

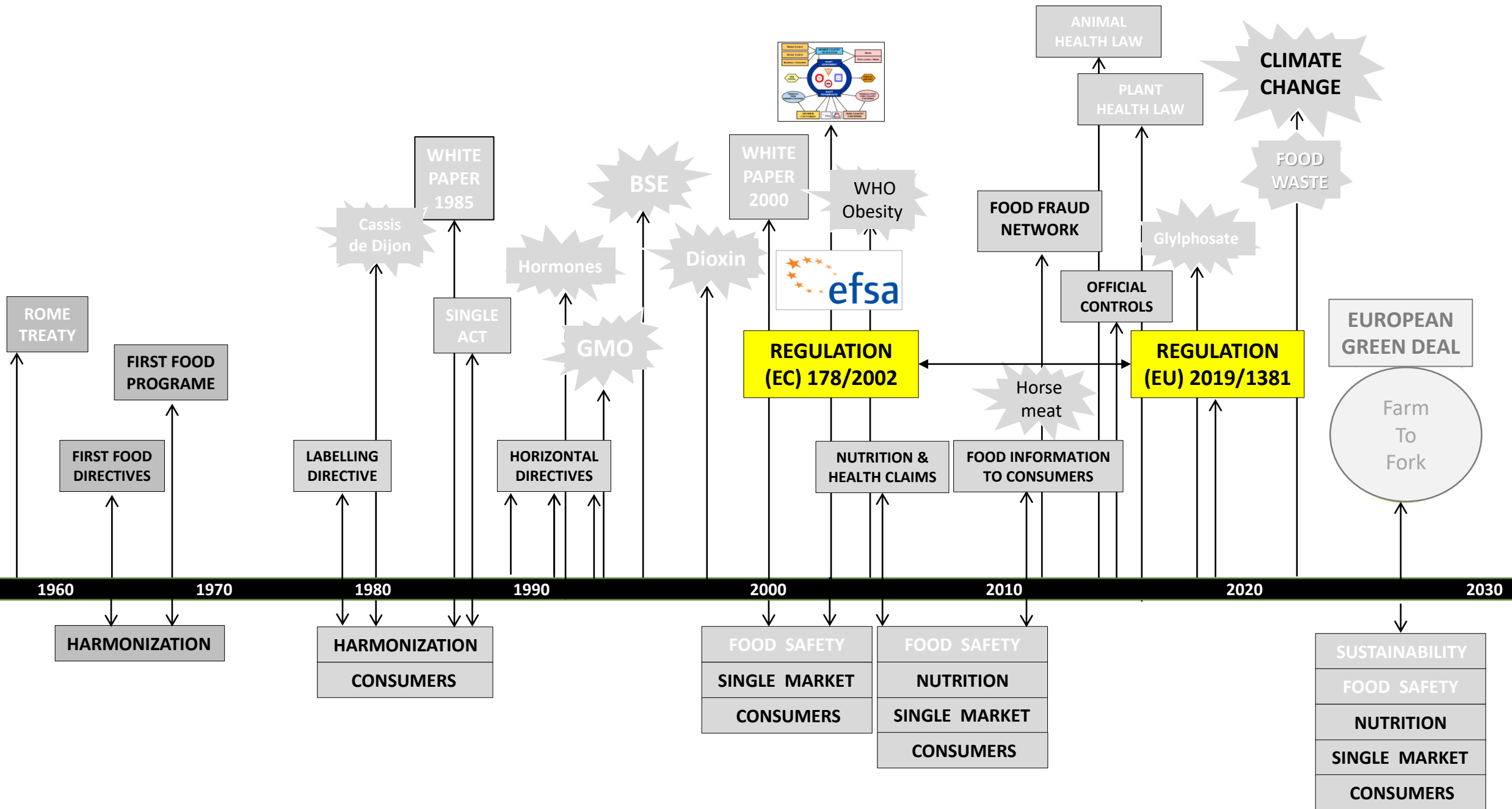


Diploma e Master Universitario in Alti Studi Europei
Collegio Europeo di Parma

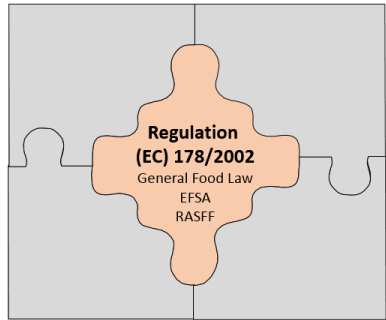
Course on:
"EU Food Law and Policy"
2023
Prof. Patrick Deboyser

2

" The EU General Food Law "
Tuesday 16 April 2024

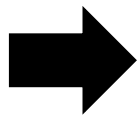


EU Food Law



❑ Regulation (EC) No 178/2002

❖ General Food Law



➤ **General principles** of food law

RISK ANALYSIS

➤ **General requirements** of food law

KEY OBLIGATIONS

➤ **General obligations** of food trade

FOOD TRADE

❖ European Food Safety Authority

EFSA

❖ Rapid Alert System for Food and Feed

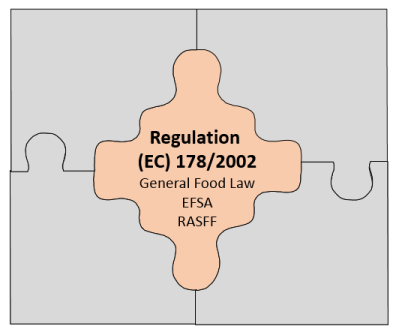
RASFF

❖ Crisis management and emergency procedures

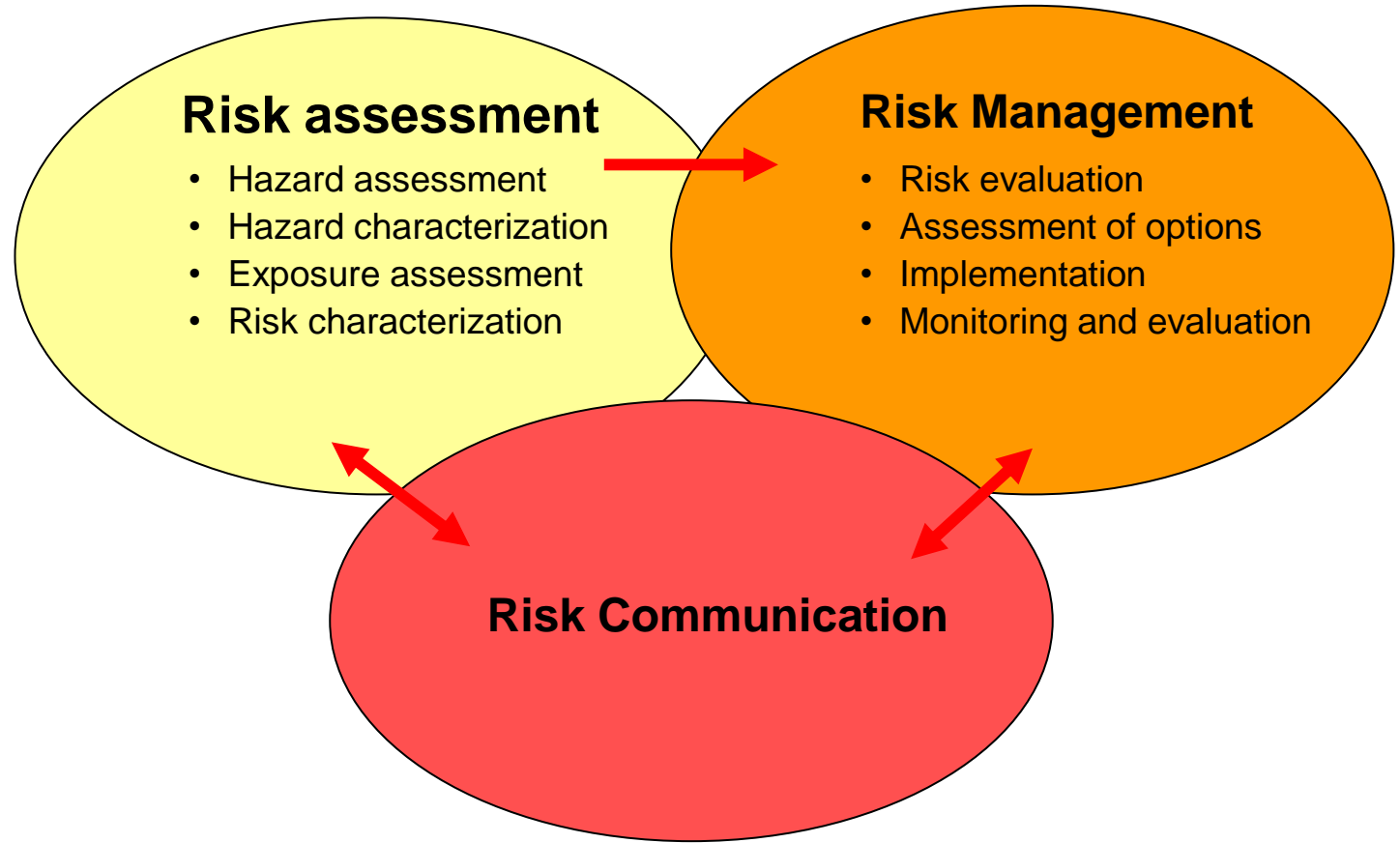
EU Food Law

➤ General principles of food law

RISK ANALYSIS



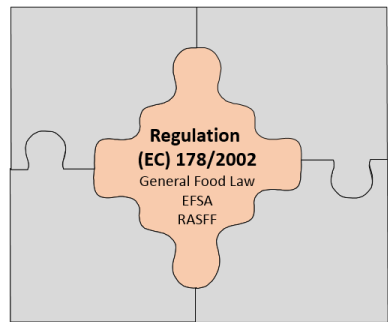
☐ Risk analysis:



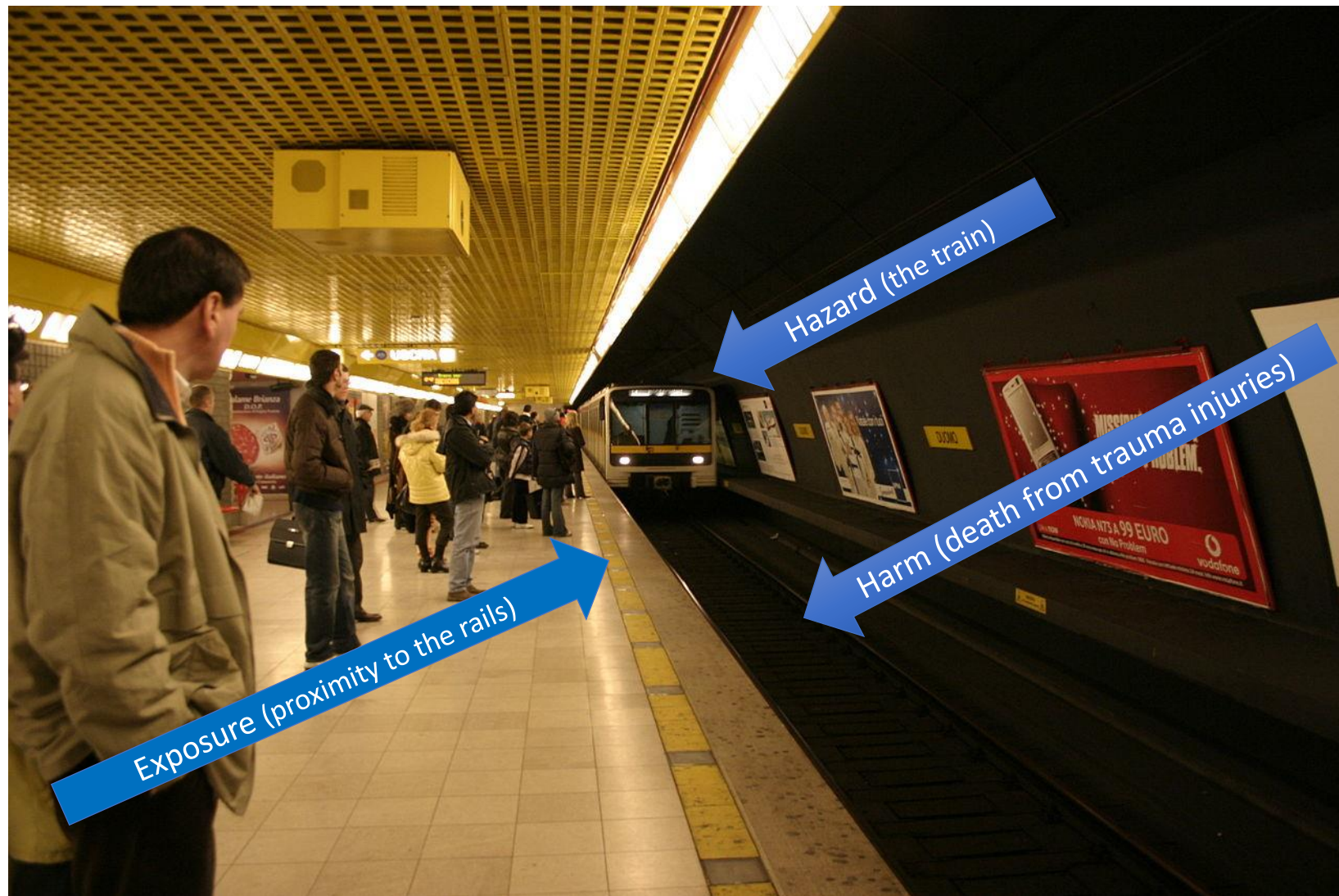
EU Food Law

➤ General principles of food law

RISK ANALYSIS



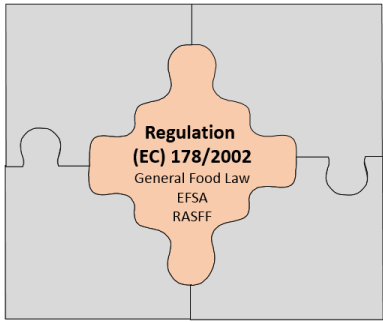
☐ Risk assessment:



EU Food Law

➤ General principles of food law

RISK ANALYSIS



❑ Risk assessment:

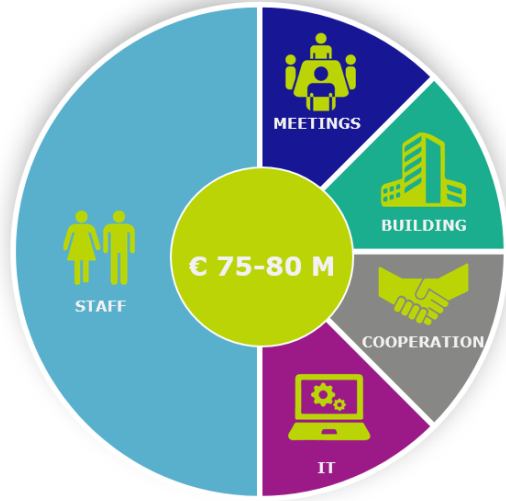
- ❖ Based on the best available science
- ❖ Conducted in an independent, objective and transparent manner
- ❖ Free from conflicts of interest

❑ Functional separation between: risk assessment and risk management

- #### ❑ At European level:
- ❖ European Food Safety Authority (EFSA)



FOCUS ON:
EFSA



> **450** staff



> **1,500** experts



1,000 meetings/year



5,000 outputs /
500 a year



FOCUS ON:

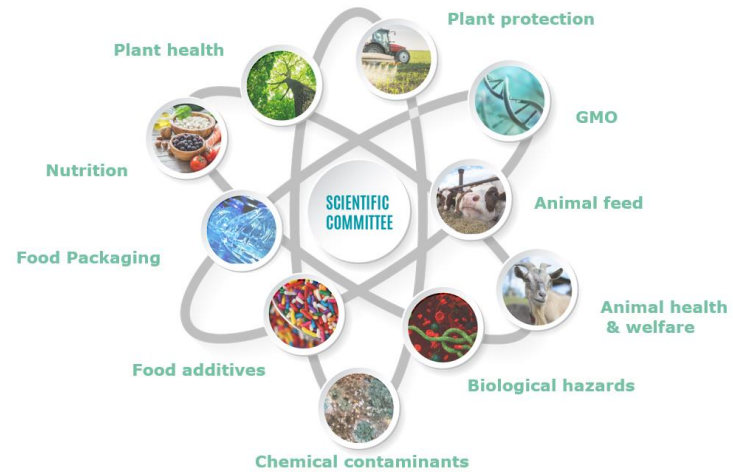
EFSA

Scientific Panels



FOCUS ON:

EFSA



EU Commission



EU Parliament



Member States



EFSA self mandate



FOCUS ON:

EFSA

Regulation (EU) 2019/1381

**1. MORE
TRANSPARENCY**



**2. MORE RELIABLE,
INDEPENDENT STUDIES**



**3. BETTER
GOVERNANCE**

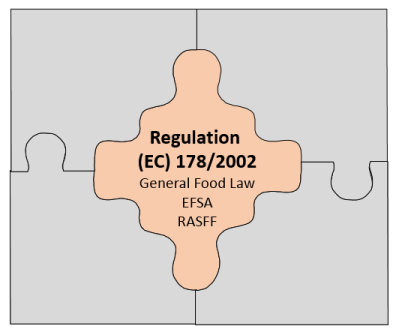


**4. EFFECTIVE RISK
COMMUNICATION**



EU Food Law

➤ General principles of food law RISK ANALYSIS



❑ Risk management:

❖ Taking into account international standards:

Can the Commission deviate from an international standard? Yes, if there is a scientific basis.

❖ Based on risk assessment:

Can the Commission depart from the EFSA opinion ?
Yes: but this decision must be duly motivated.

❖ ... and on:

- other legitimate factors
- the **precautionary principle**

❖ ... in transparency:

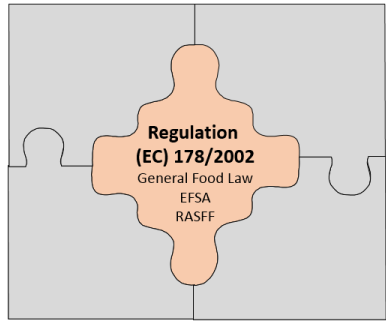
- Stakeholders' consultation
- Information of third countries (WTO)
- Motivated decisions
- Publication
- Transition periods
- Guidance documents



EU Food Law

➤ **General principles** of food law

RISK ANALYSIS



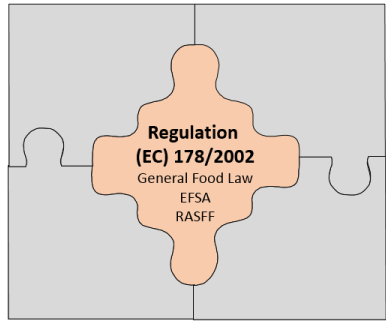
☐ **Risk management:**



EU Food Law

➤ General principles of food law

RISK ANALYSIS



☐ Risk management:

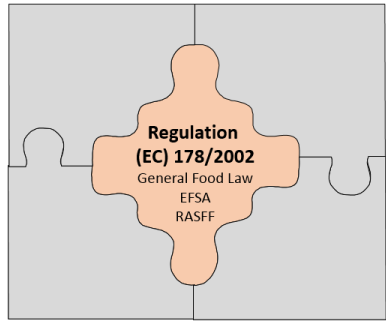


EU Food Law

➤ **General principles** of food law

RISK ANALYSIS

☐ **Risk management:**



Five contested claims

'Glucose is metabolised within body's normal energy metabolism.'

'Glucose supports normal physical activity.'

'Glucose contributes to normal energy-yielding metabolism.'

'Glucose contributes to normal energy-yielding metabolism during exercise.'

'Glucose contributes to normal muscle function.'

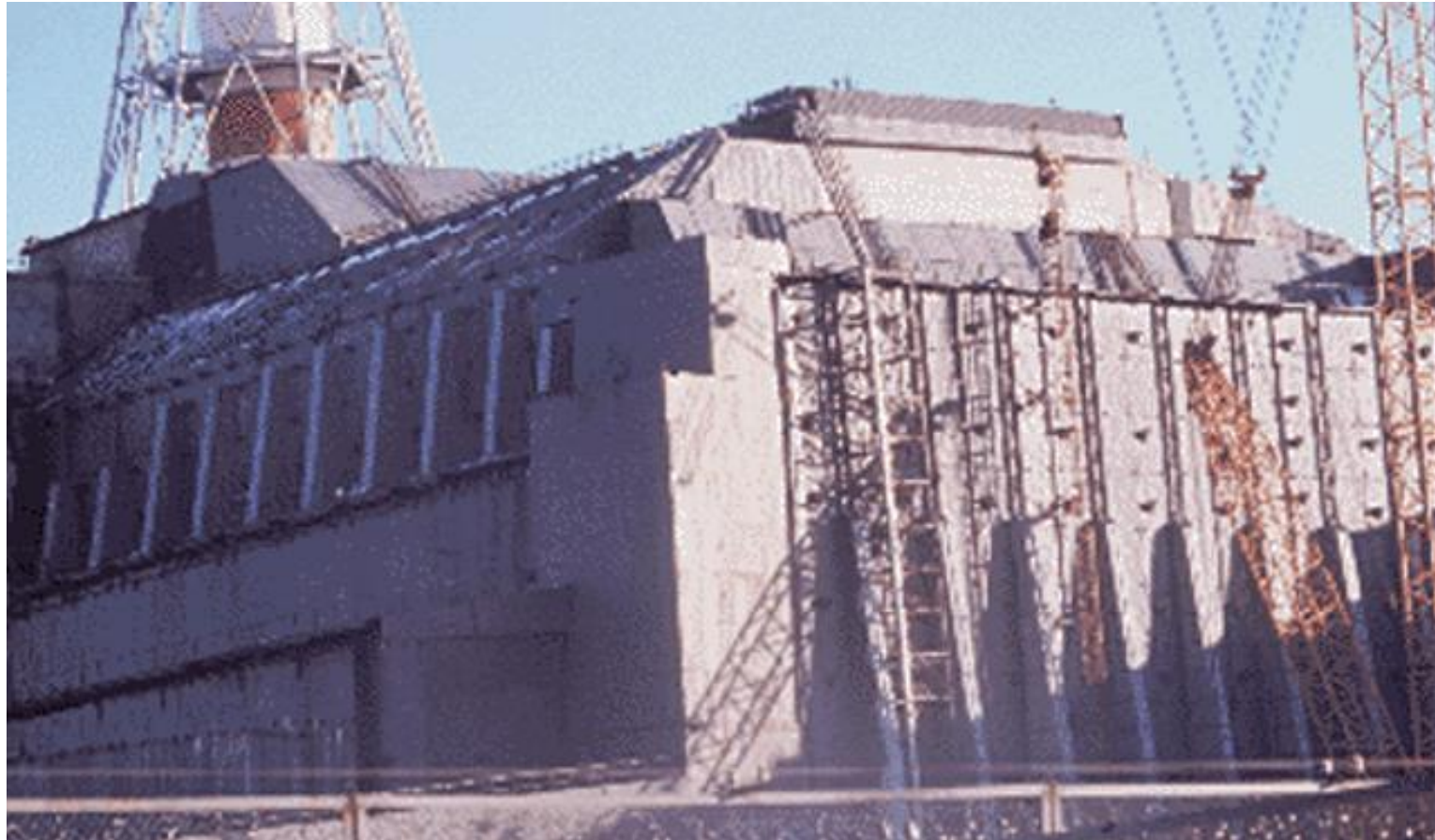
Nutrition claims

- ❖ EFSA delivered a positive opinion on the 5 claims in 2012.
- ❖ The Commission refused to authorize the claims in 2015 over concerns they could encourage excessive sugar intake in the general population.
- ❖ Dextro Energy challenged the Commission refusal in the EU General Court.
- ❖ In its 2016 judgment, the General Court observed that:
 - although the Commission had **not questioned the advice given by EFSA** (the sole task of that authority being to verify whether the health claims are based on scientific evidence and whether the wording of the claims met certain criteria),
 - it was required, as a risk-management measure, to take account of the applicable EU legislation as well as **other legitimate relevant factors**.
- ❖ Dextro Energy appealed to the European Court of Justice, which confirmed in 2017 the General Court's judgement and the Commission refusal to authorize the claims.



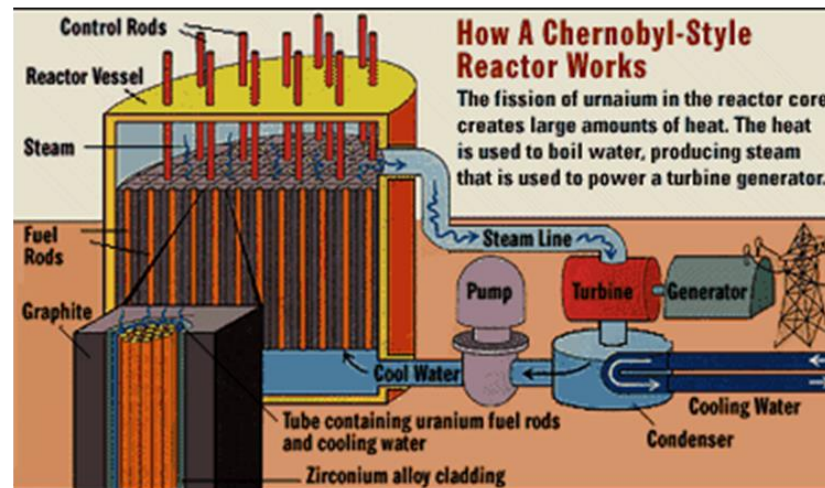
FOCUS ON:

Precautionary
Principle



FOCUS ON:

Precautionary Principle



FOCUS ON:

Precautionary
Principle



FOCUS ON:Precautionary
Principle **Chernobyl**

- **Problem:** no scientific data on risk for human health from radioactive contamination of the food supply
- **Commission Recommendation (2 May 1986):**
Maximum:
 - 90 bq/kg for fruits and vegetables
 - 125 bq/kg for dairy products
- **Council Regulation « post-Tchernobyl » (12 May 1986):**
 - Suspension until May 30th 1986 of all food imports from USSR
 - For Community products, maximum:
 - 370 bq/kg for milk and baby food,
 - 600 bq/kg for other food.
- **Council Regulation (Euratom) No 3954/87 (22 December 1987):**
Maximum:
 - 1000 bq/kg for milk
 - 1250 bq/kg for other food

FOCUS ON:

Precautionary
Principle

□ Regulation (EC) No 178/2002 – Article 7

- In specific circumstances where,
 - following an assessment of available information,
 - the possibility of harmful effects on health is identified
 - but scientific uncertainty persists,
 - provisional risk management measures
 - necessary to ensure the high level of health protection chosen in the [EU]
 - may be adopted,
 - pending further scientific information for a more comprehensive risk assessment.

- Measures adopted [...] shall be:
 - no more restrictive of trade than is required [...]
 - proportionate [...]
 - reviewed within a reasonable period of time [...]

FOCUS ON:

Precautionary
Principle

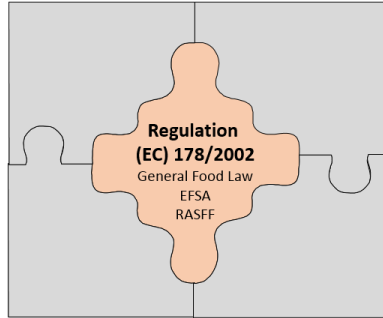
□ Regulation (EC) No 178/2002 – Article 7

- Provides a **legal basis** for **risk management measures** based on the precautionary principle to protect:
 - human health,
 - animal and
 - plant health
- Provides a **legal basis** for **challenging measures abusing** the precautionary principle to protect:
 - the internal market (e.g. ECJ judgement of 13 December 2001 in Case C-1/00)
 - international trade.

EU Food Law

➤ General principles of food law

RISK ANALYSIS



❑ Risk Communication

- ❖ **Definition:** the interactive exchange of information and opinions throughout the risk analysis process, concerning: risk, risk-related factors, and risk perceptions.
- ❖ **This exchange should take place among:** risk assessors, risk managers, consumers, industry, the academic community, and other interested parties.
- ❖ **It should include:** the explanation of risk assessment findings, and the basis of risk management decisions.

❑ The Challenge of Risk Communication !

FOCUS ON:

Glyphosate
Controversy

FOCUS ON:

Glyphosate
Controversy

- ❑ Glyphosate is an active substance that is widely used in plant protection products to combat weeds that compete with cultivated crops.



- ❑ It is the most frequently used herbicide both worldwide and in the EU and it has been used for several decades. It is best known for being the active ingredient in Monsanto's popular Roundup herbicide.



FOCUS ON:

Glyphosate Controversy

- ❑ The approval of glyphosate as an active substance in the EU under Regulation (EC) No 1107/2009 was expiring on 30 June 2016. An application for the renewal of the approval was made by Monsanto in 2013.
- ❑ In March 2015, the International Agency for Research on Cancer (IARC), a WHO agency classified glyphosate as a '*potential carcinogenic*'.



The image shows a screenshot of a news article from the website 'M Planète'. The logo 'M Planète' is at the top left. Below it is a navigation bar with tabs for 'PLANÈTE', 'Climat', 'Biodiversité', 'Ressources naturelles', 'Énergies', 'Énergies renouvelables', and 'Nucléaire'. The main headline is 'Le désherbant Roundup classé cancérigène'. Below the headline is a sub-headline: 'La décision de l'OMS concerne l'herbicide de Monsanto le plus utilisé et le plus souvent retrouvé dans l'environnement.' At the bottom, there is a timestamp: 'LE MONDE | 25.03.2015 à 12h13 • Mis à jour le 25.03.2015 à 14h33 |'.

FOCUS ON:

Glyphosate
Controversy

- ❑ In November 2015, EFSA updated the toxicological profile of glyphosate and concluded that glyphosate is '*unlikely to pose a carcinogenic hazard to humans*'.
- ❑ As a number of Member States had considered that it was appropriate to have an opinion of the Committee for Risk Assessment of ECHA (the European Chemicals Agency), the Commission extended the approval of glyphosate until 31 December 2017.



FOCUS ON:

Glyphosate Controversy

- ❑ In March 2017, the European Chemicals Agency (ECHA) concluded by consensus that no hazard classification for carcinogenicity is justified for glyphosate.
- ❑ However, in the meantime, EFSA had come under strong criticism from the press and MEPs for its assessment of glyphosate.



The
Investigative
Reporting
Award 2018 Winner

Monsanto Papers

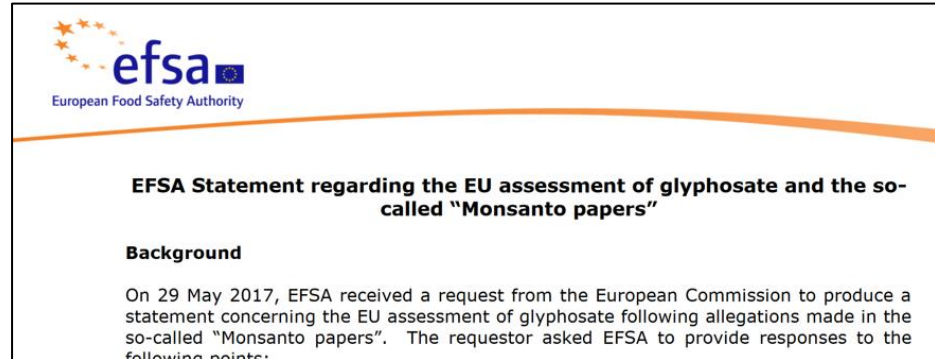
WRITTEN BY
Stephane Foucart
Stephane Horel

PUBLISHED BY
[Le Monde, France](#)

FOCUS ON:

Glyphosate
Controversy

- ❑ EFSA replied convincingly to all accusations.



- ❑ Other regulatory agencies around the World (e.g. in the U.S., Canada, Japan, Australia) agreed with EFSA. So did an expert body on pesticide residues convened by the FAO and WHO.
- ❑ On 12 December 2017, the Commission renewed the approval of glyphosate for 5 years, following support by a qualified majority of Member States in an Appeal Committee held on 27 November 2017.
- ❑ However, a lot of damage had been done to the EU decision making process for the authorization of pesticides and in particular the role that EFSA plays in it.

FOCUS ON:

Glyphosate
Controversy

- ❑ The matter was emphasized by a ruling of 7 March 2019 of the European Court of Justice (ECJ) in two cases brought by Green members of the European Parliament, among others.
 - EFSA was ordered to disclose details of studies on the toxicity and carcinogenic properties of glyphosate.
 - The ECJ said the public has an interest in accessing the information related not only to knowing what is or could be released into the environment, but to understanding the impact of those emissions.

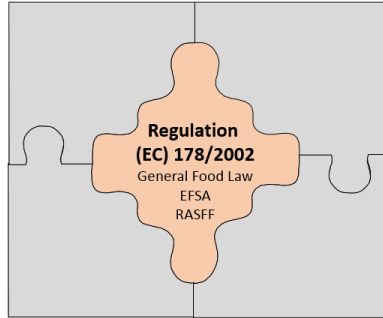


FOCUS ON:

Glyphosate Controversy

- ❑ European Citizen's Initiative
 - A European Citizens' Initiative (ECI) "Ban glyphosate and protect people and the environment from toxic pesticides" was submitted to the Commission in July 2017, supported by 1,320,517 signatures.
- ❑ Commission response
 - Announces a legislative proposal for spring 2018:
 - to enhance the transparency, quality and independence of scientific assessments of substances, such as public access to raw data;
 - to strengthen the governance of the conduct of relevant studies.
 - Following a positive vote by Member States' representatives, the Commission adopted in December 2017 a renewal of the approval of glyphosate for 5 years (rather than 10 as is usually the case).

EU Food Law



Regulation (EU) 2019/1381 (amending Regulation (EC) 178/2002)

Four Pillars

Quality & reliability
of studies

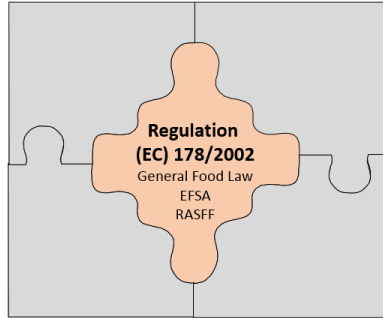
Transparency of EU
risk assessment

Sustainability &
governance of EFSA

Improved risk
communication

EU Food Law

Regulation (EU) 2019/1381 (amending Regulation (EC) 178/2002)

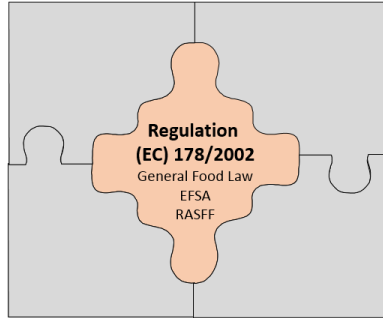


Quality & reliability of studies

- ❑ EFSA will be **notified of all commissioned studies** to guarantee that companies applying for authorisations submit all relevant information and do not hold back unfavourable studies.
- ❑ EFSA will also provide general **advice to applicants**, in particular SMEs, prior to the submission of the dossier.
- ❑ The Commission may ask the Authority to commission **additional studies for verification purposes** and may perform **fact-finding missions** to verify the compliance of laboratories/studies with standards

EU Food Law

Regulation (EU) 2019/1381 (amending Regulation (EC) 178/2002)

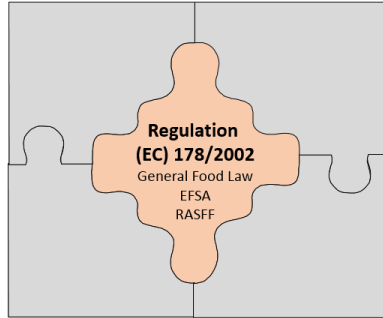


Transparency of EU risk assessment

- Citizens will have **automatic access to all studies** and information **submitted by industry** in the risk assessment process.
- Stakeholders and the general public will also be consulted on submitted studies.
- At the same time, the Regulation will guarantee **confidentiality**, in duly justified circumstances, by setting out the type of information that may be considered significantly harmful for commercial interests and therefore cannot be disclosed

EU Food Law

Regulation (EU) 2019/1381 (amending Regulation (EC) 178/2002)

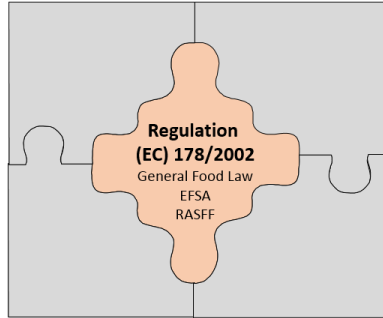


Improved risk communication

- ❑ Definition of general objectives and general principles.
- ❑ A **general plan for risk communication** will be adopted by way of an implementing act, that will ensure a coherent risk communication strategy throughout the risk analysis process, combined with open dialogue amongst all interested parties.

EU Food Law

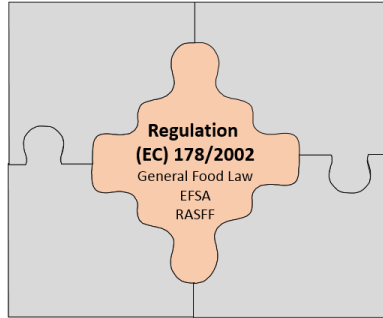
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Sustainability & governance of EFSA

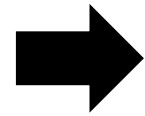
- ❑ EFSA Management Board (from 1 July 2022)
 - **Member States** representatives
 - European **Parliament** + European Commission
 - **Civil society** representatives and food chain interests.
- ❑ Active **involvement of Member States** to stimulate experts in contributing to EFSA's work (promotion of EFSA's call for experts to Scientific Panels and Scientific Committee).
- ❑ Considerable **budget increase** (EUR 62.5 million and 106 additional posts) : negotiations on-going under the Multi-Financial Framework (MFF) Programme.

EU Food Law



❑ Regulation (EC) No 178/2002

❖ General Food Law



➤ **General principles** of food law

RISK ANALYSIS

➤ **General requirements** of food law

KEY OBLIGATIONS

➤ **General obligations** of food trade

FOOD TRADE

❖ European Food Safety Authority

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❖ Rapid Alert System for Food and Feed

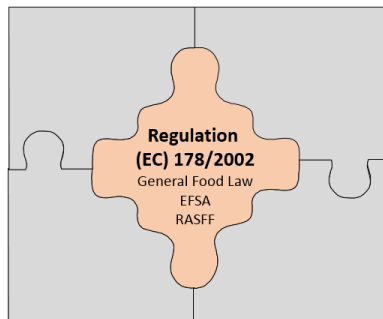
RASFF

❖ Crisis management and emergency procedures

EU Food Law

➤ General requirements of food law

KEY OBLIGATIONS



❑ A regulatory framework for **food business operators**

❖ Clearly assigned responsibilities:

➤ Producers, importers, distributors, retailers :

responsible for the safety of food

➤ Authorities:

responsible for official controls

❖ **Key obligations** of food business operators:

➤ Safety

➤ Responsibility

➤ **Traceability**

➤ Transparency

➤ Emergency

➤ Prevention

➤ Co-operation

FOCUS ON:

Traceability

What is traceability?

Regulation (EC) No 178/2002

Traceability means:

the ability to trace and follow:

- a food,
- a feed,
- a food-producing animal or
- a substance intended to be, or expected to be present in food

through all stages of:

- production,
- processing or
- distribution.

Article 18

Traceability

1. The traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be, incorporated into a food or feed shall be established at all stages of production, processing and distribution.

2. Food and feed business operators shall be able to identify any person from whom they have been supplied with a food, a feed, a food-producing animal, or any substance intended to be, or expected to be, incorporated into a food or feed.

To this end, such operators shall have in place systems and procedures which allow for this information to be made available to the competent authorities on demand.

3. Food and feed business operators shall have in place systems and procedures to identify the other businesses to which their products have been supplied. This information shall be made available to the competent authorities on demand.

4. Food or feed which is placed on the market or is likely to be placed on the market in the Community shall be adequately labelled or identified to facilitate its traceability, through relevant documentation or information in accordance with the relevant requirements of more specific provisions.

5. Provisions for the purpose of applying the requirements of this Article in respect of specific sectors may be adopted in accordance with the procedure laid down in Article 58(2).

FOCUS ON:

Traceability

What is required of business operators?

Regulation (EC) No 178/2002

- (1) Food and feed business operators shall be able **to identify any person from whom they have been supplied with a food**, a feed, a food-producing animal, or any substance intended or expected to be incorporated into a food or a feed.

To this end, such operators shall have in place systems which allow for this information to be **made available** to the competent authorities **on demand**.

ONE STEP BACK

Article 18

Traceability

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FOCUS ON:

Traceability

What is required of business operators?

Regulation (EC) No 178/2002

- (2) Food and feed business operators shall have in place systems and procedures **to identify the other businesses to which their products have been supplied.**

This information shall be **made available** to the competent authorities **on demand.**

ONE STEP FORWARD

Article 18

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FOCUS ON:

Traceability

Is 'internal' traceability required?

Regulation (EC) No 178/2002

Do business operators have to match inputs with outputs?

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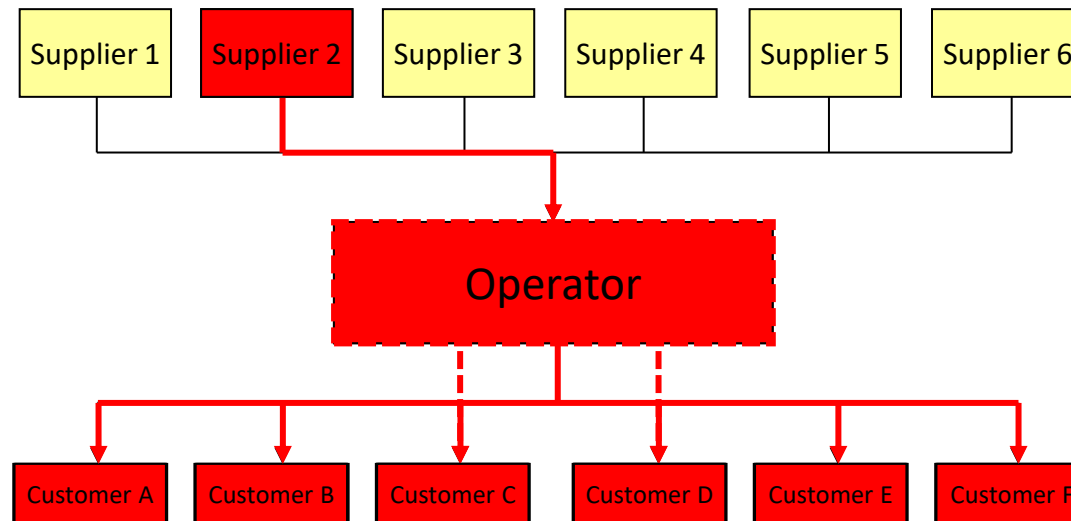
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**With
internal
traceability**

FOCUS ON:

Traceability

Is 'internal' traceability required?

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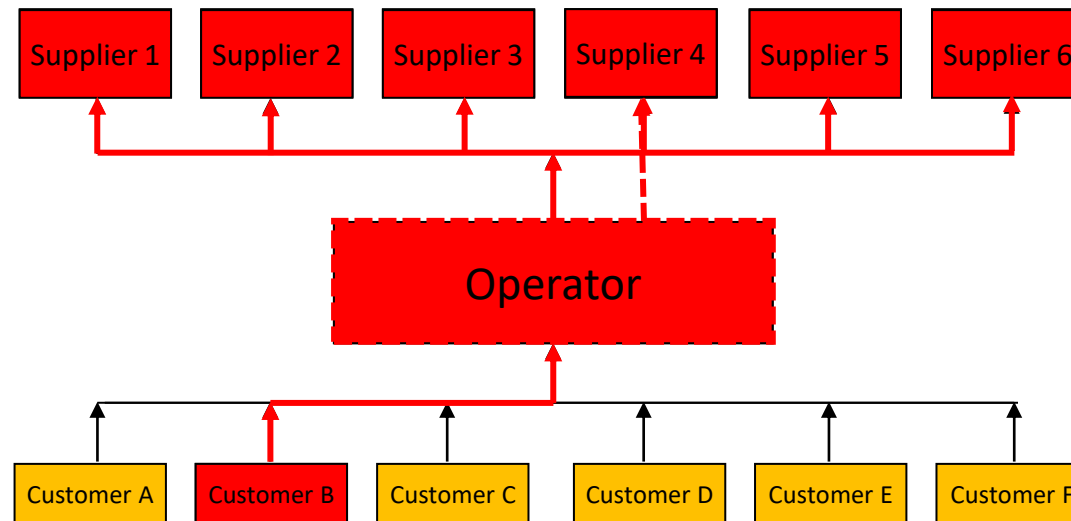
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**With
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Traceability

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2. Food and feed **ONE STEP BACK** able to identify any person from whom **ONE STEP BACK** with a food, a feed, a food-producing animal, or any substance intended to be, or expected to be, incorporated into a food or feed.

To this end, such operators shall have in place systems and procedures which allow for this information to be made available to the competent authorities on demand.

3. Food and feed **ONE STEP FORWARD** place systems and procedures to identify **ONE STEP FORWARD** their products have been supplied. This information shall be made available to the competent authorities on demand.

4. Food or feed which is placed on the market or is likely to be placed on the market in the Community shall be adequately labelled or identified to facilitate its traceability, through relevant documentation or information in accordance with the relevant requirements of more specific provisions.

5. Provisions for the purpose of applying the requirements of this Article in respect of specific sectors may be adopted in accordance with the procedure laid down in Article 58(2).

- Business operators are **not obliged** to establish a link between incoming and outgoing products.
- However, food business operators are **encouraged** to develop systems of internal traceability designed in relation to the nature of their activities (food processing, storage, distribution, etc.).



FOCUS ON:

Traceability

Is 'internal' traceability required?

Regulation (EC) No 178/2002

(1) **ONE STEP BACK**

(2) **ONE STEP FORWARD**

(3) **LABELLING**

Food or feed which is placed on the market in the EU shall be **adequately labelled or identified to facilitate its traceability**, through relevant **documentation or information** in accordance with the relevant requirements or more specific provisions.

Article 18

Traceability

1. The traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be, incorporated into a food or feed shall be established at all stages of production, processing and distribution.

2. Food and feed business operators shall be able to identify any person from whom they have been supplied with a food, a feed, a food-producing animal, or any substance intended to be, or expected to be, incorporated into a food or feed.

To this end, such operators shall have in place systems and procedures which allow for this information to be made available to the competent authorities on demand.

3. Food and feed business operators shall have in place systems and procedures to identify the other businesses to which their products have been supplied. This information shall be made available to the competent authorities on demand.

4. Food or feed which is placed on the market or is likely to be placed on the market in the Community shall be adequately labelled or identified to facilitate its traceability, through relevant documentation or information in accordance with the relevant requirements of more specific provisions.

5. Provisions for the purpose of applying the requirements of this Article in respect of specific sectors may be adopted in accordance with the procedure laid down in Article 58(2).



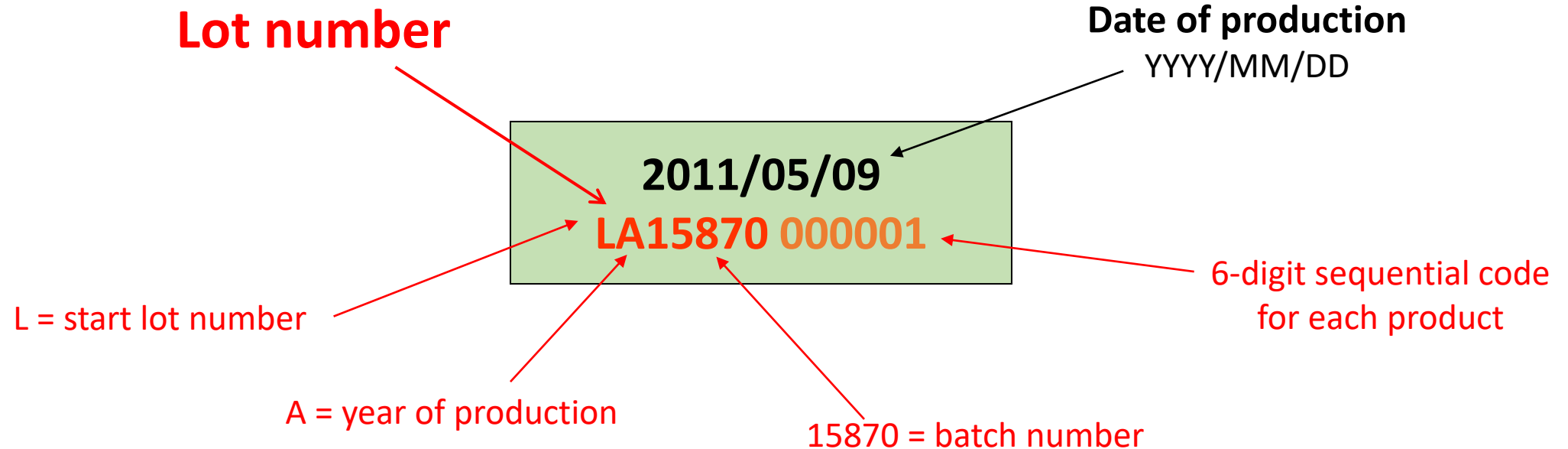
FOCUS ON:

Traceability

Prepacked food: batch number

Directive 89/396/CEE

“A foodstuff may not be marketed unless it is accompanied by an indication of the lot to which the foodstuff belongs.”



FOCUS ON:

Traceability

How is traceability organised?

Regulation (EC) No 178/2002

- ❑ Regulation (EC) No 178/2002 is **non-prescriptive**.
- ❑ **Detailed requirements** may be laid down for **specific sectors**.
- ❑ Examples:
 - ❖ Live animals
 - ❖ Fruits and vegetables
 - ❖ Fish
 - ❖ Eggs
 - ❖ Beef

Article 18

Traceability

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5. Provisions for the purpose of applying the requirements of this Article in respect of specific sectors may be adopted in accordance with the procedure laid down in Article 58(2).



FOCUS ON:

Traceability

How is traceability organised?

FISH

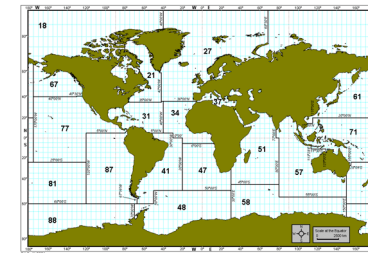
The labelling must bear (when sold to the final consumer):

➤ the commercial designation of the species

➤ the production method

➤ the catch area

Tuna	caught	in the Pacific Ocean
Salmon	caught in freshwater	in Norway
Tiger prawns	farmed (or cultivated)	In Thailand



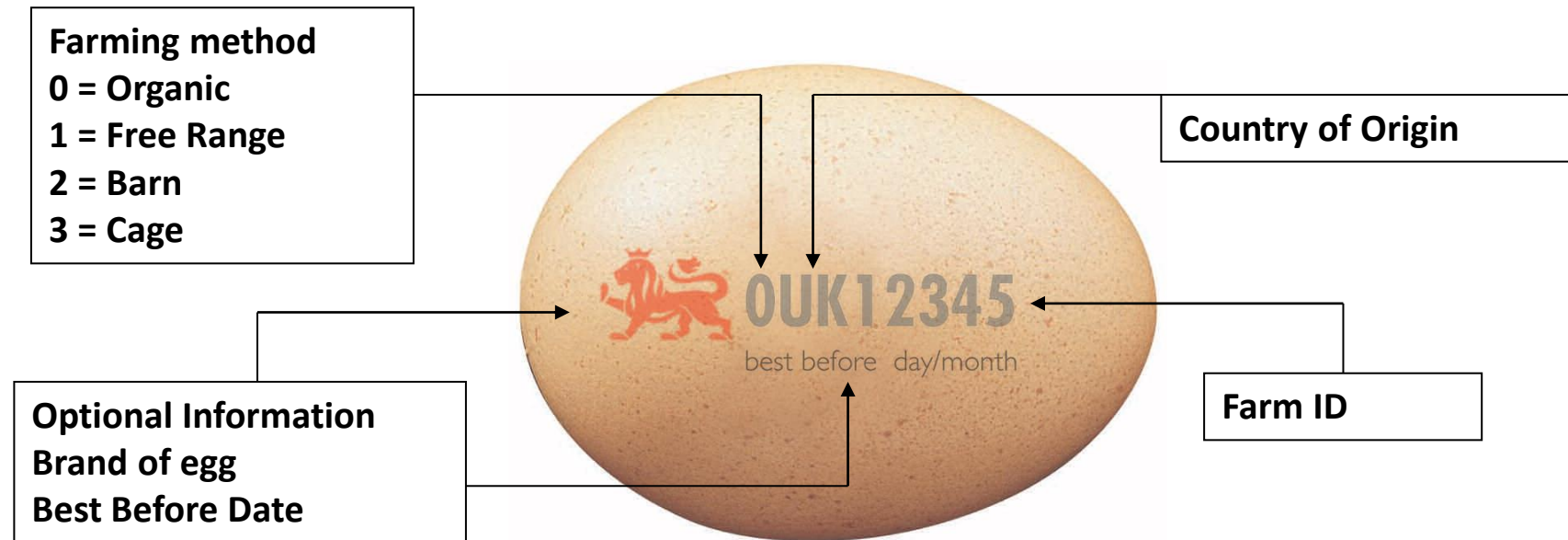
FOCUS ON:

Traceability

How is traceability organised?

EGGS

Every egg (category A) must bear a code:



FOCUS ON:

Traceability

How is traceability organised?

BEEF

Live animals:

Bovines have to carry ear tags:

Two-letter
country code

Bar code

Animal ID
number



FOCUS ON:

Traceability

How is traceability organised?

BEEF

► **Beef** (when sold to the final consumer):

Label of pre-packaged products must bear:



- Traceability bar code
- Country where animal was born
- Country where animal was fattened
- Country where animal was slaughtered



FOCUS ON:

Traceability

How is traceability organised?

BEEF

37600 LOCHES 05638

U

Le nouveau commerçant

ROTI **

ORIGINE : FRANCE

VIANDE BOVINE

N° DE LOT : 5006

Catégorie: BOEUF	MIXTE
Né en Irlande	Elevé en Irlande
Lieu d'abattage Irlande	350
Lieu de découpe	Grande Bretagne

A conserver entre 0 et 3°C

Date d'emballage 15.01.2015 11:38

A consommer jusqu'au 19.01.2015

Prix unitaire 8,50 €/kg

Poids net 1,904 kg

PRIX A PAYER 16,18€

0 202443 106138

Next :


Diploma e Master Universitario in Studi Europei
Collegio Europeo di Parma

Course on:
"EU Food Law and Policy"
2023
Prof. Patrick Deboyser

3

" The EU Agri-Food Trade "
Tuesday 16 April 2024