Food Processing Aids in the European Union

Jérôme Lepeintre 华杰鸿
Minister Counsellor for Health & Food Safety 公使衔参赞
Delegation of the European Union to China and Mongolia 欧洲联盟驻华代表团

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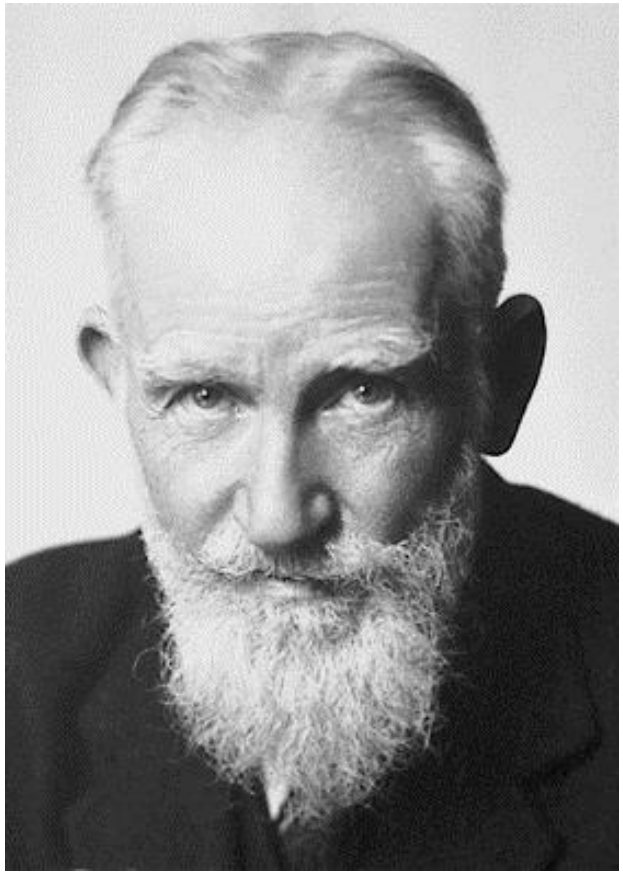


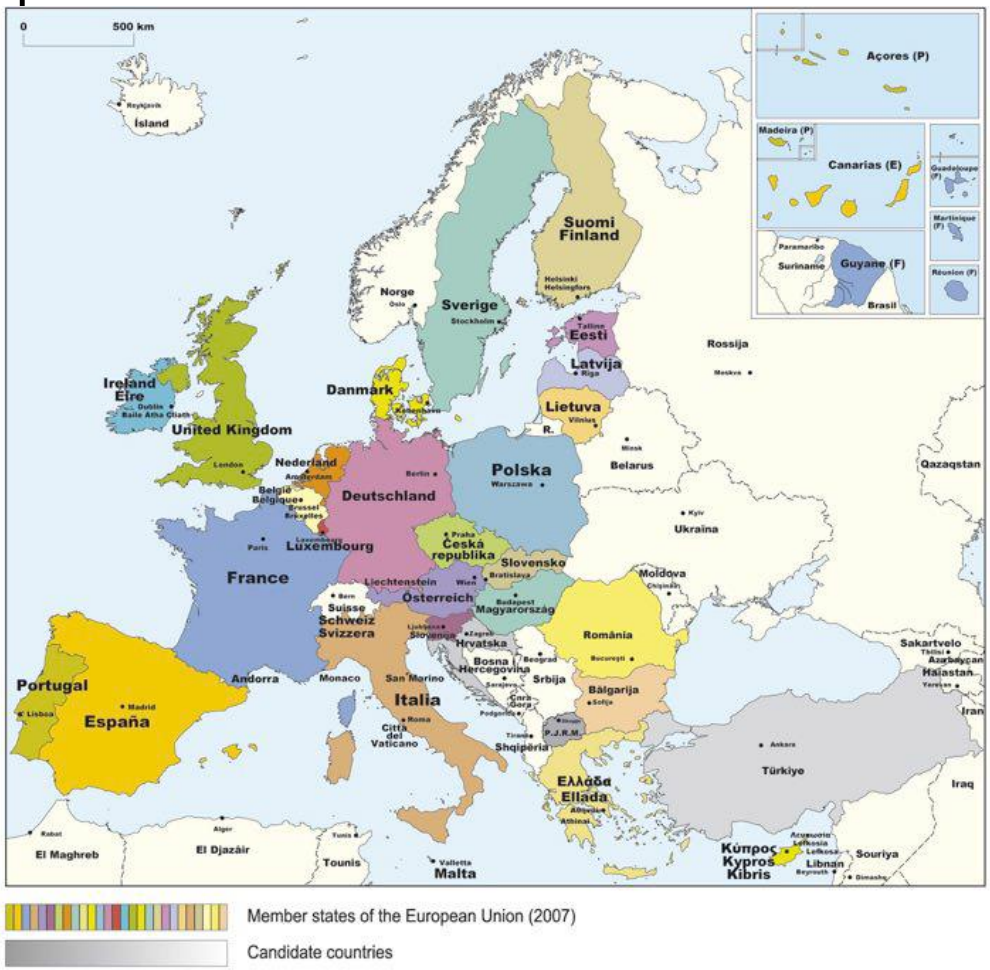
"There is no love more sincere than the love of food"

George Bernard Shaw

European Commission

What is the EU?

A unique economic and political partnership between 28 democratic European countries.



How it works?

To make these things happen, EU countries set up bodies to run the EU and adopt its legislation.
The main ones are:
- the European Parliament
- the Council of the European Union
- the European Commission

Olive oil contamination:
600 death, 25,000 disabled

Softdrink Company in Belgium recalls 2.5m bottles

BELGIUM SUFFERS EU3BIL DUE TO DIOXIN SCARE

RAZOR BLADES IN BABY FOOD

British eggs contain Salmonella! Minister resigns

Pesticide poisoning killed 203

Salmonella enteridis in egg sandwiches

Chilli paste maker jailed, fined for Food Act offence

Listeria in French cheese killed 6

E. Coli in fenugreek seeds

MAD COW DISEASE

Hamburgers infected with E.coli O157.H7

Heinz recalls its baby foods

Woman bites on mouse in MARS bar

CRISIS

"The Chinese use two characters to write the word 'crisis.'

危机

Wei Ji

crisis

One stands for **danger**;

the other for **opportunity**.

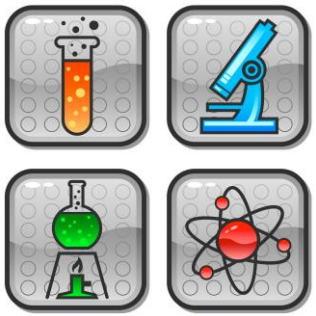
Food safety in the EU

Since 2000 the food safety policy has been reviewed and reinforced on the basis of the legislative program laid down in the White Paper on Food Safety

It included

Structural reforms:

- Reorganisation of Commission services (DG SANCO, *now DG SANTE*)
- Creation of FVO (Food and Veterinary Office, *now Health and Food Audits and Analysis*)
- Creation of EFSA (European Food Safety Authority)
- Reform of Regulatory Committee
- Creation of Advisory Group of the Food Chain



Food safety in the EU

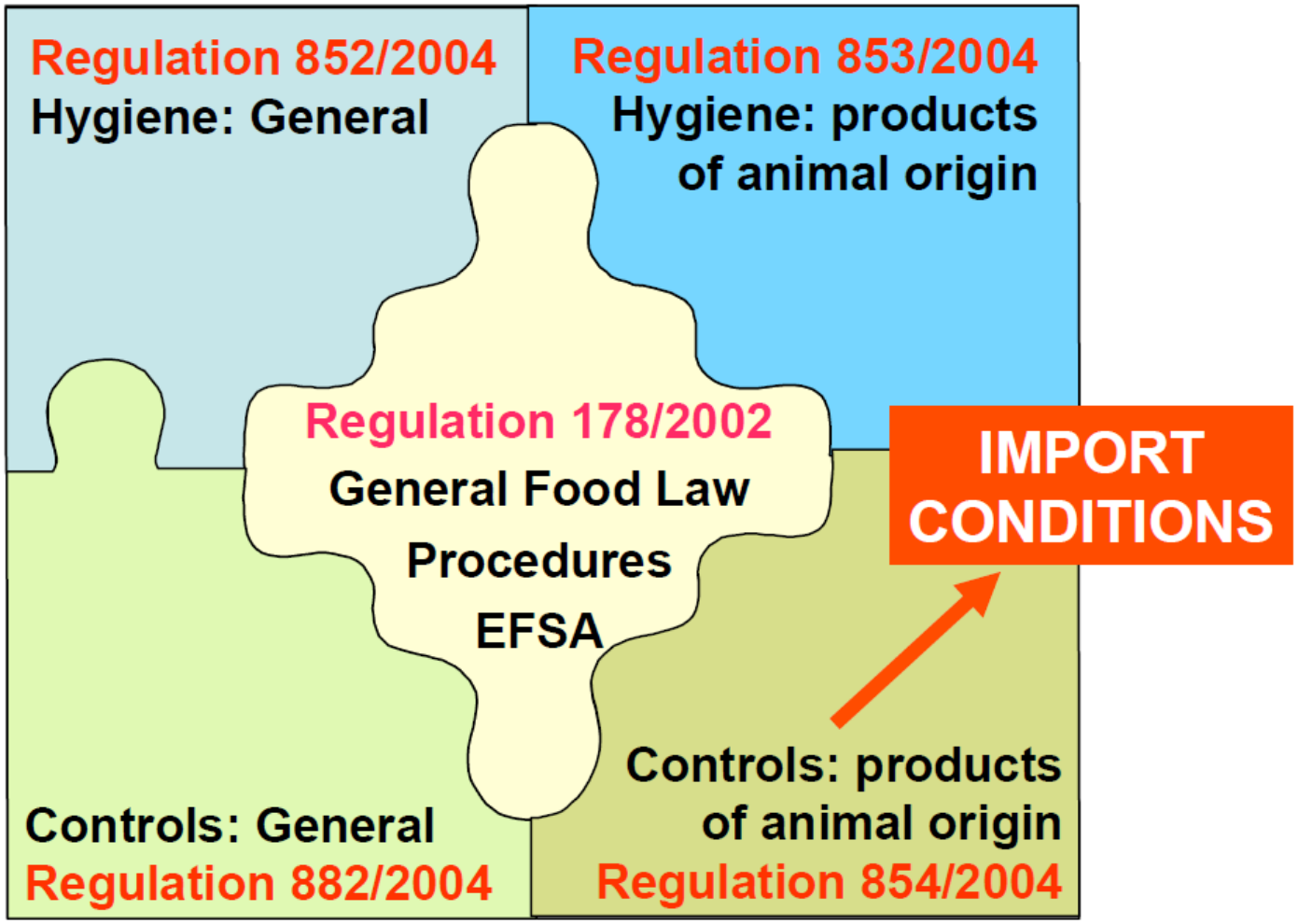
Procedural reforms:

- RASFF (Rapid Alert System for Food and Feed)
- Crisis management structure
- Emergency procedures
- CRLs (EU Reference Laboratories)
- TRACES

Legislative reforms:

- New regulatory framework
- New legislation enacted (Regulations)
- Recasting (simplification) of existing legislation (Regulations)

Food safety in the EU – basic legislation



Food safety in the EU

Legislation on "Food Improvement Agents"

- Regulation 1331/2008 – Common Authorisation Procedure (time-limited and transparent)
- Regulation 1332/2008 – Food Enzymes (first list still to be established)
- Regulation 1333/2008 – Food Additives
- Regulation 1334/2008 – Food Flavourings

The rules on "Food Improvement Agents" are harmonised in the EU.

BUT

Except for extractions solvents and enzymes used as processing aids, **other processing aids are not (yet) subject to EU harmonisation**.

It is very important **to make distinction between processing aids (PA) and food additives (FA)** – there are regulatory implications as regards the risk assessment, authorisation and labelling.

PA versus FA

The term "***processing aid***" is defined in Regulation 1333/2008 on food additives as any substance which:

(i) is **not consumed** as a food by **itself**;

(ii) is intentionally **used in the processing** of raw materials, foods or their ingredients, **to fulfil a certain technological purpose** during treatment or processing; and

(iii) **may result in** the unintentional but technically unavoidable presence in the final product of **residues** of the substance **or its derivates** provided they do **not** present **any health risk** and do **not** have **any** technological **effect on** the final **product**

PA versus FA

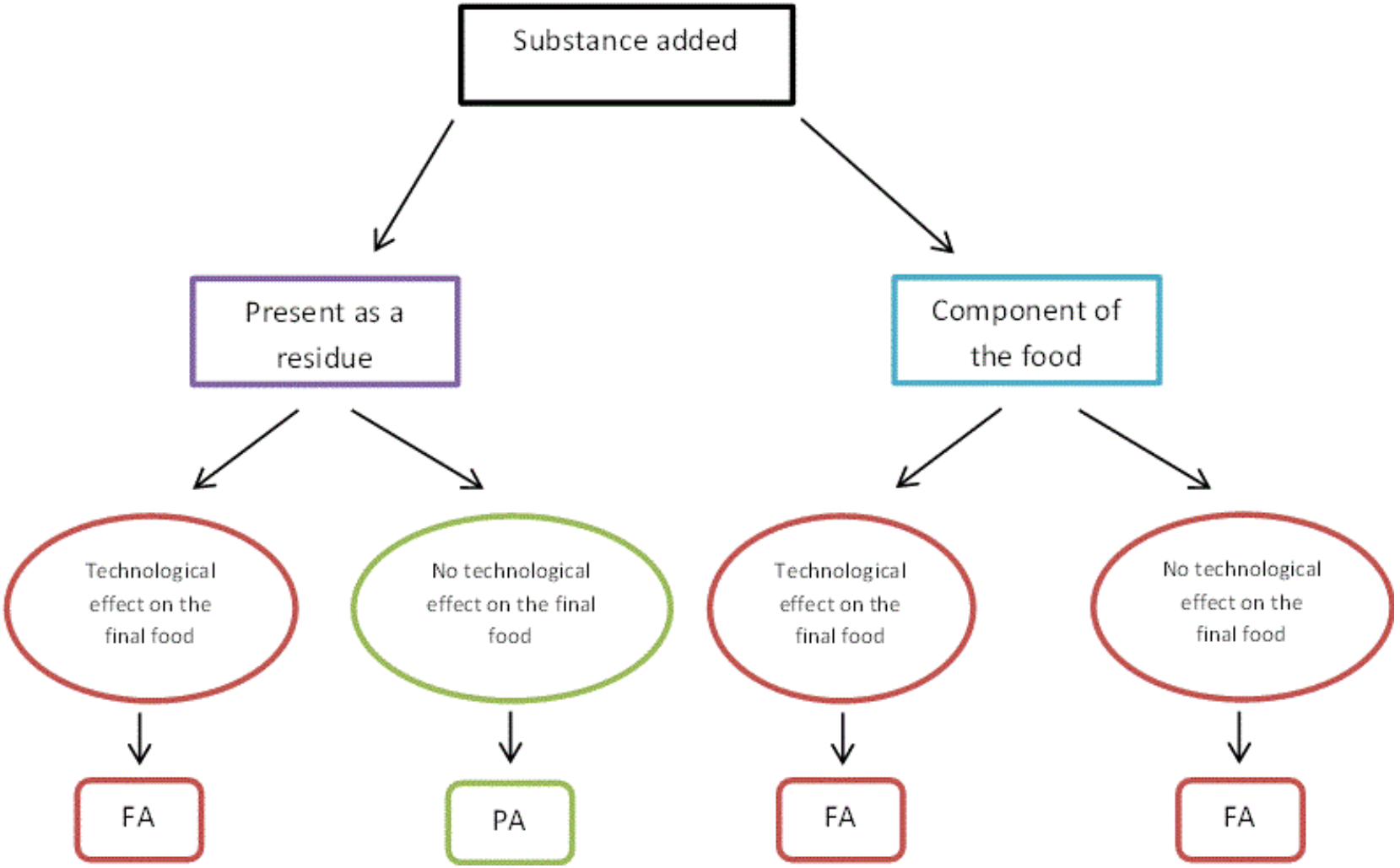
The term "***food additive***" is defined in Regulation 1333/2008 on food additives as any substance:

not normally consumed as a food in itself and **not** normally **used as a characteristic ingredient** of food, whether or not it has nutritive value, the **intentional addition** of which to food **for a technological purpose** in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food **results**, or may be reasonably expected to result, **in it or its by-products** becoming directly or indirectly **a component of such foods**

PA versus FA

Processing aid	Food additives
Intentionally used in the processing of raw materials, foods or their ingredients, to fulfil a certain **technological purpose during treatment or processing**.	Intentional use for a **technological purpose** in **the manufacture, processing, preparation, treatment, packaging, transport or storage** of food.
May result in the unintentional but technically **unavoidable presence in the final product of residues** of the substance or its derivatives.	**Becomes** directly or indirectly **a component of the food**, including its by-products.
These **residues must not present** any **health risk** and **do not** have any **technological effect on the final product**.	

PA versus FA – classification



FA versus PA - implications

FA:

- Authorisation at the EU level needed
- Risk assessment performed by EFSA needed
- Labelling requirements when used in food – by functional class followed by the specific name of an additive or by E number (there are some labelling exceptions see Article 20 of Regulation (EU) No 1169/2011)

PA:

- Rules of the individual EU MS apply + the mutual recognition principle
- Requirements for data and safety assessment given by the rules in the MS
- No labelling requirements

FA versus PA

If an interpretation whether a substance is used as a FA or PA is needed at the EU level then:

- A technical discussion can take place at the **Working Party of Governmental Experts on Additives**
- A non-legally binding opinion can be given by the **Standing Committee on Plants, Animals, Food and Feed**
- A legally binding **interpretation decision** can be taken in accordance with Article 19 of Regulation (EC) No 1333/2008

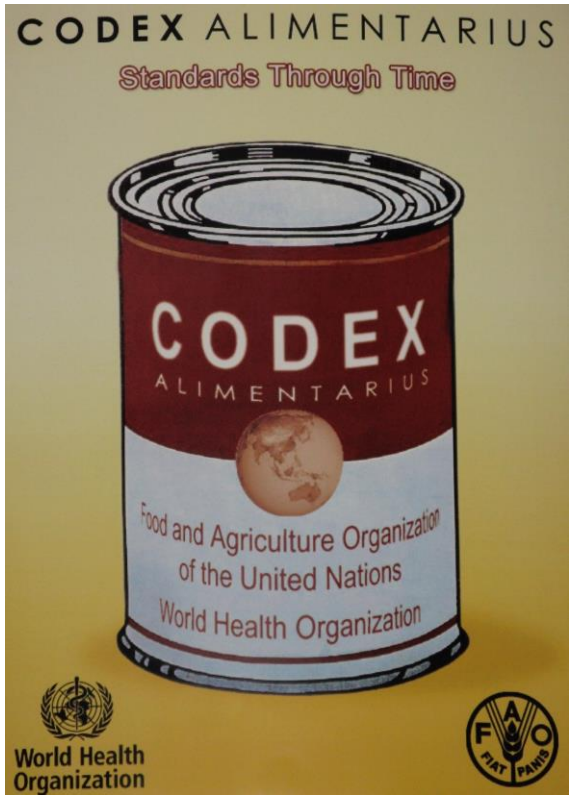
International standards for PA?

PA is **defined by Codex Alimentarius** (in the Procedural Manual) as:

any substance or material, not including apparatus or utensils, and not consumed as a food ingredient by itself, **intentionally used in** the **processing** of raw materials, foods or its ingredients **to fulfill a certain technological purpose** during treatment or processing and which **may result in** the non-intentional but unavoidable presence of **residues or derivatives** in the final product

There are Codex ***Guidelines on substances used as processing aids*** (CAC/GL 75-2010)

Database of processing aids – however, no official Codex status!



PA regulated at the EU level

Extraction solvents (ES)

ES are solvents used in an extraction procedure during the processing of raw materials, of foodstuffs, or of components or ingredients of these products and which are removed but which may result in the unintentional, but technically unavoidable, presence of residues or derivatives in the foodstuff or food ingredient.

The use of ES is fully harmonised at the EU level by **Directive 2009/32/EC**.

The EU Rules on ES take account primarily of human health requirements but also, within the limits required for the protection of health, economic and technical needs.

PA regulated at the EU level

ES – Directive 2009/32/EC

Annex I

Part I – ES to be used at GMP includes: Propane, Butane, Ethyl acetate, Ethanol, Carbon dioxide, Acetone and Nitrous oxide

Part II and III – ES for which conditions of use are specified includes: Hexane, Methyl acetate, Ethylmethylketone, Dichloromethane, Methanol, Propan-2-ol, Dimethyl ether, Diethyl ether, Cyclohexane, Butan-1-ol, Butan-2-ol, Propan-1-ol and 1,1,1,2-tetrafluoroethane

PA regulated at the EU level

Enzymes

Regulation (EC) No 1332/2008 on food enzymes

Regulation covers enzymes that are added to food to perform a technological function in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food, including enzymes used as processing aids.

However, for the time being there is no EU list of enzymes (work is ongoing) and enzymes used as processing aids are currently regulated under the legislation of the MS.

Once the EU list of enzymes is established the use of enzymes (including enzymes used as processing aids) will be fully harmonised at the EU level.

There is a Guidance for differentiating enzymes used as processing aids and as ingredients (food enzymes used as processing aids are not required to be declared in the list of ingredients on pre-packed food):

http://ec.europa.eu/food/safety/docs/fs_food-improvement-agents_enzymes-guidance-categorisation.pdf

PA NOT regulated at the EU level

I.E. all PA other than ES and enzymes

The use of PA other than ES and enzymes is not harmonised at the EU level and the rules of the MS apply. The situation differs in different EU MS.

- In the most MS PA are not regulated (CZ, EE, IE, IT, CY, LV, LT, LU, NL, AT, PL, PT, RO, SI, SK, SE, UK + NO, IS)
- In some MS there are certain rules on PA:

  BE – asks for traceability and recommends complying with the Codex Alimentarius *Guidelines on Substances Used as Processing Aids* (CAC/GL 75 – 2010)

  DK – a national order is in place concerning certain substances including PA. It specifies that PA can be used only if they are safe and gives possibilities to specify requirements concerning the use of certain processing aids (however, the latter has not been used yet)

PA NOT regulated at the EU level

I.E. all PA other than ES and enzymes

ES – no general provisions on PA, however, there are specific provisions for certain commodities, e.g. sugar, vegetable oils, etc. To authorise PA the FBO has to send a dossier with info on technological need and safety which is assessed and if appropriate a provision is included in the specific sectorial rules

FR – has general provisions for processing aids laid down in a decree amended in 2011

HR – has a national regulation on PA based on Codex Alimentarius categorisation. MoH is responsible for the authorisation of new substances

HU – has a national regulation on PA based on an authorisation procedure

The Example of France

Decree No 2001-725 of 31 July 2001:

- Applications for authorisation for marketing and use filed with the Directorate General for Competition Policy, Consumer Affairs and Fraud Control (DGCCRF)

- Assessment by the French Agency for Food, Environmental and Occupational Health and Safety (ANSES)

- Authorisations for use are issued by Interministerial order.

Order of 19 October 2006 (amended) establishes the list of authorised processing aids

Order of 27 August 2009 specifies foodstuffs to which processing aids may be added and the maximum doses

Enforcement and controls

No specific rules for enforcement and controls of PA - general principles of the food safety legislation apply:

Food business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met (e.g. traceability, HACCP etc.).

MS shall enforce food law, and monitor and verify that the relevant requirements of food law are fulfilled by food business operators at all stages of production, processing and distribution.

European Commission

谢谢