ISES Europe Training Series

DoE 7: Relevant Legislative Frameworks

Module 2: Legislation under the Remit of EFSA

Transcript Notice:

This is the transcript of the presentation. Please note that the actual spoken text may differ slightly from what is written here.

Slide 1 – Welcome

Hello and welcome to today's session in the ISES training series. This presentation falls under **Domain of Expertise 7: Relevant Legislative Frameworks**. I'm very glad you have joined us for this part of the training, and I look forward to guiding you through today's topic.

Slide 2 – Legal notice

Before we begin, just a quick legal note. All rights to the materials used here are retained by the original copyright holders.

If you would like to reuse any part of this presentation, please make sure you seek explicit permission first. Thank you for respecting these rules.

Slide 3 – Overview of All Training Videos

This training is part of a broader ISES Europe initiative. In total, there are **nine Domains of Expertise**, which together cover the breadth of exposure science. They range from the **fundamental principles** of exposure science and environmental chemistry, through topics like **exposure modelling, risk communication, and sustainability**, all the way to today's focus: legislation.

If you'd like to revisit any session, all training videos are available on the ISES-Europe website (**ises-europe.org**).

Slide 4 – Domain of Expertise (DoE) 7

Our focus today is **Domain of Expertise 7: Relevant Legislative Frameworks**. This domain is divided into three submodules:

- **Module one**, which we covered earlier, introduced the **principles of the European legislative frameworks**.
- **Module two**, which we are exploring now, concentrates **specifically on legislation under the remit of the European Food Safety Authority**, or EFSA.
- **Module three**, will deal with **legislation under the remit of ECHA**, the European Chemicals Agency.

Together, these modules provide a comprehensive picture of how legislation shapes the way exposure science is practiced in Europe.

Slide 5 – Module two

The title of today's session is *Legislations Under the Remit of EFSA*. We'll explore how exposure and risk assessments are applied in EFSA's context, and how they influence decisions that directly affect food safety and consumer health. By the end, you should have a clearer picture of the processes, responsibilities, and outcomes tied to EFSA-related legislation.

Slide 6 – Presenter

A brief introduction to myself. My name is Lucy Wilmot and I have been working in the field of chemical safety assessment for over fifteen years and I'm currently a science manager at ECETOC. It's a pleasure to have the opportunity to present this ISES-Europe training material.

Slide 7 – Context and Disclaimers

Please note that this presentation is designed as an **introductory-level session**. Some aspects have been simplified in order to provide a clear overview.

This presentation focuses exclusively on **European legislation** and reflects the situation at the time of recording. Some legislative details may have changed since this recording, so keep that in mind as you watch.

Slide 8 – Content

Here is today's roadmap:

1. We'll start with a short **introduction** to EFSA and its remit.
2. Then, we'll move into three specific regulatory fields where exposure and risk assessment play a critical role:
    - **Food additives**
    - **Plant protection products**
    - **Food contact materials**
3. Finally, we'll wrap up with a concise **summary and the key takeaways** you should leave with.

Let's begin with the introduction.

Slide 9 – Introduction

The **European Food Safety Authority (EFSA)** is a **decentralised EU agency**, located in Parma, Italy.
For more details about decentralised EU agencies in general, I encourage you to revisit Module 1.

EFSA's remit covers essentially everything that directly or indirectly impacts food and feed safety. On the slide, you can see its ten main areas of activity - from nutrition and animal health to plant protection and genetically modified organisms.

As already mentioned, our focus today is on three areas where exposure science plays a particularly visible role:

- **Food additives**
- **Plant protection products**
- **Food contact materials**

Slide 10 – Learning objectives

By the end of this lecture, you should:

- Have a clear understanding of the legal requirements for exposure assessments in relation to food additives, plant protection products, and food contact materials.

- And also know where to find additional, more detailed information if you need to explore a specific topic further.

Slide 11 – Content

Let's begin with **food additives**.

Here we'll see how EFSA carries out exposure and risk assessments, and how these translate into real-world regulatory decisions.

Slide 12 – Exposure Assessment: Food Additives

The **exposure and risk assessment** of food additives is carried out by EFSA. The key legislations are listed on the slide in case you want to look further.

The first step is to establish a benchmark value - most often an Acceptable Daily Intake, or ADI. For more detail on how ADIs and similar benchmark values are derived, I recommend revisiting the recordings from Domain of Expertise 2.

The ADIs are then compared with the dietary intake. To estimate dietary intake, EFSA combines two major datasets:

1. The **Comprehensive Food Consumption Database**, which contains detailed consumption data from around **30 European countries**, including some non-EU members. The database covers **seven age groups:** Infants: 3 months to 1 years, Toddlers: 1-3 years, Children: 3-10 years, Adolescents: 10-17 years, Adults: 18-64 years, Elderly: 65-75 years and Very Elderly: 75+ years. Some surveys also include specific data for special population groups, like **pregnant women** or **vegetarians**.

The second of the datasets used by ECHA to estimate dietary intake is

2. Data on the **use levels of food additives** across food categories, which EFSA obtains from producers. For example, a bakery producer may report maximum use levels of a colouring agent in cakes. These can be supplemented with information from independent studies.

Using these datasets together, EFSA calculates estimated dietary intake levels and compares them to the ADI. Importantly, the analysis usually focuses on **high-level consumers**, often defined as the **top 95th percentile in terms of intake in each population group**.

If a food additive is found to be safe, it receives an **E-number**, which you may recognise from ingredient lists on packaged foods. It will also be listed in the **EU Food Additive Database**, which is publicly accessible.

Slide 13 – Authorisation: Food Additives

Now we move to the process for how EFSA is requested to perform these evaluations.

For food additives, requests are made by the **European Commission**. They act on applications submitted either by **Member States** or by interested parties - which might include **food manufacturers, industry associations, NGOs, or research organisations**.

Applications must provide sufficient data to allow EFSA to estimate the dietary intake and Acceptable Daily Intake - for example, the **intended use levels**, information on **other possible sources of exposure**, and supporting toxicological data.

With the shared information, EFSA carries out its assessment across all relevant age groups. The outcome can include the establishment of **maximum permitted levels** in specific food categories to ensure safe use, i.e. that the dietary intake is not above the Acceptable Daily Intake. The allowed maximum levels (ML) per food category are publicly available in the EU Food Additive Database.

Authorisation is not the end of the process - re-evaluations are carried out, particularly for older additives. For example, EFSA is currently **re-evaluating all additives that were authorised before 2009**.

It's also worth noting that EFSA increasingly takes cumulative exposure into account, which means looking not just at one additive in isolation, but at combined exposures where relevant.

Slide 14 – Content

Let's move on to our second major topic: **Plant Protection Products**, often simply called **PPPs**.

Here, we'll explore how the approval and authorisation processes work, and the respective roles of EFSA, the European Commission, and the Member States.

Slide 15 – Exposure Assessment: PPP

The assessment of plant protection products, or PPPs, is carried out in **two main stages**:

1. First, the **active substance** itself must be approved at the EU level. This is a substance with pesticidal properties - for example, a herbicide, insecticide, or fungicide.
2. Only after the active substance has been approved can a **specific PPP product** containing that substance be authorised.

This two-step approach ensures that both the building blocks and the final formulated products meet strict safety and efficacy standards.

Let's look at these steps in more detail, starting with the approval of active substances.

Slide 16 – Exposure Assessment: Active Substance

As mentioned, approval of the active substance is required **before** any PPP can be authorised. There is **no tonnage threshold** - approval is needed regardless of market volume. Approvals are typically valid for **10 years**, though this can be shorter.

The applicant submits a **comprehensive dossier**, including physico-chemical properties, toxicological and ecotoxicological data, efficacy, and environmental behaviour.

The dossier also includes an exposure and risk assessment which is rather narrow in scope, in that it is focused on **representative uses** and key endpoints such as **dietary intake** and **water and groundwater exposure**.

Member States and EFSA then evaluate the dossier and request more information as needed. If such information is not provided by the applicant, the application may be stopped or a conclusion made based on available data which is often a negative conclusion, i.e. the active substance is not considered safe.

As part of the process, Member States and EFSA can propose **default Maximum Residue Levels (MRLs)**. These are legally binding limits for residues in food or feed.

The final decision on approval rests with the **European Commission**. Once approved, the active substance is added to the **EU Pesticides Database**, which is publicly accessible.

Slide 17 – Exposure Assessment: PPP

So, now that we've covered approval of active substances, let's turn to the authorisation of PPP. This step is more complex, so we'll keep it high level.

Authorisation is required in each Member State before a product can be marketed in that Member State. The EU is divided into three zones for the purpose of PPP authorisation - North, Centre, and South - created to take account of the different agricultural practices and climates across the EU (more on this later).

The authorisation of a PPP must be renewed every **10 years,** though this renewal period can also be shorter.

The authorisation of a PPP considers safeners, synergists and co-formulants, as well as active substances. Note that all **co-formulants** in a PPP, for example stabilisers or colourants, must also be **registered under the REACH Regulation**.

The exposure and risk assessment for PPP conducted as part of the authorisation process is much more comprehensive than under the Active Substance approval process, and must address **all intended uses**. The scope is also larger and must include:

- **An environmental exposure and risk assessment for** groundwater, water, sediment, air and soil and exposure of other non-target organism, e.g. bees.
- **A human exposure and risk assessment for** operators, workers, residents, and bystanders.
- And any **interactions** between the active substance and co-formulants.

The evaluating Member State may also conduct or request **cumulative risk assessments**. Please refer to Domain of Expertise Number 5 for more information on cumulative risk assessment.

At the end of the process, the evaluating Member State decides whether to authorise the product. Once authorised in one Member State, the registrant can request mutual recognition of the authorisation in other Member States within the same zone. However, individual Member States can adapt the conditions of use - or even refuse recognition - based on local circumstances.

For PPP authorisation EFSA's role is more limited compared to approval of Active Substances: it provides guidance and scientific methodologies, but the final decision rests with Members States. Even so, EFSA's frameworks are essential for ensuring consistency and scientific rigor across the EU.

Slide 18 – Content

With PPPs covered, we now turn to our third and final major topic: **Food Contact Materials**, often referred to as FCMs.

Slide 19 – Food Contact Materials (FCM)

Exposure and risk assessment of food contact materials is another complex area, and again we can only provide a high-level overview.

Here, EFSA's role is somewhat narrower. EFSA mainly provides scientific advice to the European Commission and Member States, but it does not directly authorise individual products. The responsibility for the exposure and risk assessment **lies primarily with the manufacturer of the food contact material**. Manufacturers must carry out exposure and risk assessments internally. These do not need to be submitted to regulators up front, but must be documented and available on request - for example, during inspections by competent authorities.

A complicating factor is that not all FCMs **fall under the same legislative framework**.

- Some, like plastics and ceramics, are **harmonised at the EU level**.
- Others, such as paper, cardboard, or silicone, are only **covered by national rules**.

This uneven regulatory landscape can make compliance challenging, especially for companies operating across multiple Member States. For a more detailed discussion of these differences, please refer back to Module 1 of this Domain of Expertise.

For today, we'll concentrate specifically on **plastic FCMs**, since these are one of the materials regulated by a harmonised EU framework.

Slide 20 – Plastic FCM: Exposure Assessment

Plastic FCMs are governed by **EU Regulation No. 10/2011**.

This regulation contains a **positive list** of authorised monomers, additives, and processing aids. To add a substance to this positive list, applicants must submit a dossier to EFSA for risk assessment.

But complying with this positive list of authorised substances is only part of the story. Manufacturers of FCM must also perform **migration testing** on the finished material to assess the migration of the authorised substance, as well as impurities.

Migration testing is designed to simulate realistic consumer exposure. Some standard assumptions include:

- A surface area of **1 dm²**, assumed to represent a daily intake of **1 litre** of food.
- For lipophilic substances, **200 grams of fat consumption per day** is assumed.
- The regulation specifies which **food simulants** must be used, depending on the product's intended use.
- Migration testing also considers temperature, duration, and repeated use to reflect realistic consumer scenarios.

EFSA has established **specific migration limits** for many substances. If no specific limit exists, an **overall migration limit of 10 mg per dm²** applies, ensuring safety across the board.

Slide 21 – Plastic FCM: Exposure Assessment

The results of migration testing are crucial, as they determine **under which conditions a material can be safely used**.

If restrictions apply - such as "not suitable for fatty foods" or "do not use at high temperatures" - these must be communicated clearly to users.

It's important to highlight that, as mentioned earlier, **manufacturers are not required to submit their full exposure and risk assessments** for pre-approval. They must, however, document them internally and make them available to competent authorities upon request.

Non-authorised substances — substance not on the positive list — may still be used, provided they are placed behind a **functional barrier** and migration remains below **0.01 mg/kg of food**.

But there are exceptions: this rule does not apply to substances classified as carcinogenic, mutagenic, or toxic for reproduction (CMRs), nor does it apply to nanomaterials.

And finally keep in mind, there are additional regulatory requirements for:

- **Recycled plastics,** where additional safety checks are needed to account for potential contaminants.
- **Active and intelligent materials**, which deliberately interact with food. Such as release substances into food or absorb substances from food

---

Slide 22 – Content

Now that we've covered all three main regulatory areas, let's bring everything together in a short summary.

Slide 23 – Summary: Key Takeaways

The processes of exposure and risk assessment differ quite significantly depending on the legislation in question.

- In some cases, the **authority performs the assessment** itself—for example, EFSA's role with food additives authorisation.
- In other cases, the **producer is fully responsible**, as with food contact materials.
- And **sometimes responsibility is shared**, as in the case of plant protection products.

Safe thresholds are central in all three systems, but they are derived and applied in very different ways. **Communication of safe use also varies**:

- For food additives and PPPs, it takes the form of maximum permitted levels or residue limits.
- For FCMs, restrictions often specify the conditions under which materials can or cannot be safely used.

Another key difference lies in the scope of assessments—sometimes covering single substances, sometimes full products, and sometimes cumulative exposures.
Finally, the **physiological and use assumptions** behind the assessments also **differ across the frameworks**.

Slide 24 – Where to Find more Information?

Here you'll find a list of additional resources to explore. These include official EFSA guidance documents and websites of national agencies.

If you are working in this field or expect to in the future, I encourage you to consult these documents directly. They provide detailed methodologies, case studies, and regulatory requirements that go beyond what we can cover in today's overview.

Slide 25 – Consequent Modules

Looking ahead, **Module three** of this training will turn to legislation under the remit of **ECHA - the European Chemicals Agency**. This will allow us to compare and contrast EFSA's role with ECHA's, and to see how different regulatory cultures shape exposure science.
And further down the line, ISES Europe may release additional specialised materials, allowing us to explore individual topics in greater depth.

Slide 26 – Closing thanks

That brings us to the end of today's session.

Thank you very much for your attention and participation. I hope the material has given you a clearer understanding of how EFSA operates within the legislative landscape, and how exposure and risk assessments are integrated into food safety regulation.

Please continue exploring ISES - Europe's training series for more insights into exposure science and risk assessment.

As a reminder, all training materials are available on the ISES-Europe website (**ises-europe.org**).

Slide 27 – Further Reading

On this final slide, you'll find suggested reading materials for further study relating to chemical regulation in Europe. We won't go through them here, but I recommend you review them afterwards.

Thank you very much, and goodbye.
