

# 1st International Food Supplement and Nutrition Conference

Ankara 23 November 2017

Real and perceived risk in developing  
regulatory and control plans

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# Controversies and concerns about regulation of food supplements

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## Safety concerns

- Reported by some early scientific findings
- Advanced by consumer and other health NGOs
- Emerge from actions of food control authorities

Press reports and articles enhance the concerns and controversy and often lead to requests for 'appropriate' legislation

- **Are such requests justified and legitimate?**
- **How should regulators react?**
- **How can legislation respond to public concern and fix problems in the market?**

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# Recent reports in EU RASFF system

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- Unauthorised novel food ingredient Epimedium (Epimedin C and Icariin) in food supplements from Spain
- Unauthorised substances sildenafil and tadalafil in food supplement from Spain
- Undeclared milk ingredient and soya in a food supplement from the United Kingdom

# Recent reports in specialised press

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- Athletic doping is a growing area of concern, athletic bodies advise to avoid supplement use
- Dutch authorities captured anabolic-androgenic steroids intended for use in sports nutrition supplements

# Other press reports

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- Food safety agencies in the UK have seized large quantities of DNP (2, 4, Dinitrophenol) following a multi-agency effort
- Caffeine containing products linked to severe incidents/deaths alone or in mixture with other substances

# Legal framework for food supplements

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In the majority of national/regional jurisdictions and at international level (Codex Alimentarius):

- Food supplements are regulated as foods
- Specific and horizontal food legislation is applicable to them

# Definition of 'food'

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'Food' means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans

It shall not include:

- Medicinal products
  - Cosmetics
  - Tobacco
  - Narcotic or psychotropic substances
- Doping substances should not be present in foods intended for professional sportspeople

# Definitions of food supplement

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Most definitions include the following elements

*“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 .....*

Codex guidelines concern vitamin and mineral supplements



# Structure of legislation in the food area

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## General Food Law Regulation-setting principles

- Horizontal legislation
  - Applicable to all foods (hygiene, additives, contaminants, pesticides, food contact materials, labelling, nutrition and health claims, official controls etc.)
- Vertical legislation
  - Specific to certain categories of foods (novel foods, food supplements, fortified foods, foods for specific groups, etc.)

# General principles of food law

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- Based on risk analysis (other legitimate factors may come to play)
- Precautionary principle, where appropriate
- Protection of consumers' interests from fraud, adulteration, misleading practices, enable informed choices
- Transparency of the adoption process (consultation, public information)

# Risk Analysis

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Consists of:

- Risk Assessment-by risk assessor (scientific advisory body)
- Risk Management-by risk manager (regulators)
- Risk Communication-coordinated between risk assessor and risk manager

# General requirements of food law

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## Example from the EU basic food law

- Food safety requirements-no placing on the market of unsafe food
- Products information-no misleading labelling, presentation and advertising
- Responsibilities of Food Business Operators (FBOs) and authorities
- Traceability

# General requirements of food law

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## Responsibilities of FBOs

- Hygiene at all stages of production chain
- Compliance with all requirements of food law and, if necessary, withdrawal of unsafe products
- Traceability-one step up, one step down
- Information to authorities and public

# General requirements of food law

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## Responsibilities of competent authorities

- to enforce, monitor and control
- public communication

# Reported problems under food law scrutiny

## Food safety

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Unauthorised novel food ingredient  
Epimedium (Epimedin C and Icariin) in food  
supplements from Spain

- Epimedium not a novel food authorised for use in foods, therefore should not have been used
- FBO should not have placed the food supplement on the market-Case of food adulteration

# Food safety/misleading consumers

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## Unauthorised substances sildenafil and tadalafil in food supplement from Spain

- Sildenafil-active substance of Viagra
- Tadalafil-active substance of Cialis
- Active substances of medicines. Should not be used in foods
- Added, without being declared, to supplements 'proposed' for conditions of libido problems. FBO should not have placed the food supplement on the market-Case of food adulteration



# Food safety

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Undeclared milk ingredient and soya in food supplement from the United Kingdom-incorrect labelling

- Ingredients which, in addition, are potential allergens and should be declared in the list of ingredients highlighted
- FBO should have listed/declared the ingredients appropriately in the labelling of the product-Given the nature of the ingredients not clear if ignorance, omission or fraud

# Safety/Misleading of consumers

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- Athletic doping is a growing area of concern; athletic bodies advise to avoid sport supplements use
  - Cases of deliberate but undeclared addition of substances prohibited by WADA.
  - Fraudulent addition of non declared substances- FBO responsibility; users responsibility?
- Dutch authorities captured anabolic-androgenic steroids intended for use in sports nutrition supplements

# Food safety

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Food safety agencies in the UK have seized large quantities of DNP following a multi-agency effort

- DNP is a dangerous substance that can cause severe damage/death. It has been found in sports and slimming food supplements
- FBO would be placing on the market unsafe food

Close cooperation between control authorities, national food crime unit, internet companies acting before products are placed on the market

# Caffeine case

Food safety or popular and media pressure ?

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Authorisation of claims on caffeine in the EU blocked by the European Parliament

- ✓ Favourable opinion of the European Food Safety Authority (EFSA) under specified conditions of use
- ✓ Positive safety evaluation for the conditions of use

Is blockage justified by food law principles?

# Cases discussed

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All above are cases of problems with products on the market were infringements of normal general food law principles

- No extraordinary/additional measures would have prevented their marketing
- No extraordinary/additional measures are necessary

All cases were discovered by routine control measures

# Official controls-EU update

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- **A new provision clarifies that official controls must be performed in a manner that minimises the burden on businesses.**
- A new key element to strengthen the fight against frauds is the requirement for Competent Authorities to take into account the **likelihood of fraudulent and deceptive behaviour when deciding the appropriate frequency of controls.**
- In particular, Competent Authorities in performing controls and adjusting their frequencies should **take account of the likelihood that consumers might be misled** about the properties, quality, composition or country of provenance of the food they buy.

# Official controls

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- To deter fraudulent behaviour and foster fair competition among businesses, the Regulation introduces **more stringent rules for financial penalties** imposed. Those penalties will need to reflect the **economic advantage of the operator or a percentage of the operator's turnover**.
- The Regulation also introduces new provisions **to protect whistle-blowers** to encourage and facilitate the reporting of non-compliance. Requirement to have a mechanism in place for that purpose
- More sophisticated means of **controlling internet sales** and up to closing the website of the operator

# Basis of regulating food supplements

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Safety/quality of these foods should be ensured by appropriate rules based on safety/risk analysis



# Role of authorities and stakeholders

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- Control authorities should enforce the rules vigorously and uniformly across the national territory
- Food business operators (FBOs) should be responsible; unscrupulous FBOs should not be allowed to operate
- Close consultation and cooperation of authorities and FBOs is essential
- Administrative burden should be contained/reduced
- International trade issues should be taken into account

Thank you for your attention.

Any questions?

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