



Botanicals in food and food supplements in the EU

Basil Mathioudakis
Milan, 21 May 2015

Fundamental legal aspects

Botanicals are recognised as **ingredients** that may be used in foodstuffs:

 Definition of foods (Regulation 178/**2002**)

 Definition of food supplements (Directive **2002/46**)

 Addition of vitamins, minerals and certain other substances (Regulation 1925/**2006**)

Definition of foods

For the purposes of Reg. 178/2002 (General Food Law)

*‘food means **any substance or product**, whether processed, partially processed or unprocessed, intended to be or reasonably be expected to be **ingested by humans**’.*

‘It shall not include [...] medicinal products, [...], cosmetics’

 There is no nutritional qualification in this definition!

Definition of food supplements

*‘food supplements’ means foodstuffs the purpose of which is to supplement the normal diet and which are **concentrated sources of nutrients or other substances with a nutritional or physiological effect**, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities’*



Addition of vitamins, minerals and certain other substances to foods

Article 2: Definitions

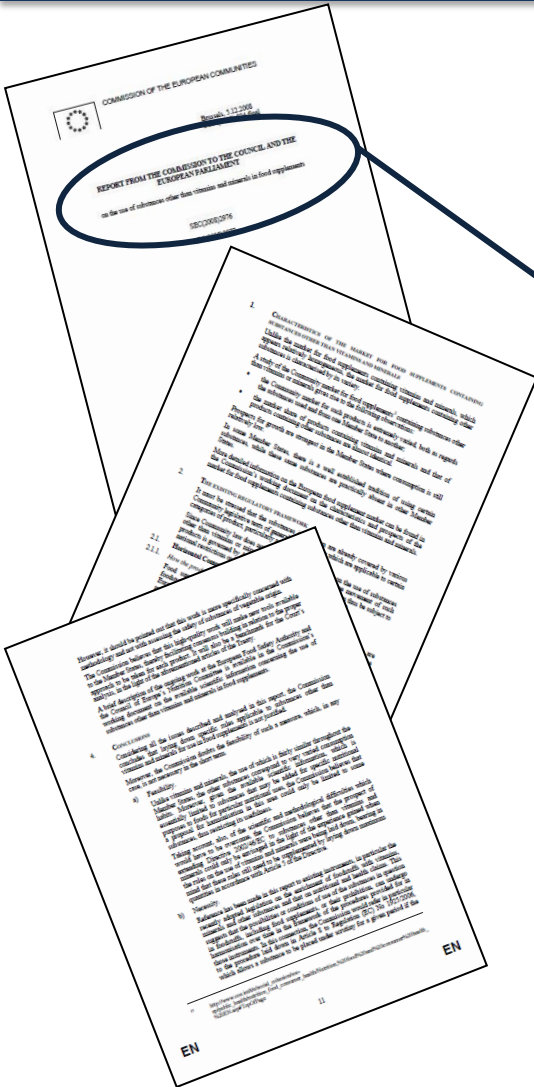
For the purpose of this Regulation:

- 1) [...]
- 2) *'other substance' means a substance other than a vitamin or a mineral that has a nutritional or physiological effect'*

Food Supplements

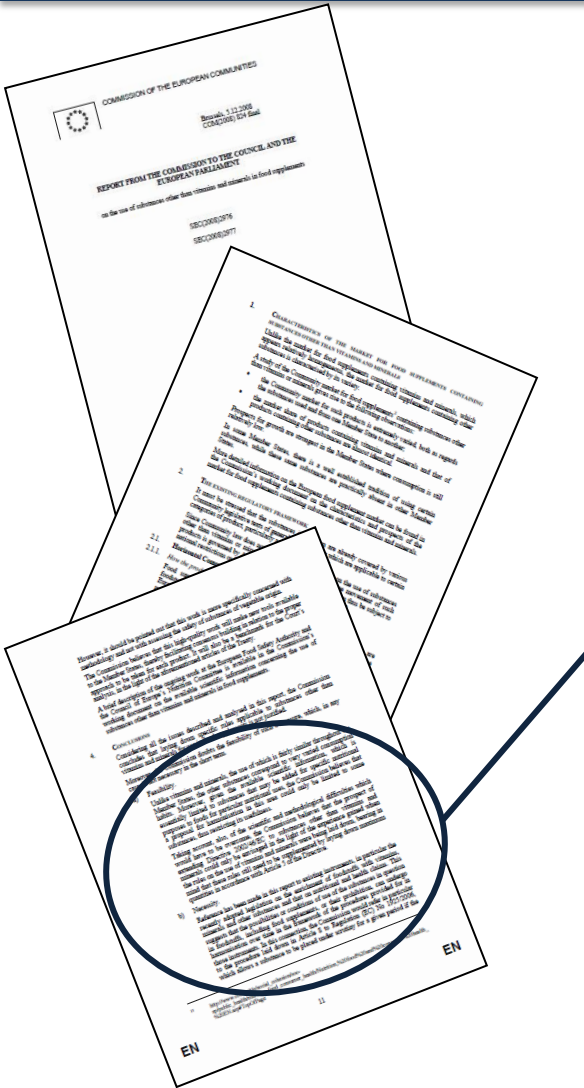
-  Harmonisation regarding vitamins and minerals
 - list of permitted vitamins and minerals,
 - list of sources,
 - criteria for setting maximum amount and eventually,
 - setting minimum and maximum amounts
-  No harmonisation for other substances

Harmonisation of substances other than vitamins/minerals



Report from the Commission to the Council and the Parliament on advisability of establishing specific rules for the use of substances with a nutritional or physiological effect other than vitamins and minerals **(05.12.2008)**

Harmonisation of substances other than vitamins/minerals



Conclusions of report:

- The Commission believes it is not opportune to lay down specific rules for the use of other substances;
- **However, it does not rule out the possibility, at a later stage, of carrying out a supplementary analysis to this report, examining the conditions for the addition of these substances to foodstuffs in general.**

The effect of the Regulation on claims

The **application** of the Regulation on nutrition and health claims brought the **botanicals** to the front scene



Only permitted claims may be used on foods



Principal criterion for authorisation of claims

↳ **Scientific substantiation** by generally accepted **scientific data**

↳ *"health claims should only be authorised for use in the Community after a **scientific assessment of the highest possible standard**"*

Actual situation on claims



30

permitted
nutrition
claims

260

permitted
health claims



2026

non-
authorised
health claims

2078

health claims
on botanicals
'on hold'



Claims on Botanicals in foods v. indications for THMPs

More than **500 claims** on botanical received a **negative** EFSA opinion

Reflection on claims on 'botanicals' became inevitable



Similar ingredients in Food Supplements and Traditional Herbal Medicinal Products



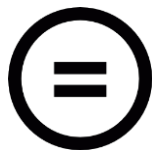
Different approach for allowing claims / therapeutic indications



Evidence of 'traditional use' carries different weight under the different rules

Options for dealing with Botanicals

Option 1:



Resume evaluation under current rules on claims

Option 2:



Develop specific legislation on botanicals used in food, including food supplements

PROBLEM

Difficult to substantiate health claims for botanicals under current rules

SOLUTION ?

- 'traditional use' accepted as for THMP?
- Other aspects than labelling/claims to be regulated?

Member States request: Safety & Quality

- A number of variants for legal measures:
 - ① Revision of Regulation on claims
 - ② Revision of Directive on food supplements
 - ③ Specific legislation on botanicals that will cover claims, quality and safety aspects
- All necessitate co-decision procedure
- Variant 3 offers most advantages for justifying comprehensive action on botanicals that would cover all required aspects

International context

While the reflection in the EU is ongoing other parts of the world are also considering rules on food supplements and botanicals



Latin America



India



ASEAN



China

International context

Botanicals are used in over 30 to 50% of food/health supplement products worldwide.

Key challenges for legislators are:

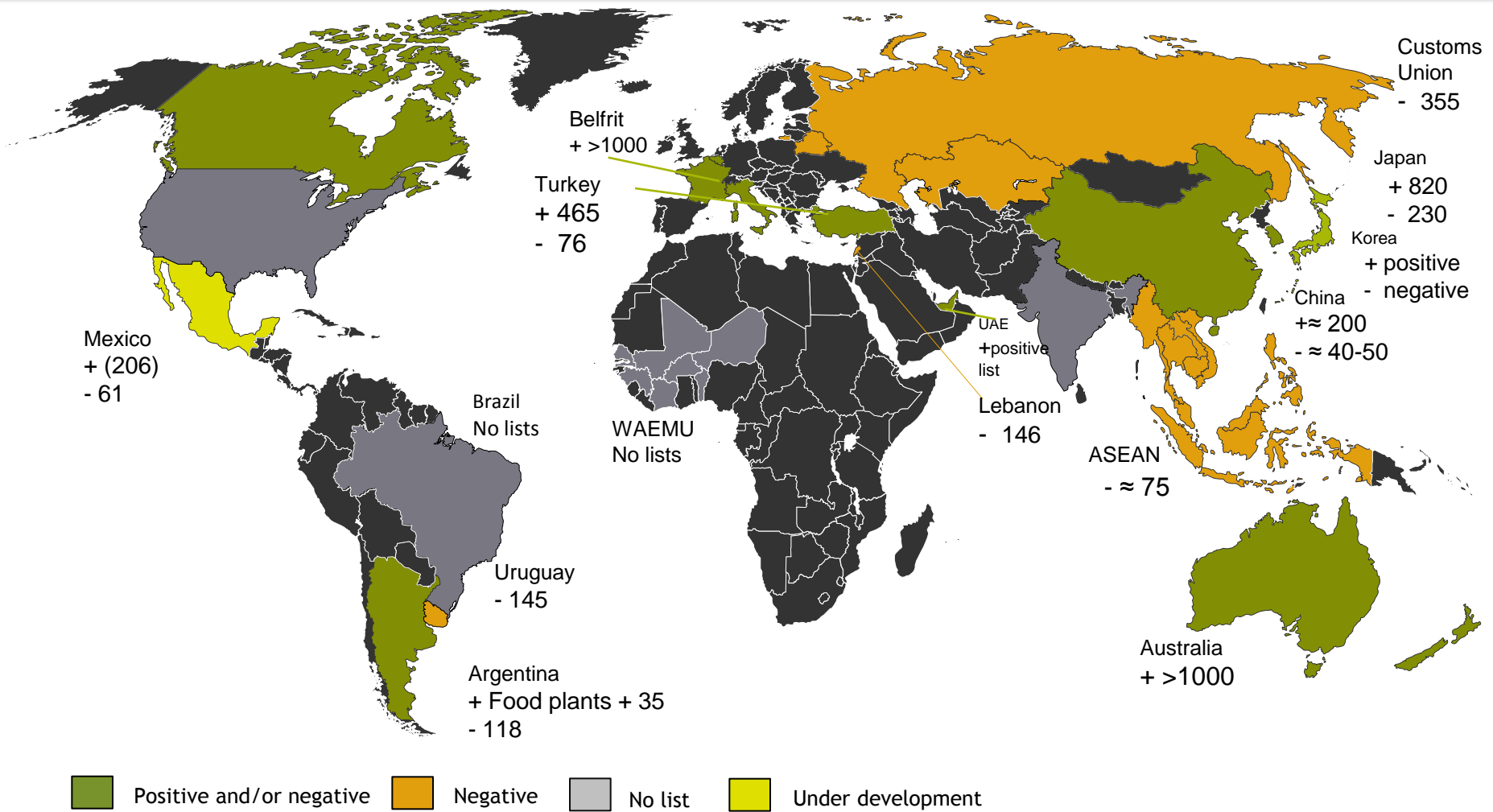
- Complexity of products
- Specificity and diversity of botanicals

Approaches outside the EU

Elements included or considered to be included in legislation by third countries:

- Safety
 - Lists (positive/negative)
 - Market Access Procedure (notification/registration/prior authorisation)
 - Adverse Event Reporting System
- Quality requirements (GMP)

Safety: different approaches in the world



GRAZIE

&

QUESTIONS?