subsequent application without the consent of the applicant for a period of five years, after which the authorisation becomes generic. Following authorisation, a novel food is placed on the Union List which was established through Commission Implementing Regulation (EU) 2017/2470. The Union List includes information on the specifications characterising the novel food as well as the food categories in which it may be used, maximum levels and additional labelling or other requirements.

Also introduced by the NFR is the option of a "notification" process for traditional foods from third countries. This process, detailed in Commission Implementing Regulation (EU) 2017/2468 allows an applicant to submit a dossier through the Commission's electronic submission system demonstrating consumption of the traditional food in a third EU country by a significant number of people for at least 25 years. Where EFSA or Member States do not submit reasoned safety objections, the Commission can authorise the food and update the Union List. However, where a reasoned safety objection is submitted, the applicant may either withdraw the notification, or else submit a full application under the regular procedure. EFSA has produced guidance on the preparation and presentation of a notification or subsequent application dossier for traditional foods from third (non-EU) countries.



## 2.2. Objectives

The main objective of the training is to develop cooperation activities on novel food with non EU trade partners with a view to further raise awareness and contribute to a better understanding and more efficient use of existing EU rules applicable to the authorisation and placing on the EU market of novel foods

The specific objectives of this course are for participants to be aware of and understand:

- the EU legal framework relating to Novel Foods and Traditional Foods from third countries
- the various regulatory roles played by the Commission, EFSA and Member States
- the definitions of novel foods and traditional foods from third countries
- How to determine the novel food status of a food or ingredient
- the rules that apply to authorisation procedures for both novel foods and traditional foods from third countries
- the principles of risk assessment used by EFSA
- the guidance documents related to Article 10 of the NFR for novel foods and Article 14 for traditional foods to help to prepare submission documents
- the information needed to be able to apply for novel foods or traditional foods to be included in the Union List

## 3. Training Programme

### 3.1. Topics covered

In order to reach the indicated objectives, the following topics will be addressed:

- What is new on novel foods and on traditional foods from third countries
- The EU legal framework applicable to Novel Foods and Traditional Food from third countries
- The EU/National regulatory bodies involved in assessment and authorization of novel and Traditional foods
- Article 4 requests
- The major novel foods and traditional foods and their classification
- Categorisation of novel and traditional foods





- The Regulation 2015/2283
- How to prepare a novel foods application
- How to prepare a traditional foods notification and application
- The outcome of a successful application
- The differences between risk assessment (what EFSA actually does) and risk management (how the Member States and the Commission in the Novel Foods WG respond)
- How to submit a dossier through the e-submission system
- Labelling of Novel Foods

### 3.2. Methodology

The training sessions will be held on 4 days (2 half days and 2 full days). It will start in the afternoon of the first day, and end at midday of the fourth day.

The training programme is a mix of interactive presentations, workshops and discussion sessions. It is distributed in the 4 panels as follows:

#### Panel I: Background for constructing a dossier

- Overview of the EU legal framework applicable to Novel Foods and Traditional Food
- Overview of the EU/National regulatory bodies involved in assessment and authorization of novel and Traditional foods and Article 4 requests
- Classification of Novel and Traditional Foods
- Uncertainty analysis on Novel Foods

#### Panel II: Preparation of a dossier

- How to prepare Novel Food and Traditional Food Notifications and Applications
- Principles of risk
- How, to submit a dossier through the e-submission system
- What is the outcome of a successful application – Union list of novel food.

#### Panel III: Management of a dossier

- Scope of the authorisation including specifications, conditions of use, post-market monitoring requirements, confidentiality, history of consumption
- Labelling of Novel Foods and additional specific labelling requirements

#### Panel IV: Summary and wrap up



### 3.3. Overview of the training programme

The detailed training programme can be found in annex to this document. It presents the different training activities of the session, their objectives and a brief description of the content they will cover.

## 4. Invited countries

The training session will bring together 33 representatives from 7 different countries: Bangladesh, Bhutan, India, Nepal, Maldives, Pakistan, Sri Lanka

Each invited country has been allocated a certain numbers of seats, which you can find in the table below.

Invited Countries	Number of allocated seats
Bangladesh	4
Bhutan	3
India	12
Nepal	4
Maldives	3
Pakistan	4
Sri Lanka	3
TOTAL : 33	

**Important Note:** these 33 participants are “funded participants”. The costs related to their participation will be fully covered by the project. They should meet the requested profile described in the following section.

As a National Contact Point, you should identify and submit **AT LEAST** the number of participants according to the number of seats your country has been allocated. You are welcome to submit **MORE** participants than expected as “reserve candidates”. These will be offered a seat if available. For information on how to submit participants, please refer to chapter 5.4.1. “Responsibilities of the NCPs”.



## 5. Selection of participants

### 5.1. “Funded participants”’ profile

The course is addressed to officials from Competent Authorities in the beneficiary non-EU countries involved, preferably at central level, verifying compliance with rules applicable to placing novel foods and traditional foods on the EU market and from one of the following categories:

- Decision/policy makers / senior officers from Food safety competent authorities
- Decision/policy makers / senior officers from Food export competent authorities
- Decision/policy makers / senior officers from Public Health competent authorities
- Senior officers from already existing national and/or regional networks on topics links to Novel Food

**Important Note:** each invited country should identify and submit at least the number of participants that is mentioned in the table above (cfr. Section “Invited countries” – extra “reserve candidates are welcome – they will be offered a seat if available). These “funded participants” should meet the profile described here above. The total cost of these participants’ attendance (travel costs, catering, accommodation, etc.) will be covered by the project.

### 5.2. Self-funded participants

People from the following categories can also attend the training session as “self-funded participants”; they are not included in the number of seats per country stated in the table above. These participants are additional and should cover the costs of the participation themselves:

- **National Food associations/ Union companies representatives** might be considered to be invited as they may do the submissions of Novel Food and Traditional Food.
- In the absence of the above, it could be considered personnel from public associations or internationally or nationally funded projects working in the development and support to traditional foods;

**Important Note:** you should disseminate the information about this training course among those categories as well and inform them that they can attend the session as well, but at their own costs.

**Please bear in mind that these participants are not included in the number of seats that your country has been allocated. They should be registered on top of the number of participants that you are invited to submit.**

For these “self-funded participants”, the procedure of registration should be the same as for the “funded participants” (see chapter 5.4.1. “Responsibilities of the NCPs”).

The self-funded participants will be contacted after their registration forms have been received and will be invited to pay for a training package covering the following costs:

- Access to the fully equipped meeting room
- Accommodation (3 nights at the hotel where the session will be held)
- Subsistence (lunches, coffee breaks and dinners for the whole duration of the session)
- Participation to the social event
- Provision of the training material and training documents

This package will be paid to the organizers (prior to the training session), who will take care of booking the accommodation and catering for the self-funded participants. The final price of this training package will be communicated at a later stage.

Please note that the self-funded participants should take care themselves of their transport to/from Delhi, India, and of their transfers to/from the hotel where the session will be held.

### 5.3. Pre-requisites

Prior to the training session, all participants will be asked to:

- provide some examples of the novel foods or traditional foods that could be submitted to the EU Commission
- send some examples of food labelling to reflect on during the course.
- familiarise themselves with following documents (provided to them in advance):
  - The European Union Regulation (EU) 2015/2283 on Novel Foods.



- Commission Implementing Regulation (EU) 2017/2469 on administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 on novel foods,
- Commission Implementing Regulation (EU) 2017/2468 administrative and scientific requirements concerning traditional foods from third countries in accordance with Regulation (EU) 2015/2283 on novel foods.
- Commission Implementing Regulation (EU) 2018/456 on the procedural steps of the consultation process for the determination of novel food status in accordance with Article 4 of Regulation (EU) 2015/2283.
- EFSA Guidance on the preparation and presentation of the notification and application for authorisation of traditional foods from third countries in the context of Regulation (EU) 2015/2283
- EFSA Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283
- EFSA Administrative guidance on the submission of applications for authorisation of a novel food pursuant to Article 10 of Regulation (EU) 2015/2283.
- Example novel foods applications (redacted/made up to avoid identification of particular companies or real submission. In case the real submission is chosen, specific attention will be given to respect RGPD and confidentiality)
- Example traditional food notifications and applications (redacted/made up to avoid identification of particular companies or real submission. In case the real submission is chosen, specific attention will be given to respect RGPD and confidentiality)
- Training pack with presentations and exercises; training pack will also be provided as a printed version and distributed on the spot

## 5.4. Responsibilities

### 5.4.1. Responsibilities of the NCPs

The National Contact Points are requested to:

- **Be aware of the number of participants** funded by the project according to the table presented in the Chapter 4. “Invited countries”;
- **Disseminate the information** to the relevant competent authorities at national level dealing with the contents of the training programme;
- **Select the participants** considering the requested profile, and make them fill in the standard BTSF registration form (attached as an excel form in the communication submitted with this document).



- Send the registration forms the project management mailbox [20189607NF@jvl-c.com](mailto:20189607NF@jvl-c.com) by the set deadline (see Chapter 7. “Deadlines”).
- Be aware of the visa requirements to entry the country where the session will take place.

#### 5.4.2. Responsibilities of the Project Management team

The Project Management team will:

- Verify the compliance of the selected participants with the requested;
- Inform the NCP if the application has been accepted or if there is any aspect to be clarified;
- Organise all logistics for the training session;
- Contact the participants before session to organise their travel to the training location and to send them all relevant and useful information to prepare their participation, and after the session to submit them a questionnaire about the dissemination measures they have taken, considering this is a pre-condition request for participating in the training.

## 6. Organisation of the training session

JVL Consulting will organise all the logistical aspects of the training session in Delhi, India. The project management team can be contacted on the following email address: [20189607NF@jvl-c.com](mailto:20189607NF@jvl-c.com).

### 6.1. Travels

For each funded participant who does not live in the city where the session will take place, the project will provide a return flight ticket or a return train ticket.

Upon arrival, the transfer from the airport or station to the hotel will be arranged by the event manager, as well as the transfer from the training site to the airport on the last day of the training.

Travel costs from the participants' homes to the nearest airport / bus station / train station are covered by the project budget if requested, after presentation of corresponding receipt / invoice of the cost incurred.

### 6.2. Accommodation

The project will provide full-board accommodation for the funded participants for the period of the training:



- Hotel room from 31<sup>st</sup> October to 1<sup>st</sup> November 2023 (3 nights). Extra nights are covered in accordance with flight schedules (unavoidable arrival/departure day before/after the training).
- Breakfasts, lunches and dinners from 31<sup>st</sup> October to 1<sup>st</sup> November 2023.

**Important note:** any additional expenses that may occur during the stay of the participants (e.g. bar consumptions, mini bar, etc.) will be directly paid by the participants, as they are costs not covered by the project.

**No “perdiem” or “pocket money” will be distributed to participants in addition to what is indicated here above. All personal expenses such as individual local transport, mini bar, laundry, room services, and extra drinks/meals will be charged to the participants by the hotel.**

### 6.3. Session and Documentation

For the funded participants, the following costs will be covered by the project:

- Access to fully equipped meeting rooms;
- Participation to the social event.

The project will also provide the following material:

- Stationary (notepad, pen, notepad-holder);
- USB stick containing all the training material in electronic version;
- A group photo;
- A bag for keeping all materials and documentation;

### 6.4. Visa requirements

Most of the invited countries will need an visa (e-visa or paper visa) to travel to India.

<https://india.visaonlinegov.org/>

It is recommended to check with the diplomatic mission of India in your country prior to travel to ensure that you have all the necessary paperwork for travel. We dearly ask the National Contact Points to check if their participants need a visa to entry in the country and to be aware that the application for the visa could take several days.

As NCP, you should confirm that the registered participants have valid passport and facilitate that they receive support from the relevant authorities during the application process.

As soon as the participants have confirmed their attendance, the project management team will send an official invitation letter to support the administrative process of their participation.

## 7. Deadlines

Please be aware of and respect the following important deadlines:

Action	WHO	Time frame	Deadline
Invitation letter and information on the training session sent to the NCPs	JVL	22-02-2023	N.A.
Submission of the registration forms (for the funded participants AND the self-funded participants) to the organisers	NCP	22-02-2023 to 19-06-2023	19-06-2023
Confirmation of the registration of the participants to the National Contact Points	JVL	22-02-2023 to 19-06-2023	N.A.
Communication with the registered participants and booking of their flights by the organisers	JVL	As soon as the registration forms are received	N.A.
Training session in Dehli, India		31-10 to 1-11-2023	N.A.





## 8. Annex – Draft Training Programme

Time	Title of activity	Tutors	Format	Learning objectives	Content summary
12:00				<i>Lunch at the hotel</i>	
13:15				<i>Registration</i>	
13.30 (15')	Presentation on BTSF initiative	Training Coordinator or DG SANTE	Video	<ul style="list-style-type: none"> <li>Participants will be familiar with the BTSF initiative</li> </ul>	An introduction to BTSF initiative
13.45 (30')	Introduction of delegates and tutors	Training Coordinator or DG SANTE	Interactive introduction game	<ul style="list-style-type: none"> <li>Participants will know each other and the tutors</li> <li>Participants will be familiar with the course programme and logistical arrangements</li> </ul>	<p>Each participant will be invited to introduce him/herself to the audience.</p> <p>They will register to an on-line interactive platform and will be requested to fill in basic information (name, surname, country and level of work: Ministries-Administrations, National-Regional Networks, Others)</p>



<b>DAY 1 Tuesday</b>					
<b>Time</b>	<b>Title of activity</b>	<b>Tutors</b>	<b>Format</b>	<b>Learning objectives</b>	<b>Content summary</b>
14.15 (15')	<b>Completion of the Initial Knowledge Questionnaire</b>	Training Coordinator	Online Interactive Questionnaire (Socrative)	<ul style="list-style-type: none"> <li>To obtain an overview of the general level of knowledge of participants</li> <li>Participants will reflect on the challenges of novel and traditional foods</li> <li>Participants will reflect on possible novel and traditional foods in their own country</li> </ul>	<p>This information will immediately be transferred on a virtual nametag that will appear on a map of World displayed on the main screen. The complete map will be saved, printed and displayed in the meeting room.</p> <p>Participants will be requested to fill in a questionnaire aimed at finding out about their knowledge on the topics covered by the training programme.</p>
14.30 (30')	<b>General introduction: What's new on novel foods and on traditional foods from third countries</b>	Experts from EFSA WG / Panel	Presentation including interactive Q&A software (Shakespeak)	<ul style="list-style-type: none"> <li>Participants will be familiar with the main and most recent developments or 'state of knowledge' as basis of a correct understanding of novel foods legislation</li> </ul>	<p>What are likely novel foods? Definition and examples for each category listed in the definition. What scientific advances will change novel foods – no history of consumption in the EU prior to May 15 1997, technologies such as Nanotechnology, New Processing Technologies (HPP, cold plasma, Pulsed Electric Field) -</p>



## DAY 1 Tuesday

Time	Title of activity	Tutors	Format	Learning objectives	Content summary
				<ul style="list-style-type: none"> <li>Participants will learn that despite major uncertainties and unknowns, an efficacious EU legislation could be developed based on scientific advice, leading to the present favourable situation</li> <li>Participants will be familiar with the provenance of traditional foods that have been approved and will have some idea about what is not accepted and why</li> </ul>	<p>What new sources of foods are likely – insects, algae, mycobacteria, non-conventional foods e.g. tree bark</p> <p>What are likely Traditional Foods from third countries. Some examples of already authorised novel food that could have benefitted are Baobab fruit pulp and chia seed and the few already authorised as traditional foods.</p> <p>Some of the reasons why applications for traditional foods from third countries might be not accepted and the different stages where an application may stall or be rejected will also be mentioned in general terms. For example, it may not be validated by the Commission due to a poor quality evidence or insufficient data or not preparing the documents appropriately or may be rejected due to a reasoned safety objection by a Member State or EFSA.</p>
15.15	<b>Questions/Discussion</b>				



## DAY 1 Tuesday

Time	Title of activity	Tutors	Format	Learning objectives	Content summary
15.25 (60')	Overview of the EU legal framework applicable to Novel Foods and Traditional Food from third countries	Tutor from EU Acquis country	Presentation including interactive Q&A software (Shakespeak)	<ul style="list-style-type: none"> <li>Participants will understand the legal background to the EFSA process</li> </ul>	<p>As an introduction, a short exercise will explain what is the rationale behind the legislation – why is it necessary – what are the main safety considerations (allergenicity, toxicity in different forms...). Participants will be asked to list the main considerations and basic principles of the Novel Food regulation.</p> <p>The presentation will give an overview of the regulation and it implementing acts as:</p> <ul style="list-style-type: none"> <li>Regulation (EU) 2015/2283 lays down rules for novel food.</li> <li>Commission Implementing Regulation (EU) 2017/2469 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283.</li> <li>Commission Implementing Regulation (EU) 2017/2468 laying down administrative and scientific requirements concerning traditional foods from third countries in accordance with Regulation (EU) 2015/2283.</li> <li>Commission Implementing Regulation (EU) 2017/2470 on establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283.</li> <li>Commission Implementing Regulation (EU) 2018/456 on the procedural steps of the consultation process for the determination of</li> </ul>

<b>DAY 1 Tuesday</b>					
Time	Title of activity	Tutors	Format	Learning objectives	Content summary
					<p>novel food status in accordance with Article 4 of Regulation (EU) 2015/2283.</p> <p>EFSA guidance on the administrative requirements for the submission of novel food application dossier, EFSA guidance on the preparation and presentation of an application for a novel food authorisation and EFSA guidance on the preparation and presentation of notifications and applications concerning traditional foods from third countries will be mentioned.</p> <p>Novel Food catalogue will also be referred to and cases where the new Novel Food regulation does not apply will be reminded:</p> <ul style="list-style-type: none"> <li>• Food enzymes within Regulation (EC) No 1332/2008.</li> <li>• Food additives within Regulation (EC) No 1333/2008.</li> <li>• Flavours for use in foods within Regulation (EC) No 1334/2008.</li> <li>• Extraction solvents used in the production of foods within Directive 2009/32/EC approximating EU countries' laws.</li> <li>• GMOs for food and feed, covered by Regulation (EC) No 1829/2003.</li> <li>• Food supplements:</li> </ul>



## DAY 1 Tuesday

Time	Title of activity	Tutors	Format	Learning objectives	Content summary
					<ul style="list-style-type: none"> <li>- Firstly, food supplements are governed by Directive 2002/46/EC and under the old NF Regulation by a Standing Committee resolution a history of consumption of an ingredient in supplements only allowed that ingredient to be used in supplements but not general foods. This is now covered specifically in Article 3.2(a)(x) of the new NF Reg 2015/2283.</li> <li>- Secondly, even though food supplements are covered by Directive 2002/46/EC as amended, a new vitamin/mineral or a new source may fall within the scope of the novel food Regulation and therefore be required to be authorised as a novel food (Reg 2015/2283) and added to the Union list and separately be added to the list of vitamins and minerals in the Annex of food supplement directive</li> </ul> <p>Nutrition and health claims are covered under separate legislation and have no impact on novel food authorisations but can go hand in hand with innovative foods</p> <p>Where it is unclear whether a food or ingredient falls within the scope of the novel food or additives legislation for authorisation purposes, the food additives working group and the novel food working group discuss</p>



## DAY 1 Tuesday

Time	Title of activity	Tutors	Format	Learning objectives	Content summary
16.25	<b>Questions/Discussion</b>	<i>Chair</i>			separately with a view to reaching a definitive and mutually acceptable conclusion.
16.35				<i>Tea/coffee break</i>	
17.05 (45')	<b>Overview of the EU/National regulatory bodies involved in assessment and authorization of novel and Traditional foods and Article 4 requests</b>	Tutor from EU Acquis country or DGSANTE representative if available	Presentation including interactive Q&A software (Shakespeak)	<ul style="list-style-type: none"> <li>Participants will have a clear view of the different actors and roles and understand the consultation process during the authorization and notification procedures</li> </ul>	<p>Individual and collective roles of the Commission, EFSA and Member States in the authorization and notification procedures will be described.</p> <p>Consultation process based on Article 4 of the Novel Food Regulation (CIR 2018/456) will be explained in detail the following day.</p> <p>The Commission coordinates all aspects of the application for authorization of a novel food or a traditional food from third country.. EFSA is concerned with risk assessment. The Novel Food Working Group is where the details of proposed authorisations are discussed at technical level and the Standing Committee on Novel Food and Toxicological Safety decides through Member State votes whether to authorize a novel food or not.</p>
17.50	<b>Questions/Discussion</b>	<i>Chair</i>			

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<b>DAY 1 Tuesday</b>					
Time	Title of activity	Tutors	Format	Learning objectives	Content summary
18.00				<i>Closing session</i>	
18.15				<i>Press conference</i>	
19.15				<i>Welcome drink at the hotel</i>	
20.15				<i>Dinner at the hotel</i>	



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## DAY 2 Wednesday

Time	Title of activity	Tutors	Format	Learning objectives	Content summary
09.00 (45')	What are the major novel foods and traditional foods? How are they classified?	Tutor from EU Acquis country supported by experts from EFSA WG / Panel	Presentation including interactive Q&A software ( <i>Shakespeak</i> )	<ul style="list-style-type: none"> <li>Participants will understand the scope of the relevant Regulation (EC) No 2015/2283</li> <li>Participants will know about the different novel foods and how they are categorised. They will also know about traditional foods and what the differences are</li> <li>Many foods submitted for authorisation are derivations from other foods. The participants will know whether these should be considered as completely novel or whether they are essentially the same food</li> </ul>	<p>This presentation will review the major novel foods and traditional foods and how they are categorized in the relevant Regulation(s) 2015/2283.</p> <p>The presentation will answer specific questions, going through the Regulation, such as:</p> <ul style="list-style-type: none"> <li>- What differentiates a novel food from a non-novel food?</li> <li>- What differentiates a traditional food from a novel food?</li> <li>- When a substance is derived from another food, is it still a novel food? Does this apply to traditional foods?</li> <li>- What if parts of a food are used that previously were disposed of? For example: shells of nuts, eggshell membranes.</li> <li>- Are plant leaves with a history of use for infusion/tea novel for other uses?</li> </ul>
09.45	<i>Questions/Discussion</i>	<i>Chair</i>			
09.55 (30')	Categorisation of novel and traditional foods	Tutor from EU Acquis country supported	Exercise in pair on novel foods – are they or are	<ul style="list-style-type: none"> <li>Participants will experience practically the difficulties of categorising novel foods correctly.</li> <li>Participants will be able to identify whether foods can be considered</li> </ul>	<p>Categorization of novel foods will be illustrated through an exercise.</p> <p>Using an interactive software, the participants, in pairs, will have to answer questions putting forward various Novel Foods and</p>

## DAY 2 Wednesday

Time	Title of activity	Tutors	Format	Learning objectives	Content summary
10.25 (45')	Workshop: How do my own foods fit into Regulation 2015/2283?	Tutor from EU Acquis country supported by EFSA WG / Panel Expert and local tutor	they not? Using an interactive software Quizizz	<p>novel or traditional, or whether they are, in fact, novel foods at all</p> <ul style="list-style-type: none"> <li>Participants will derive a good grasp of the complexity of definitions</li> <li>Participants will know and understand the regulation and the relevance to their own agendas</li> </ul>	<p>Traditional Foods (origin, nature, process, context...) and to categorize them through an interactive software with colours yellow (Novel Food), green (Traditional Food) and white (none). After each question, answer will be asked to the audience and the tutor will facilitate the discussion.</p> <p>This is a critical part of the process of preparing a submission. The participants need to know how their own food or foods relate to the regulations and how they will address the requirements of the legislation.</p> <p>Interaction with other food legislation is also an important facet. For example, new sources of vitamins and minerals will need to be authorised as novel food and then added to the list of approved vitamins and minerals for supplements and fortified foods.</p> <p>This section will go through the regulation, examining why it is in place, what is it relevant and not relevant to.</p> <p>Participants will be divided into 6 groups of 5 people.</p> <p>The groups will work through the regulations together and use three similar examples to determine whether and how they fit into</p>

## DAY 2 Wednesday

Time	Title of activity	Tutors	Format	Learning objectives	Content summary
11.10				<i>Coffee/tea break</i>	
11.40 (45')	Presentation of outputs and discussions	Repr. of group/	Discussion session		Presentation of the results of one working group to the audience with other groups challenging in order to foster the general discussion.
12.25 (30')	How to prepare an Article 4 consultation request on the novel food status of a food or ingredient	Tutor from EU Acquis country	Interactive presentation	<ul style="list-style-type: none"> <li>Participants will understand how to prepare an Article 4</li> </ul>	<p>If a food business is unsure of the novel food status of their food product, even following dialogue with the competent authority of a Member State(s), they should submit an Article 4 request to the Member State where the food is to be marketed. The electronic submission should follow the procedural criteria set out in CIR 2018/456. Questions should be answered, and further information provided in accordance with timelines agreed with the recipient Member State.</p> <p>Participants will be informed about this possibility, the procedure and what is the required information to be submitted according to Annex I and II.</p>

## DAY 2 Wednesday

Time	Title of activity	Tutors	Format	Learning objectives	Content summary
12-55				<i>Lunch at the hotel</i>	
14.00 (30')	How to prepare a novel foods application: examining the guidance document	Experts from EFSA WG / Panel	Interactive presentation	<ul style="list-style-type: none"> <li>Participants will know the EFSA guidance document and how to use it in preparing a novel foods application</li> </ul>	<p>The EFSA Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283 (<a href="https://www.efsa.europa.eu/en/efsajournal/pub/4594">https://www.efsa.europa.eu/en/efsajournal/pub/4594</a>) will be presented and explained section by section.</p> <p>Emphasis will be given to the target population of the Novel Food, as well as the potential inadvertent consumption by groups not targeted (Article 5(6) of CIR 2017/2469).</p>
14.30 (120')	Workshop: How to prepare a novel foods application	Experts from EFSA WG / Panels Tutors from EU Acquis country Local tutor	Group work	<ul style="list-style-type: none"> <li>Participants will be familiar with the novel foods dossier structure established by CIR 2017/2469 and will have a good idea of what is needed to put in a successful dossier.</li> </ul>	<p>This workshop will introduce appendix A of the dossier.</p> <p>Participants will be divided into four groups. Each group will be facilitated by one tutor.</p> <p>Submission could be a real submission or a made up example. Examples of novel foods from ones commonly eaten might include a shrimp peptide dossier or a submission on egg shell membrane hydrolysate as an interesting example of a novel food from a food that is very commonly eaten. If a real submission is</p>

<b>DAY 2 Wednesday</b>				
Time	Title of activity	Tutors	Format	Learning objectives
				<p>chosen, specific attention will be given to respect RGPD and confidentiality.</p> <p>Two groups will work on a similar strong made up example or real submission. The two other groups will work on a similar poor made up example or real submission.</p> <p>All groups will go through the checklist, section by section and discussing the most important parts. Special attention will be given to the more contentious sections -- which are not simple descriptions, and which may require references to external data.</p> <p>The facilitators will consider the relative importance of randomized control trials, prospective cohort studies and epidemiological studies in assessing the novel foods. Distinction between confidentiality and data protection will be emphasized and the procedure for getting both data protection and confidential treatment will be explained. The new provisions on Regulation (EU) 2019/1381 (transparency regulation), in particular on confidentiality will be explained.</p>



## DAY 2 Wednesday

Time	Title of activity	Tutors	Format	Learning objectives	Content summary
16.30				Coffee/tea break	
17.00 (90')	Presentation of outputs and discussions	Repr. of group/tutors above	Discussion session		<p>Presentation of the results of two groups to the audience and plenary discussion. Two groups will present one strong and one poor made up example or real submission.</p> <p>Groups will have the possibility to discuss together to see what is missed.</p> <p>As the group presents, the training coordinator will intervene at the end of each heading and describe how the assessors on the WG and Panel will look at the document.</p> <p>Short conclusion summarizing the key points in preparing a novel food application</p>
18.30				Closing session	
19.45				Social event & Dinner	



**DAY 3 Thursday**

Time	Title of activity	Tutors	Format	Learning objectives	Content summary
08.30 (30')	How to prepare a notification and application for traditional foods: examining the guidance document	EFSA WG / Panel Experts	Interactive presentation	<ul style="list-style-type: none"> <li>Participants will know the EFSA guidance document and how to use it in preparing a notification and application for traditional foods</li> </ul>	<p>EFSA Guidance on the preparation and presentation of the notification and application for authorisation of traditional foods from third countries in the context of Regulation (EU) 2015/2283 <a href="https://www.efsa.europa.eu/en/efsajournal/pub/4590">https://www.efsa.europa.eu/en/efsajournal/pub/4590</a></p> <p>Message will be conveyed on the importance of providing relevant data for safety evaluation to EFSA and Member States and on why it is required for food that is traditionally consumed by human population.</p>
09.00 (90')	Workshop : How to prepare a traditional foods notification and application	EFSA WG / Panel Experts Tutors from EU Acquis country Local tutor	Group work	<ul style="list-style-type: none"> <li>Participants will be able to prepare a notification and application for traditional foods that meets the EU MS and EFSA criteria and that will be accepted. or will be able to show that the evidence is not to the standard needed, and will be able to determine what extra information will be required</li> </ul>	<p>This workshop will point out how to define a traditional food, what evidence is needed, what sort of evidence is acceptable, what sort of evidence is not acceptable.</p> <p>Participants will be divided into four groups. Each group will be facilitated by one tutor.</p> <p>Each group will be provided with a batch of a similar strong real submission or made up example and a different poor real submission or made up example.</p>



<b>DAY 3 Thursday</b>			
			<p>The first phase of the workshop will consist of re-examining the guidance, in conjunction with applications that are very poor, then with one that is good and meets the guidance.</p> <p>The second stage will go through the process, step by step, identifying evidence needed and how to put that in context. Important areas such as preparation methods, nutritional evidence from the grey literature will be covered. History of consumption, similar way to consume the food, use of own data or public data will be emphasized</p>
<b>10.30</b>	<b>Tee/coffee break</b>		
<b>11.00 (60')</b>			Continuation and finalisation of group work
<b>12.00 (90')</b>	<b>Presentation of outputs and discussions</b>	<b>Repr. of group/ Discussion session</b>	<b>Presentation of the results of one group to the audience and plenary discussion. Other groups will have the possibility to discuss together to see what is missed and to illustrate the debate with their different poor real submission or made up examples.</b>





**DAY 3 Thursday**

					As the group presents, the training coordinator will intervene at the end of each heading and describe how the assessors on the WG and Panel will look at the document.  Short conclusion summarizing the key points in preparing a traditional food application
13.30	<i>Lunch at the hotel</i>				
14.30 (45')	What is the outcome of a successful application?	Tutor from EU Acquis country	Presentation including interactive Q&A software (Shakespeak)	<ul style="list-style-type: none"> <li>Participants will understand the limits to any authorization, the conditions that need to be satisfied and how to consider post-market monitoring</li> </ul>	<p>The Union list – What does it mean?</p> <p>This presentation will go through the commission implementing regulation (EU) 2017/2470 and use the headings of the legislation to discuss the individual features of the Union List. Confidentiality as well as generic and non-generic authorisations will also be addressed.</p> <p>It will be highlighted that the majority of entries in the current Union List are historical authorisations transferred from the original Commission Decisions and authorisations by the EU Member States under Regulation (EC) 258/97 and foods/ingredients that did not go through the full authorisation process but were authorised by the "Substantial equivalence" option (e.g. Aqueous extracts of dried leaves of Ilex guayusa).</p>



<b>DAY 3 Thursday</b>				
				<p>Through the two tables and different columns of the Union list, the following topics will be addressed and illustrate with examples:</p> <ul style="list-style-type: none"> <li>- Descriptive name of the authorised novel food: which can be very scientific and complicated, brand names are not accepted</li> <li>- Conditions of use: Applications are usually (not always -- e.g. Adansonia digitata (Baobab) dried fruit pulp and Isomaltulose) authorised for defined uses thus the heading "Conditions under which the novel food may be used". Specified food-use categories are generally proposed by the participant but alterations can be made by risk managers or proposed by EFSA as the risk assessor. Maximum values are scientifically set by EFSA or taken from separate food legislation.</li> <li>- Additional specific labelling requirements will be only mentioned here and address the next day during the presentation on labelling of novel foods</li> <li>- Other requirements: It can include post market monitoring, food categories that should not contain the food/ingredient or population sub-groups who should be advised not to consume the food/ingredient (e.g. Methylcellulose is not to</li> </ul>



<b>DAY 3 Thursday</b>				
15.15	<b>Questions/Discussion</b>	<b>Chair</b>		<p>be used in foods specially prepared for young children). These are relatively rare for existing authorisations. Whether food operators/companies representatives attend the session, small exercise could be proposed to potential applicants based on Article 3 of the Authorisation Decision 2000/500/EC on authorising the placing on the market of 'yellow fat spreads with added phytosterol esters' as a novel food. Potential applicants could be asked how they would set up such monitoring in the EU.</p> <p>- Specifications: the extent and type of specification is decided at risk management level and while details are extracted from the application, science is not necessarily the only consideration. A few examples might help to explain a point or demonstrate an exception.</p>
15.25 (35')	<b>Principles of risk: risk assessment or risk management?</b>	Experts from EFSA WG / Panel supported by Tutor from EU Acquis country	<p>Presentation including interactive Q&amp;A software (Shakespeak)</p> <ul style="list-style-type: none"> <li>Participants will understand the differences between risk assessment (what EFSA actually does) and risk management (how the Member States and the Commission in the Novel Foods WG respond)</li> </ul>	<p>Conflating risk assessment and risk management is a common problem and can lead to a dossier being rejected.</p> <p>A short overview of Regulation (EC) No 178/2002, which defines risk management and risk assessment, will be provided.</p> <p>A presentation will explain the differences between risk management and risk assessment and explain the role of risk</p>



<b>DAY 3 Thursday</b>				
				<p>assessors (EFSA) and the Member States and also the role of risk managers, Commission and Member States. The presentation will be illustrated with examples for interactive discussion with participants.</p> <p>For instance, examples can include novel foods containing a particular toxin or new allergen with a risk assessment in terms of potential exposure and inherent levels or health impact of the toxin or allergen. Then, some risk management options in order to counter possible safety concerns could be discussed in an interactive way with participants.</p>
<b>Tea/coffee break</b>				
16.00	16.30 (45')	<p>How to submit a dossier through the e-submission system?</p>	<p>Tutor from EU Acquis country or DG SANTE representative if available</p>	<p>Individual and collective roles of the Commission, EFSA and Member States in the authorization and notification procedures will be shortly reminded.</p> <p>Consultation process and e-submission will be explained in detail using DG SANTE website and internet connection. Specific attention will be given on who to contact, when and how at each step of the procedure. Stop-clock letters and how to respond to them will also be addressed</p>
		<p>Presentation including interactive Q&amp;A software (Shakespeak)</p>	<p>Participants will be able to understand the application process and will be confident in advising others on the process and the way forward</p>	



## DAY 3 Thursday

17.15	Questions/Discussion	Chair		
17.30			<i>Finish</i>	
17.30 (30')	Extra module: I want to be a key contact point on Novel Food	Training Coordinator Local Expert	<p>• Participants who have been identified and who are willing to become a key contact point are informed about their role and tasks</p>	<p>Participants who have been identified and have expressed their willingness to become a key contact point on Novel Food in their own country will be informed on the future role and tasks of a key contact point.</p> <p>The objective of this module will be to introduce the concept of contact point but also to keep the potential contact points committed to.</p> <p>Then, an additional session could be considered more specifically orientated to supporting tasks to companies/food operators, where and how to find the information for specific issue, where and how to keep tracks for update and new developments on the topic. This "extra" training session can be organized as a webinar of one or two days in one or two inputs and be supported by a training pack sent as an electronic version. The content of this additional session will be designed based on the outcomes and feedback of the first training sessions in hosting countries in order</p>

<b>DAY 3 Thursday</b>				
				to be very practical and be adapted as much as possible to the needs and regional background.
<b>18.00</b>	<b>Closing session</b>			
<b>19.45</b>	<b>Dinner at the hotel</b>			



## DAY 4 Friday

Time	Title of activity	Tutors	Format	Learning objectives	Content summary
09.00 (60')	Labelling of Novel Foods	Tutor from EU Acquis country	Interactive presentation including interactive Q&A software ( <i>Shakespeak</i> ) and Group Work	<ul style="list-style-type: none"> <li>To ensure participants understand the labelling and the rationale behind it</li> </ul>	<p>Novel food is subject to the general labelling requirements laid down in Regulation (EC) No 1169/2011.</p> <p>The presentation will address the general and specific additional requirements and will go through examples of ingredients lists and of participants own labelling. Through the presentation, participants working in pairs will be invited to reflect on their own labelling and to see how much work is needed to bring their labelling into line with EU labelling rules.</p> <p>Following considerations will be explained as major allergens – are there novel foods that will add to the allergens – chia seeds, insects, for example. Are there new considerations that might need to be included – GMO derived foods, for example, in specific situations only where GM microorganisms can produce ingredients without requiring GM authorisation or labelling (processing aids). What are the relative requirements of the general public and the food industry?</p>



<b>DAY 4 Friday</b>					
Time	Title of activity	Tutors	Format	Learning objectives	Content summary
10.00	<b>Making sure you understand everything!</b>	All tutors	Interactive summary presentation	<ul style="list-style-type: none"> <li>To ensure all participants understand the process of applying for admission of a</li> </ul>	<p>It will be highlighted that nutrition and health claim can only be made in accordance with the requirements of the Health and Nutrition Claims Regulation (EC) No 1924/2006. Provisions on Article 28 (authorisation procedure in case of a parallel application for the authorisation of a health claim) of the novel food regulation will be explained.</p> <p>Specific additional requirements for the labelling of a novel food may also apply and can originate with the applicant, or be proposed by EFSA, Member States or the Commission. Generally, it can include a more understandable name for product labels where the descriptive name is too scientific and complicated for the average consumer. But this is not always achieved (e.g. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Gum base (including 1,3-butadiene, 2-methyl- homopolymer, maleated, esters with polyethylene glycol mono-Me ether)' or 'Gum base (including CAS No: 1246080-53-4)')</p> <p>This will be a review of the process of collating a dossier. It will summarise the steps involved, and will remind participants where problems usually arise.</p>





<b>DAY 4 Friday</b>					
Time	Title of activity	Tutors	Format	Learning objectives	Content summary
(45')			and discussion including interactive Q&A software ( <i>Shakespeak</i> )	novel food or a traditional food onto the Union list	
10.45	<b>Questions/Discussion</b>	<i>Chair</i>			
10.50					
<b>Coffee/tea break</b>					
11.20 (15')	<b>Final discussion/ Unanswered questions</b>	Training Coordinator	Discussion	<ul style="list-style-type: none"> <li>Participants will be given an opportunity to raise questions on technical and scientific issues relate to EU legislation and Novel Foods</li> <li>Training coordinating and tutors will respond to unanswered questions which may have raised during the training session</li> </ul>	The Training coordinator and tutors will answer all possible last questions from the audience on any topics of the training programme



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## DAY 4 Friday

Time	Title of activity	Tutors	Format	Learning objectives	Content summary
11.35 (30')	Dissemination module	Training Coordinator	Discussion and reflection on dissemination Online Interactive Questionnaire (Socratic)	<ul style="list-style-type: none"> <li>Participants can transfer the course content into their own setting</li> <li>Participants have identified a key action for themselves based on their learning</li> </ul>	<p>The set of 'practical dissemination tools' and the Train-the-Trainer handbook will be presented, highlighting practical tips on how to become a trainer and disseminate the training content.</p> <p>The presentation "make sure you understand everything" will be presented as a tool to be used in dissemination as a review of the process of collating a dossier summarizing the steps involved and remind participants where problems arise.</p> <p>Participants will identify a key action to translate the newly acquired knowledge into their work environment to assure impact and retention in an interactive way</p>
12.05 (15')	Completion of Final Knowledge Questionnaire	Training Coordinator	Online Interactive Questionnaire (Socratic)	<ul style="list-style-type: none"> <li>To assess the level of knowledge of participants at the end of the session</li> <li>To assess the efficiency of the course by comparing the results of the questionnaire at the beginning and at the end of the session</li> </ul>	<p>Participants will be requested to fill in the same questionnaire they have been presented to at the beginning of the session.</p> <p>Then, the training coordinator will go through the questions with the audience and give the correct answers.</p>



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## DAY 4 Friday

Time	Title of activity	Tutors	Format	Learning objectives	Content summary
12.20 (15')	Completion of feedback on-line & distribution of certificates	Training Coordinator	online evaluation survey	<ul style="list-style-type: none"> <li>To have an overview of the relevance and usefulness of activities proposed</li> </ul>	Participants will fill in the CHAFEA online evaluation survey. Certificates will be distributed after completion
12.35	<i>Closing session: lunch and departure</i>				



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# Better Training for Safer Food

## Training Course on

### EU rules applicable to the authorization and placing on the market of novel food and traditional foods coming from non-EU countries

**Subject:** Invitation to participate in a training session on EU rules applicable to the authorization and placing on the market of novel foods and traditional foods coming from non-EU countries

Dear Madam, Sir,

We are pleased to inform you that the European Commission Directorate General for Health and Food Safety (DG SANTE) is organising a three-day training course on EU rules applicable to the authorization and placing on the market of novel foods and traditional foods coming from non-EU countries in Delhi, India, from 31<sup>st</sup> October to 3<sup>rd</sup> November 2023 under the Better Training for Safer Food initiative.

"Better Training for Safer Food" (BTSF) is an initiative of the European Commission's Health and Food Safety Directorate-General (DG SANTE) aimed at organising a European Union (EU) training strategy in the areas of food law, feed law, animal health and animal welfare rules, as well as plant health rules.

The training will bring together 33 representatives from 7 countries, including : Bangladesh, Bhutan, India, Nepal, Maldives, Pakistan and Sri Lanka

4 seats have been allocated to Pakistan for this training session.

We kindly ask for your assistance and cooperation as National Contact Point (NCP) in identifying and submitting suitable participants. Please return the completed Training Application Form(s) of the selected participant(s) to us by email at your earliest convenience but no later than by **19<sup>th</sup> June 2023** at:

**[20189607NF@jvl-c.com](mailto:20189607NF@jvl-c.com)**

Please note that the course is addressed to officials from **Competent Authorities in the beneficiary non-EU countries involved, preferably at central level, verifying compliance with rules applicable to placing novel foods and traditional foods on the EU market and persons from one of the following categories:**

- **Decision/policy makers / senior officers from Food safety competent authorities;**
- **Decision/policy makers / senior officers from Food export competent authorities;**
- **Decision/policy makers / senior officers from Public Health competent authorities;**
- **Senior officers from already existing national and/or regional networks on topics links to Novel Food;**



Please note that, in addition to the minimum 4 participants meeting the profile described above and that you should identify, you can also submit people from the following categories as “self-funded participants” (for further explanation, please check Chapter 5 of the Information document attached):

- **National Food associations/ Union companies’ representatives** might be considered to be invited as they may do the submissions of **Novel Food and Traditional Food**.
- In the absence of the above, it could be considered personnel from public associations or internationally or nationally funded projects working in the development and support to traditional foods;

The main objective of the training is to raise awareness and contribute to a better understanding and more efficient use of existing EU rules applicable to the authorization and placing on the EU market of novel foods as set out in the European Union Novel Food Regulation (EU) 2015/2283.

The course will aim at making participants be aware of and understand:

- the EU legal framework relating to Novel Foods and to Traditional Foods from third countries
- the various regulatory roles played by the Commission, by the European Food Safety Authority (EFSA) and by Member States
- the definitions of novel foods and traditional foods from third countries
- the process of determining the novel food status of a food
- the rules that apply to authorization procedures for both novel foods and traditional foods from third countries
- the principles of risk assessment used by EFSA
- the EFSA guidance documents related to Article 10 of the Novel Food Regulation for novel foods and Article 14 for traditional foods to help to prepare submission documents
- the information needed to be able to apply for novel foods or traditional foods to be included in the Union List

### Pre-requisites

Prior to the training session, participants will be asked to:

-provide some examples of the novel foods or traditional foods that could be submitted to the EU Commission

-send some examples of food labelling to reflect on during the course.

-familiarise themselves with following documents (provided to them in advance):

- The European Union Regulation (EU) 2015/2283 on Novel Foods.
- Commission Implementing Regulation (EU) 2017/2469 on administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 on novel foods,
- Commission Implementing Regulation (EU) 2017/2468 administrative and scientific requirements concerning traditional foods from third countries in accordance with Regulation (EU) 2015/2283 on novel foods.
- Commission Implementing Regulation (EU) 2018/456 on the procedural steps of the consultation process for the determination of novel food status in accordance with Article 4 of Regulation (EU) 2015/2283.
- EFSA Guidance on the preparation and presentation of the notification and application for authorisation of traditional foods from third countries in the context of Regulation (EU) 2015/2283
- EFSA Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283
- EFSA Administrative guidance on the submission of applications for authorisation of a novel food pursuant to Article 10 of Regulation (EU) 2015/2283.
- Example novel foods applications (redacted/made up to avoid identification of particular companies or real submission. In case the real submission is chosen, specific attention will be given to respect RGPD and confidentiality)
- Example traditional food notifications and applications (redacted/made up to avoid identification of particular companies or real submission. In case the real submission is chosen, specific attention will be given to respect RGPD and confidentiality)
- Training pack with presentations and exercises; training pack will also be provided as a printed version and distributed on the spot

Participants will be provided with the necessary tools and resources to disseminate the knowledge gained through the training course to colleagues in their home countries. By attending the course, they commit themselves to engage actively in a dissemination process via different dissemination methods

Please note that participants:

- Will be requested to fill-in an Initial Knowledge Questionnaire at the beginning of the training session and a Final Knowledge Questionnaire at the end of the session;
- Will be requested to fill-in an Online evaluation questionnaire at the end of the training session;
- Will be requested to fill-in a questionnaire on their dissemination actions and the impact of the BTSF course on their work two months after the session.



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TS 8 – Delhi, India  
Oct-Nov 2023

Financial costs related to the participants' travel, stay and attendance (travel, accommodation, meals, material, etc.) will be covered by the project (if they are not self-funded). Any other personal costs are to be paid by the participants.

Once the participants are registered, we will communicate directly with the proposed participants, providing them with all the necessary information, administrative and logistic support to ensure their successful participation in the course.

The calendar of actions will be the following – please be so kind to respect the deadline:

1. Information sent to National Contact Points	22/02/2023
2. Deadline for submitting Training Application forms	19/06/2023
3. Confirmation of registrations to NCPs	22/02 to 19/06/2023

If you wish to submit **additional training application forms**, please feel free to do so. Should a seat be left empty, we will try to reallocate it to your country.

Should you have any further queries, please, contact JVL Consulting at [20189607NF@jvl-c.com](mailto:20189607NF@jvl-c.com)

Looking forward to collaborating with you,

Thank you very much and best regards,

Fablana Quadu – Project Manager  
Anthony Messina – Event Manger  
JVL-Consulting  
[20189607NF@jvl-c.com](mailto:20189607NF@jvl-c.com)  
[www.jvl-c.com](http://www.jvl-c.com)





Funded by  
the Better Training for Safer Food  
Initiative of the European Union

## REGISTRATION FORM TO BTSF TRAINING

# EU RULES APPLICABLE TO THE AUTHORIZATION AND PLACING ON THE MARKET OF NOVEL FOODS AND TRADITIONAL FOODS COMING FROM NON-EU COUNTRIES

Submit filled registration form to: [20189607NF@JVL-C.COM](mailto:20189607NF@JVL-C.COM)

**TYPE REGISTRATION FORM IN ENGLISH. ONLY TYPED REGISTRATION FORMS WILL BE ACCEPTED.**

**Participant information must be correct according to his/her passport.**

**Applications will be subject to approval by National Contact Point (NCP).**

**Non-attendance or cancellations will be reported to the Health and Digital Agriculture Executive Agency.**

<b>YOUR</b>	<b>SELECT THE DATE OF PARTICIPATION</b>	Choose from the list
If not listed:		type here
<b>COURSE AND</b>	<b>SELECT THE DATE OF PARTICIPATION</b>	TS8 - Oct-Nov 2023 - India
<b>APPLICATION</b>	<b>APPLICATION ON THE RESERVE LIST</b>	Choose from the list

**Note:** t.b.c. means to be confirmed

<b>1 PARTICIPANT INFORMATION</b>	
<b>1.1 Gender</b>	Choose from the list
<b>1.2 Family name</b>	as it appears in the passport or ID
<b>1.3 First names</b>	as it appears in the passport or ID
<b>1.4 Date of birth</b>	as it appears in the passport or ID
<b>1.5 Nationality</b>	Choose from the list
<b>1.6 Mobile phone (add international code) where you could be reached during travel</b>	a number from which you can be contacted before/during travel
<b>1.7 E-mail</b>	an address through which we can easily be in contact with you
<b>1.8 Home address</b>	
<b>2 CONTACT DETAILS OF YOUR INSTITUTION</b>	
<b>2.1 Name of institution / organization</b>	
<b>2.2 Telephone (add international code)</b>	
<b>2.3 Address</b>	
<b>2.4 ZIP Code</b>	
<b>2.5 Town</b>	
<b>2.6 Country</b>	Choose from the list



3 CURRICULUM VITAE		
3.1 Education		
	<b>Degree or Diploma Obtained</b>	Choose from the list
	<b>Field of study</b>	Choose from the list
	<b>If other, please specify</b>	
	<b>Institution (name and country)</b>	
<b>3.2 Language skills (Basic - Independent - Proficient) The self-assessment grid is based on the six level scale of the common European framework of references for languages developed by the Council of Europe - <a href="http://europass.cedefop.europa.eu/LanguageSelfAssessmentGrid/en">http://europass.cedefop.europa.eu/LanguageSelfAssessmentGrid/en</a></b>		
<b>English</b>	Reading	Choose from the list
	Speaking	Choose from the list
	Writing	Choose from the list
<b>Other: Please indicate the</b>	Reading	Choose from the list
	Speaking	Choose from the list
	Writing	Choose from the list
3.3 Professional experience		
	<b>Current position: describe your position and main functions and responsibilities</b>	
	<b>Number of years you've held this position</b>	
	<b>Level of working</b>	Choose from the list
	<b>If other type, please specify</b>	
<b>3.4 Years of total experience in the field of work</b>		
<b>3.5 Description of your experience within the field of training</b>		

4 INFORMATION DISSEMINATION	
<b>What measures do you envisage to disseminate the information learned in the training? Please list some of your foreseen actions (distribution of documents, training actions, informative articles in national, international journals, e-learning, any other dissemination action) *</b>	
<b>5 DIETARY AND MEDICAL REQUIREMENTS</b>	
<b>5.1 Specific Dietary requirements (if any)</b>	Choose from the list
<b>If other, please specify</b>	
<b>5.2 Severe food allergies</b>	
<b>5.3 Phone number of a contact person in case of an emergency</b>	
<b>5.4. Medical conditions requiring special attention in case of an incident</b>	

6 TRAVEL INFORMATION	
<b>Note: Tickets will be booked upon availability considering starting and ending timing of the</b>	
<b>6.1 Passport or ID number</b>	as it appears in the passport
<b>Place and date of issue</b>	
<b>Expiry date</b>	
<b>6.2 Preferred means of travel</b>	Choose from the list
<b>6.3 Place of Departure (airport/station). Please</b>	

<b>7 VISA INFORMATION</b>	
Please send a <b>PASSPORT COPY</b> together with this registration form.	
<b>7.1 I have a valid PASSPORT (Please make sure it is valid up to at least 6 months after your return trip)</b>	Choose from the list
<b>7.2 I have a valid VISA for India (Please make sure the VISA covers the whole training period)</b>	Choose from the list
<b>7.3 I need an invitation letter from the organiser for visa application/internal clearance</b>	Choose from the list
<b>7.4 List of other documents are required in your country for applying the VISA</b>	