BTSF: FOOD SAFETY RISK ANALYSIS

KUALA LUMPUR, MALAYSIA, 4TH MARCH – 7TH MARCH 2024

DR. NURUL AYUNI BINTI CHE JAAPAR
BAHAGIAN KESIHATAN AWAM VETERINAR
18.06.2025

LATAR BELAKANG LATIHAN

BTSF ialah inisiatif latihan European Commission untuk meningkatkan pengetahuan dan pelaksanaan peraturan EU yang meliputi undang-undang makanan dan makanan haiwan, kesihatan dan kebajikan haiwan, ONE HEALTH, serta peraturan mengenai kesihatan tumbuhan dan produk perlindungan tumbuhan.

Telah diadakan di Aloft Hotel, Kuala Lumpur, Malaysia dari 4 – 7 Mac 2024

Disertai oleh peserta dari Negara India, Laos, Malaysia, Buthan, Vietnam, Bangladesh, Thailand, Sri Lanka, Maldives, Cambodia, Philippines, Pakistan dan Nepal

Penyertaan Malaysia terdiri daripada 10 pegawai dari DVS, PKKM, DOA, DOF dan MPOB

OBJEKTIF

1) Meningkatkan pemahaman peserta berkaitan prinsip dan kaedah pengurusan analisis risiko dalam bidang keselamatan makanan, tumbuhan serta produk perubatan veterinar
2) Meningkatkan pendedahan kepada kaedah pengurusan krisis
3) Meningkatkan kefahaman berkaitan peraturan dan kawalan rasmi perundangan Eropah

AKTIVITI UTAMA YANG DILAKUKAN

Plenary lectures

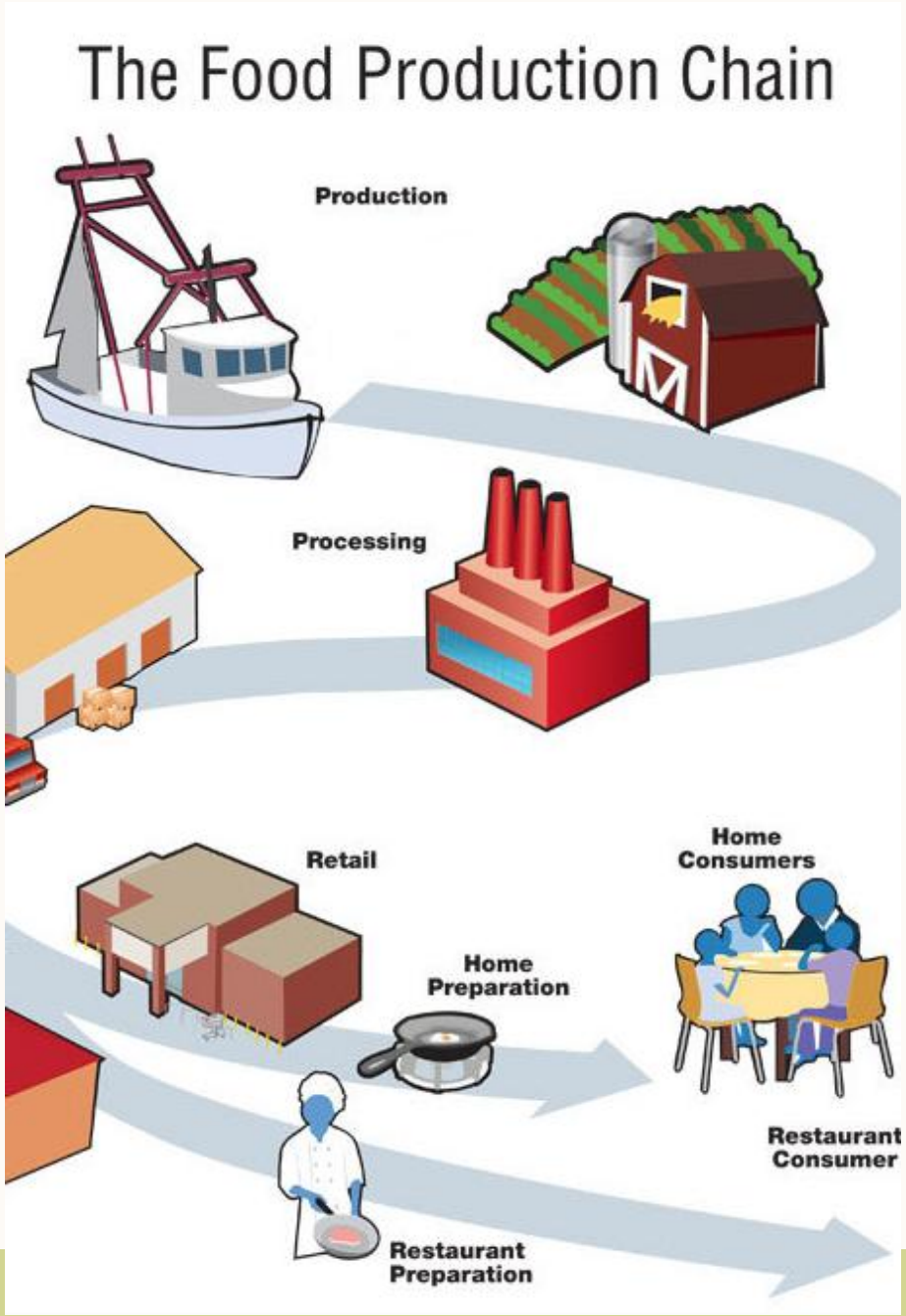
1.EU General Food Law
2.Three Pillars of Risk Analysis – EU Approach
3.Plant Health
4.Chemical Contaminants
5.Food Contact Materials
6.Regulated Products
7.Veterinary Medicinal Products
8.Zoonoses & Microbiological Risk Assessment
9.Official Controls

Kahoot quizzes

Discussions

Group work and case studies

PENGALAMAN PEMBELAJARAN



FROM FARM TO FORK: THE EU GENERAL FOOD LAW

BACKGROUND/INTRODUCTION

- Legal basis: Regulation (EC) No. 178/2002 ´**General Food Law**´ (GFL)

- Founded on the international framework of the **three pillars** as defined by **WHO/FAO**

GENERAL PRINCIPLES OF FOOD LAW

General objectives

Protection of:

- human life and health
- consumers' interests
- animal health
- animal welfare
- plant health
- environment

Risk analysis

Based on the available scientific evidence and undertaken in an independent, objective and transparent manner

Precautionary principle

The principle is used to justify discretionary decisions in situations where there is the possibility of harm from making a certain decision when extensive scientific knowledge on the matter is lacking

Protection of consumers' interests

Prevention of:

- fraudulent or deceptive practices
- the adulteration of food
- any other practices which may mislead the consumer

GENERAL REQUIREMENTS OF FOOD LAW

- **Food** should **not** be **placed on the market,** if it is **unsafe.**
- **Feed** should **not** be **placed on the market** or fed to any food-producing animal, if it is **unsafe**.
- **Labelling, advertising** and **presentation** should **not mislead** consumers (e.g. shape, appearance, packaging, packaging materials used, display, information).
- **Food and feed business operators** at all stages of production, processing and distribution within the businesses under their control should **ensure that requirements** of food law are **satisfied** and should **verify** that such requirements are met.

THE THREE PILLARS OF RISK ANALYSIS – THE EU APPROACH

PRINCIPLES OF RISK ANALYSIS

- Overall **objective** for food safety: to ensure **human health** protection.

- Principles apply equally to issues of **national food control** and **food trade** situations.
- Should be applied **consistently** and in a **non-discriminatory** manner.
- **Precaution** is an inherent element.
- **EU** at the **forefront** in Risk Analysis as a methodological approach underpinning food policy orientations and its international acceptance.

PRINCIPLES OF RISK ANALYSIS – THREE PILLARS

GFL *(Art.3.(10))* defines `Risk Analysis' as a process consisting of three interrelated components (Pillars):

I. Risk assessment

II. Risk management

III. Risk communication

GFL *(Art.6)* refers to it as a basis for the adoption of any food safety measure at EU level.

PRINCIPLES OF RISK ANALYSIS - COMPETENCES

Breakdown of Risk Analysis to **three** components (Pillars) is not purely theoretical, but has **institutional** relevance:

I. Pillar - Risk assessor:

EFSA within the EU Risk Assessment process *(Art.22(2) GFL).*

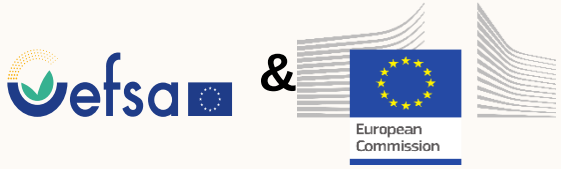
II. Pillar - Risk manager:

European Commission + assisted by **Member States** (as appropriate).

III. Pillar - Risk communication:

Shared competence between **EFSA** (risk assessment) and **European Commission** (risk management)

(Art. 40(1) GFL). (n.b. competencies are sometimes blurred).



I. PILLAR – RISK ASSESSMENT

Scientifically based process consisting five steps:

Problem formulation	Hazard identification	Hazard characterisation	Exposure assessment	Risk characterisation
Describing the precise nature of the scientific question and what is outside of scope *("What to answer?")*	Identification of known or potential health effects associated with a particular agent (i.e. types of injury and conditions of exposure)	The qualitative and/or quantitative evaluation of the nature of adverse effects associated with biological, chemical and physical agents which may be present in food. Dose-response assessment should be performed (if data obtainable)	The qualitative and/or quantitative evaluation of the degree of intake likely to occur	Integration of the previous steps into an estimation of the adverse effects likely to occur in given population, including attendant uncertainties. (risk is the possibility that an adverse effect will occur)

II. PILLAR – RISK MANAGEMENT

- a process, **distinct** and initially independent from **risk assessment**, of weighing **policy alternatives** in consultation with interested parties, considering risk assessment and other legitimate factors (relevant for the health protection of consumers and for the promotion of fair practices in food trade), and, if need be, **selecting appropriate prevention and control** options.
- decisions should be **proportionate** to the assessed risk.
- Components of risk management framework (defined by WHO):
  - Preliminary risk management activities.
  - Evaluation of risk management options.
  - Implementation of the risk management decision.
  - Monitoring and reviewing.
- Traceability (TRACES)

II. PILLAR – RISK MANAGEMENT

Traceability

Reacting rapidly to health threats by tracing the movements of consignments and facilitating the risk management of rejected consignments.

TRACES - TRAde Control and Expert System

- European Commission's multilingual **online management tool** for all sanitary requirements on intra-EU trade and importation of animals, semen and embryo, food, feed and plants.
- 23 official EU languages and in **34 languages** in total and **works 24/7**, free of charge.
- Main objective is to **digitise** the entire certification **process** and linked procedures, and is in line with the declaration of the Digital Agenda for Europe.
- More than **55.000 users** from more than **90 countries worldwide** are interconnected through TRACES, centralising all data, simplifying and accelerating the trading process.
- Facilitates the **exchange of information** between all involved trading parties and control authorities and speeds up the administrative procedures.

III. PILLAR – RISK COMMUNICATION

- **Integral** and ongoing part of the Risk Analysis exercise.
- **Clear, interactive** and **documented** communication amongst risk assessors and risk managers.
- **Reciprocal** communication with all interested parties in all aspects of the process.
- Ideally **all stakeholder groups** (industry and consumers) should be involved from the start (WHO 2009).
- Various stakeholder groups: consumers, industry, NGOs, politicians and scientists – **different roles and interests.**
- Should be more than “just” dissemination of information.
- Major function: to ensure that **all information** and opinion required for effective risk management is **incorporated** into the decision-making process.
- Make **stakeholders aware** of the process throughout Risk Analysis, i.e. when risk assessment is performed or risk management decisions are taken.

III. PILLAR – RISK COMMUNICATION

- **Transparency** and openness with respect to consumers´ needs.
- Relates to food safety (= health related) ➡ requires **prudent** and **in-depth consideration** before being realised as wrongful messages may have devastating effects on public opinion and on the economy.
- From risk assessment perspective: risk communication helps to ensure that the **logic, outcomes, significance** and **limitations** of such assessment are **understood** and **accepted** by all stakeholders.
- It may occur that stakeholders hold information that may be of relevance for performing a full risk assessment (e.g. unpublished data from industry that is a crucial complement to risk assessors).
- Risk communication shall fulfil the objectives and respect the general principles set out in Articles 8a and 8b Regulation (EC) No 178/2002 (amending by Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain). The Commission shall adopt, by means of implementing acts, a **general plan for risk communication** in order to achieve the objectives and general principles set out in Articles 8a and 8b. The Commission shall keep that general plan updated, taking into account technical and scientific progress and experience gained.
- EFSA detailed document 2012 (necessity of setting up practical and common framework for risk communication activities) - ***"When Food is Cooking up a Storm: Proven Recipes for Risk Communications."***

CHEMICAL CONTAMINANTS

CHEMICAL RISK ASSESSMENT

A scientifically based process consisting of the four steps

1. Hazard identification

Origin of the hazard
Physico/chemical properties

2. Hazard characterization

Toxicokinetics - Toxicodynamics
Dose-response-assessment

3. Exposure assessment

Concentration data - Food consumption data

4. Risk characterization

Calculation of the likelihood that a particular substance will cause harm

RISK MANAGEMENT-*COMMITTEES*

DG SANTE / UNIT E2
Health and Food Safety Directorate General

STANDING COMMITTEE

on Plants, Animals, Food and Feed (SCPAFF)
Section: Novel Food and Toxicological Safety of the Food Chain

EXPERT COMMITTEES

Expert Committee on Agricultural Contaminants (AGRI)
Expert Committee on Environmental Contaminants (ENVI)
Expert Committee on Persistent Organic Pollutants in Food (POPS)

RISK MANAGEMENT
PREVENTION AND CONTROL OPTIONS

- SETTING OF MAXIMUM LEVELS (ML)
- MONITORING: Data collection from Member States (MS)
- ADVICE TO CONSUMERS: fish consumption, barbecuing
- FOOD AND VETERINARY OFFICE (FVO): Inspection of Member States
- RAPID ALERT SYSTEM FOR FOOD AND FEED (RASFF)
- IMPORT RESTRICTIONS

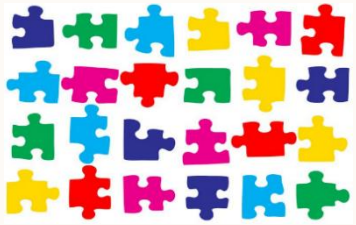
RISK MANAGEMENT-*MAXIMUM LEVELS*

- RISK ASSESSMENT FROM EFSA
- DATA – BACKGROUND LEVELS
- FOOD CONSUMPTION DATA / HABITS
- ANALYTICAL POSSIBILITIES (levels of detection, uncertainties, equipment)
- PRACTICAL FEASIBILITY OF CONTROL (sampling etc.)
- HEARING OF INDUSTRY ON NATIONAL BASIS AND VIA EU

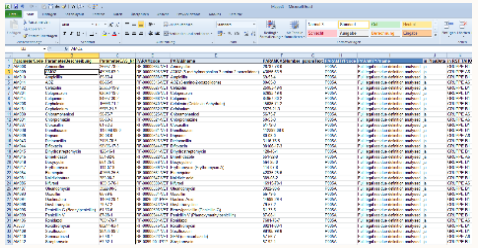
RISK MANAGEMENT-*DATA COLLECTION*

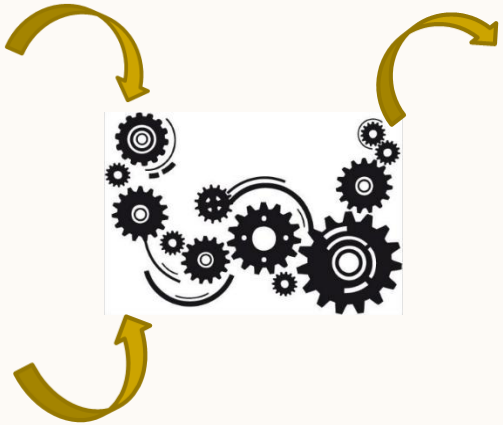
- Electronic Transmission of **Chemical Occurrence Data** to EFSA
- Use of mapping catalogues covering international requirements
- Each entry or unique combination of entries will be mapped to an entry in the corresponding catalogue.

Raw data

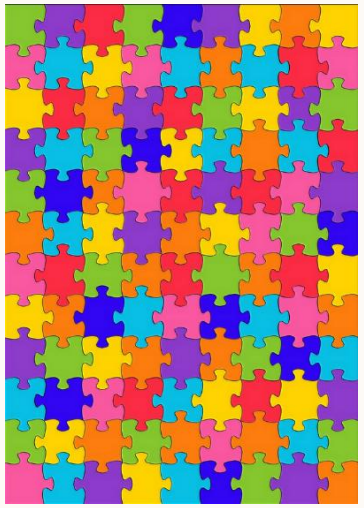


mappings





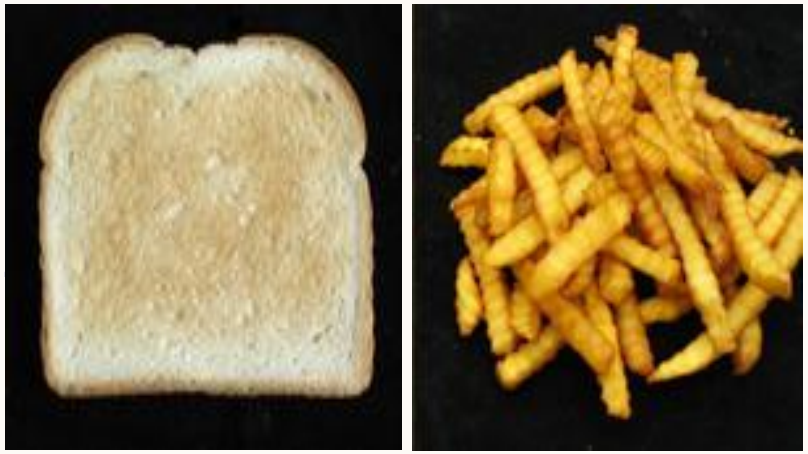
Coded data



EXAMPLES-*ACRYLAMIDE*

- Classification as "*probably carcinogenic to humans*“ (IARC, 1994)
- Regulation (EC) 2017/2158 establishing mitigation measures and benchmark levels for the reduction of the presence of acrylamide in food
- Monitoring
- Consumers advice 'golden yellow and not golden brown’
- Different stakeholders` interests
- Infants, toddlers and other children are the most exposed groups

Scientific Opinion on acrylamide in food. EFSA Journal 2015;13(6):4104



VETERINARY MEDICINAL PRODUCTS

BTSF Risk Analysis on VMP

Risk Management Authorisation

Procedures Centralised
Decentralised
Mutual recognition

Risk Assessment

European Medicines Agency (EMA) scientific evaluation MRL assessment.
Committee for Medicinal Products for Veterinary Use (CVMP)

Risk Management

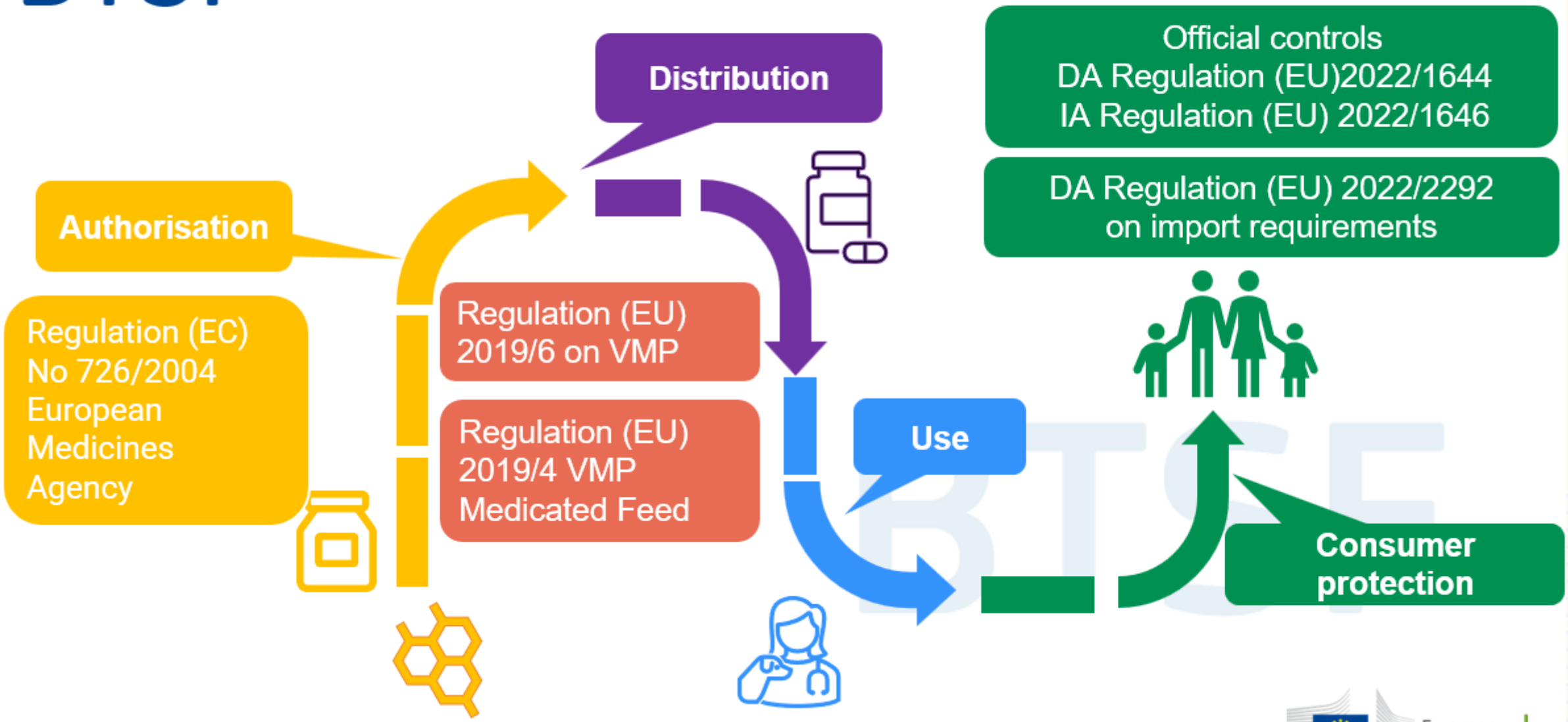
Marketing
Distribution
Use
Medicated feed
MRL in Food
Official Control all steps
Rules for Import

Risk Communication

EU Commission
EMA
Member States
Stakeholders

European Commission

BTSF Legislative Framework VMP



European Commission

BTSF Regulation VMP Distribution

Distribution

Any activity which includes the purchase, sale, import, export, or any other commercial transaction in veterinary medicinal products, whether or not for profit

Authorization by national competent authority (for its territory)

Online Sales:

VET

Click to verify if this website is operating legally

Wholesalers

Purchase **only authorized veterinary medicinal products**

- Technically competent staff suitable
- Sufficient premises
- Annual stocktaking
- Detailed records
- Emergency plan (recall)

Sale **only to persons permitted to carry out retail activities**

Retail

Only by people allowed to carry out such operations according to the legislation of the Member State.

Veterinarian prescription

Any prescription of VMP's issued by a professional person qualified to do so.

European Commission

ZOONOSES AND MICROBIOLOGICAL RISK ASSESSMENT

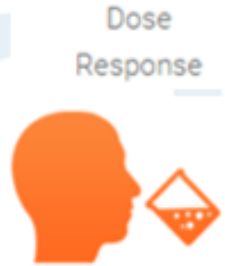
BTSF

Steps of Microbiological Risk Assessment

1. Hazard Identification

2. Hazard Characterization

3. Exposure Assessement



4. Risk Characterization

European Commission

RISK MANAGEMENT

1. Consumer awareness and information
2. Establish regulatory requirements
3. Establish control measures specifying relevant requirements for industry
4. Establish requirements for inspection and audit procedures, certification or approval procedures
5. Develop (or encourage the development of) specific documents and guides
6. Define a Food Safety Objectives (FSO) for a particular food safety issue

PENGALAMAN PEMBELAJARAN

CABARAN

PENGETAHUAN DAN KEMAHIRAN YANG DIPEROLEHI

CADANGAN PENAMBAHBAIKAN KEPADA PERKHIDMATAN DVS

Mengaplikasikan prinsip pengurusan risiko dalam bidang tugas seperti contoh; penetapan piawaian bagi parameter pensampelan

KESIMPULAN

- Pengurusan analisis risiko yang berkesan adalah penting dalam menjamin keselamatan makanan.

TERIMA KASIH