

Public powers: Controls, Enforcement and Incident management

Bernd van der Meulen

Renmin EU Food Law 05: 24 March 2017



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Italy cracks whip on health claim abusers - fines could reach €5m

By Shane Starling+, 10-Nov-2014

Related topics: Botanicals & Herbals, Polyphenols, Immune support, Regulation & Policy, Health claims, Botanicals, Food, Supplements, Botanicals

Regulators in Italy's €1.2bn food supplements market are cracking the harshest whips against health claims abusers in the EU – a firm was recently fined €250,000 – but will the wounds be deep enough to change the market?

One pundit praised the regulator while wondering if the whip cracking is enough to sway a market that has long-exercised marketing alacrity over solid scientific data, or as the pundit put it, a tendency toward "guru" science.

"There are two questions," stated EU food law expert Luca Bucchini. "First will firms be able to build a business model around authorised health claims, replacing the current curative/guru-scientist food supplement model? I would advise such companies to think hard about alternatives. Second, will authorities in Italy and elsewhere keep up the pressure?"

The fines could in theory go as high as €5m under Italian law.

Recent censorings include Named Spa, a significant €33m Italian player, which Italy's Market and Competition Authority fined €250,000 for exaggerated and unauthorised immunity claims for a fermented papaya extract called Immun'Age. The claims dated back to 2007.

That fine is believed to be the biggest ever administered for a breach of the EU nutrition and health claims regulation (NHCR) in any of the European Union's 28 member states.

The Italian authority previously fined Humana, another local firm, €110,000 for similar breaches for some of its food supplements.

Neither company has spoken of the fines, or its post-fine intentions, but Rome-based consultant Bucchini said the firms were ~~availing for trouble~~ with marketing that was clearly outside EU law – especially after the imposition of the NHCR in 2007 and the bulk publication of authorised/non-authorised article 13.1 claims at the back-end of 2012.

Two dead from Listeria in mung bean sprouts



By Joe Whitworth+ 

10-Nov-2014

Last updated on 10-Nov-2014 at 11:10

The FDA isolated *Listeria monocytogenes* from mung bean sprouts and sprout irrigation water samples during a routine assignment on August 13 at the company.

Based on this, the agency held an inspection from August 12 to September 3 and isolated *Listeria monocytogenes* from 25 environmental swabs.

Wholesome Soy Products ceased production of sprouts on August 28 and resumed on September 15 after the pathogen was not identified in finished product.



WGS findings, sprout consumption history of two patients and inspection findings suggest the illnesses are related to products from the firm, said CDC

Related tags: Wholesome Soy Products, PFGE, WGS, FDA, CDC, Listeria, Mung bean sprouts, Recall, Pathogen, Isolate, Samples, Strain

Related topics: Cleaning and hygiene, Track and trace, Food Outbreaks, Fresh produce

Mung bean sprouts contaminated with *Listeria* have been linked to the death of two people and illness of three others, according to the US Centers for Disease Control and Prevention (CDC).

Infringement on *food* law

- Producer brings food to the market knowing it is unsafe. Consumer falls ill and has to spend expensive days in hospital.
- What do we do to the perpetrator?
- What about the risk?
- What about the victim?
- What about other businesses?



Overview today

■ Context

- Introduction
- Materials
- Structure
- Context

■ Official controls

- On FBOs
- On MS
- On 3rd countries

■ Measures

- FBO
- MS
- EC

■ Recent developments

- Horse fraud

■ Sanctions



Materials

■ Source of law

- GFL, Art. 17, 18, 19, 53, 54
- Regulation 882/2004 on official controls

■ Literature

- Bernd van der Meulen and Annelies Freriks, Millefeuille: The Emergence of a Multi-Layered Controls System in the European Food Sector
https://papers.ssrn.com/sol3/papers.cfm?abstract_id=991291



European Food Law

Powers for public Authorities

Requirements for food Businesses

Principles and concepts

- Risk analysis
- Precaution
- Transparency
- Food
- Food business
- Food law

Executive tasks

- Scientific risk assessment (EFSA)
- Implementing measures (EC/MS)
- Decisions (EC/MS)
- Information and risk communication (EFSA/EC/MS)

Enforcement

- Official controls (MS)
- Sanctions
 - Administrative (injunctions, fines) (MS)
 - Criminal (fines, prison) (MS)
- EU second line inspections on MS enforcement (FVO)

Emergency and Incident management

- Communication (RASFF)
- National measures (impose recall) (MS)
- Emergency measures (EC)

Product

- Product standards
 - Agriculture quality
 - Verticals
- Authorisation requirements
 - Food supplements
 - Food additives
 - GMOs
 - Novel foods
- Food safety limits
 - Microbiological criteria
 - MRLs (pesticides; veterinary drugs)
 - Contaminants

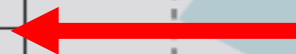
Process

- Producer
 - Premises
- Production
 - Hygiene
- Trade
 - Traceability
- Incidents
 - Withdrawal
 - Recall

Presentation

- Labelling
- Advertisement
- Risk communication

Interests of Consumers



Compliance with food law

■ Art. 17(1) GFL

- Responsibility food and feed business operators
- 'Food and feed business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods or feeds satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met.'

■ Art. 21 GFL

- Without prejudice to Product liability directive



Enforcement of Food Law

■ Art. 17(2) GFL

● Responsibility Member States

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

For that purpose, they shall maintain a system of official **controls** and other activities as appropriate to the circumstances, including public communication on food and feed safety and risk, food and feed safety surveillance and other monitoring activities covering all stages of production, processing and distribution.

Member States shall also lay down the rules on **measures** and **penalties** applicable to infringements of food and feed law. The measures and penalties provided for shall be effective, proportionate and dissuasive.



Concepts

- Complying with the law
 - Doing what you have to do

- Enforcing the law
 - Make others do what they have to do
 - Controls
 - Measures
 - Sanctions



Official Controls Regulation (882/2004)

■ Art. 54

- Action in case of non-compliance
- → objective: solve the problem

■ Art. 55

- Sanctions
- → objective: deter (punish)



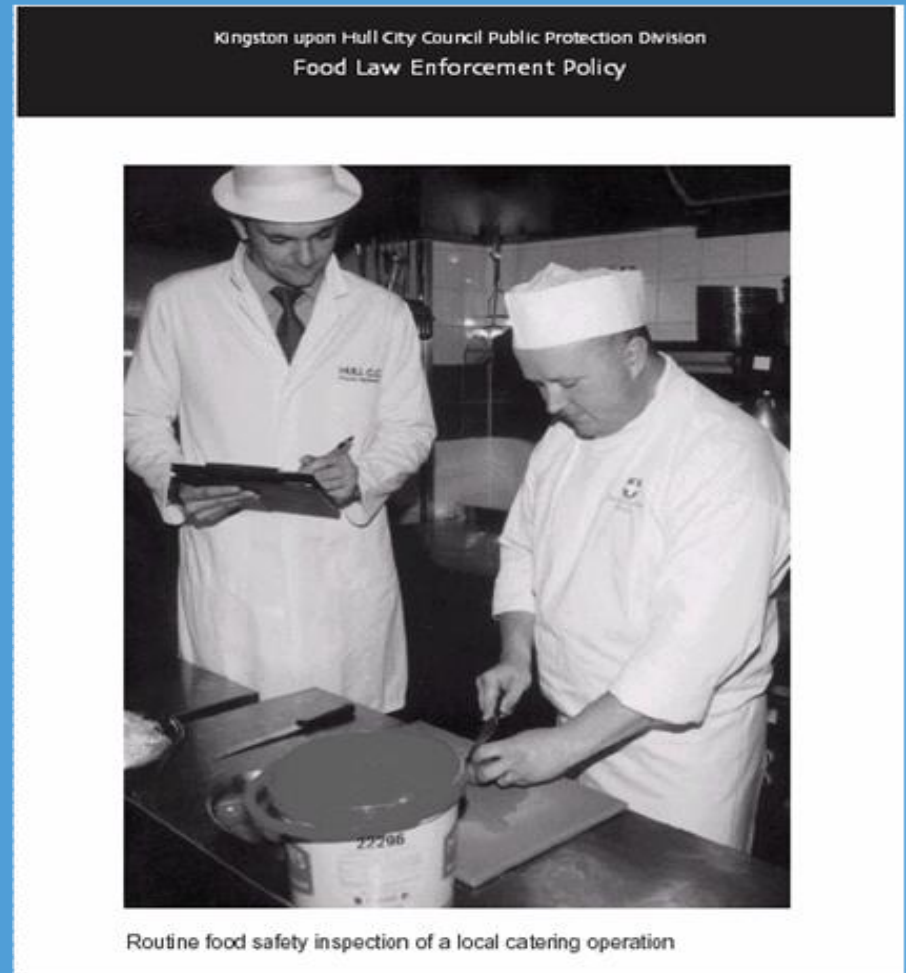
Official Controls Regulation

- Regulation 882/2004
- Scope
 - Food and feed law
 - Animal health & animal welfare law
 - Not included: common market agriculture
- Objectives
 - Prevent risks to humans and animals
 - Protect consumers' interests
- Content
 - Controls + measures + sanctions



Official Controls

- General obligations
- Member States shall:
 - Organise controls on regular basis
 - Without prior warning (as a rule)
 - Any stage of production, processing, distribution
 - Import/export same care



Official Controls

- Staff performing official controls
 - shall have received appropriate training for their area of competence
 - shall be regularly kept up-to-date in all issues of their area of competence
 - shall respect the rules of confidentiality



Second line inspections ('audits')

- European Commission 'Guardian of the Treaty'
 - Infringement procedures
 - Art. 258 TFEU
- Member States are responsible to EU
- Art. 45 Reg. 882/2004: Community controls



Second line inspections



HEALTH AND FOOD SAFETY

- Directorate-F (former FVO)
 - Part of DG SANTE (directorate / agency)
 - Inspects national enforcement
 - Reports are published on the internet
 - Inspects food safety systems in third countries
- Always in cooperation with national authorities



Inspections in **third** countries

- Directorate-F
 - 'EU rules must be respected...'
- Sovereignty
- Jurisdiction
- No legal obligation, but
 - Requirement for market access
- Always in cooperation with national authorities



Extra territorial ambitions I

- Article 11 GFL

Food and feed imported into the Community for placing on the market within the Community shall comply with the relevant requirements of food law or conditions recognised by the Community to be at least equivalent thereto or, where a specific agreement exists between the Community and the exporting country, with requirements contained therein.



Extra territorial ambitions II

- Article 46 Reg. 882/2004
Community controls in third countries
Commission experts may carry out official controls in third countries in order to verify (...) the compliance or equivalence of third-country legislation and systems with Community feed and food law (...).





EUROPEAN COMMISSION

DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Directorate F - Health and food audits and analysis

DG(SANTE) 2015-7640 - MR

FINAL REPORT OF AN AUDIT
CARRIED OUT IN
CHINA
FROM 18 NOVEMBER 2015 TO 26 NOVEMBER 2015
IN ORDER TO
EVALUATE THE CONTROLS SYSTEMS FOR GENETICALLY MODIFIED
ORGANISMS IN RESPECT OF FOOD AND FEED INTENDED FOR EXPORT TO THE
EUROPEAN UNION

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6 OVERALL CONCLUSIONS

Overall, there is a comprehensive export control system in place to ensure that food, feed and feed additives exported to the EU are compliant with the EU legislation regarding GMOs.

A detailed supervision system is implemented by the Chinese authorities to ensure compliance with the requirements of Decision 2011/884/EU. The system is supported by a well-established and up-to-the standard laboratory capacity and includes procedures to follow up on RASFF notifications. The number of GMO related RASFF alerts has decreased and attempts have been made to combat illegal trade which is currently stated by the Chinese authorities to be the main reason for EU non-compliances detected in the EU.

The GMO field trials are adequately controlled and extensive controls are in place in Hubei Province aiming to ensure that rice cultivation is not contaminated with GMO. Some GMO controls of rice cultivation are performed in other rice growing provinces. It is known that GM rice is present in the rice cultivation in China. Therefore there is a potential risk that GM rice enters in the production of commodities other than those regulated and controlled for EU export. Some efforts are made to mitigate such risk.



Measures to address food safety problems



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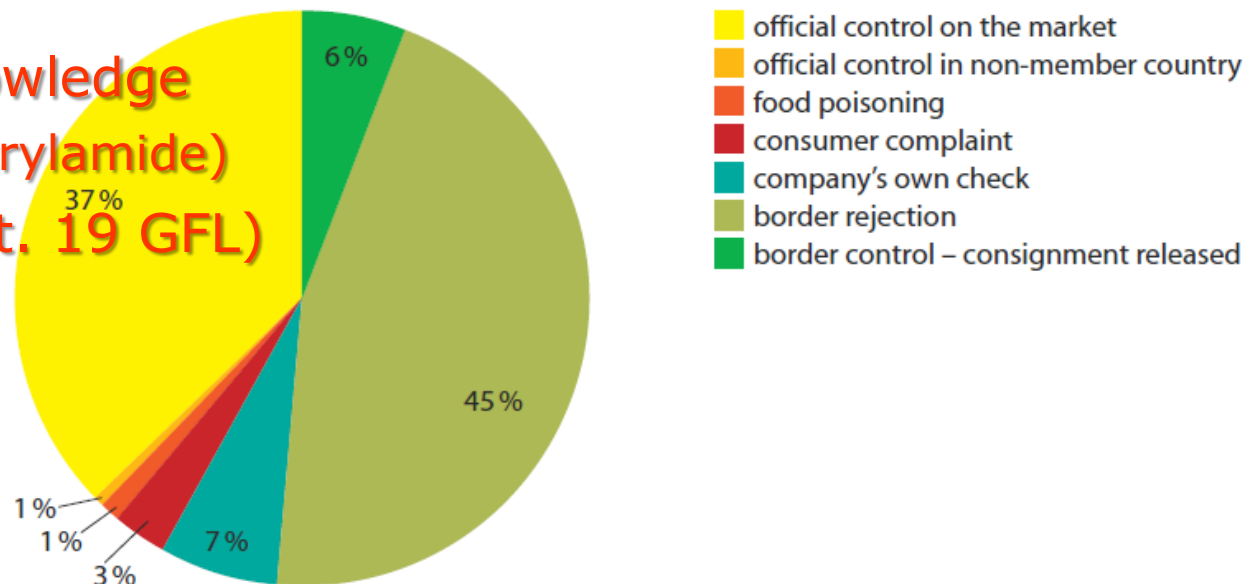


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Identification of food safety problem I

- Complaint
 - By competitor
 - By consumer
 - to food business operator
 - to authorities
- Inspection
- Border control
- New scientific knowledge
 - EFSA (e.g. acrylamide)
- Food business (art. 19 GFL)

2009: BASIS FOR NOTIFICATION



Identification of food safety problem II

■ Extent of the problem

- Art. 14-6 GFL

Where any food which is unsafe is part of a batch, lot or consignment of food of the same class or description, it shall be presumed that all the food in that batch, lot or consignment is also unsafe, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment is unsafe.

■ Where is the rest of the lot?

■ Art. 18 GFL: traceability

- One step up, one down
- Information to authorities on demand



Consequences of food safety problem I

- **Business level**
- 14-1 GFL no placing on the market
- 19-1
 - Withdraw from the market
 - Inform authorities (19-3)
 - Inform consumer
 - Recall from consumer
- 19-4 collaborate with authorities
- 18-2/3 make traceability information available on demand of competent authorities



Recall

- **GFL 19**
- **Who is responsible?**
 - **Importer**
 - **Producer**
 - **Processor**
 - **Manufacturer**
 - **Distributor**
- **When?**
 - **Has reason to believe that a food is not in compliance with food safety requirements**
- **What?**
 - **Take measures to restore high level of food safety**
 - **Withdraw from customer**
 - **Recall from consumer**



Which business?

- Art. 19 GFL
- When:?
 - Has reason to believe a food ... is not in compliance with food safety requirements
- Who?
 - Has imported, produced, manufactured or distributed
 - ≠ guilty!



Consequences of food safety problem II

- **Member State level**
- 17-2 GFL have national legislation in place
 - Inspections
 - Communication
 - Sanctions
- Subsidiarity principle / 53 GFL
 - First responsibility: Member States
- Art. 34 TFEU Treaty: no trade barriers
- Art. 36 TFEU: exception for protection of health
 - Borders may be closed
- 18 GFL: demand traceability information
- 10 GFL: public information



Transparency / disclosure / naming & shaming

- Art. 17(2) GFL including public communication on food and feed safety and risk
- Art. 10 GFL: warn the consumer



Inspection Report



Establishment **Restaurant Testy**

Address **117, Nørrebrogade**

Postal Code/City **2200, Copenhagen N.**

Smiley-rules inspected	Result*
Hygiene: Handling of food	1
Cleaning	1

This inspection, date:	
2.2.2006	
Previous inspections	
Date 9.9.2005	

Art. 54 Reg. 882/2004

- When the competent authority identifies non-compliance, it shall take action to ensure that the operator remedies the situation.
 - Impose measures to ensure food safety
 - Restrict placing on the market
 - Order recall, withdrawal or destruction of food
 - Suspend or close business
 - Any other measure the competent authority deems appropriate



Consequences of food safety problem III

- The European Commission
- 53 GFL interim measures
 - Suspension of placing on the market
 - Suspension of imports
 - Conditions
 - Any other
- 54 GFL Member States may act when Commission does not



European Commission

- Art. 53 GFL
 - Food
 - From EU
 - From 3rd country
 - Likely to constitute serious risk
 - Cannot be contained by MS concerned
 - Immediately take emergency measures
 - Suspend placing on the market / import
 - Special conditions
 - Any other



European Commission

- Art. 53 procedure
 - PAFF
 - Emergency: provisional measures → PAFF



Failing Commission

- Article 54 GFL
- Art. 53 applies
 - MS requested
 - EC has not acted
 - MS interim protective measures
 - Inform other MS
 - Inform Commission
 - Within 10 days Commission - PAFF



Emerging issues: Horse meat scandal

- Horse sold as beef
- Can it be tackled with food safety measures?
- Ireland, Italy: horse not unsafe: Art. 19 GFL recall only for unsafe food – we have no national legislation
- Germany, France: horse not unsafe: Art. GFL recall only for unsafe food – however, we have national legislation
- NL, Greece, Portugal: fraud results in unsafety → recall based on Art. 19 GFL



Recall horse meat NL

- 50.000.000 kg
- No indication of risk to public health
- Origin unclear → safety cannot be guaranteed.

Vanwege de onduidelijke herkomst van de partijen vlees kan de voedselveiligheid van dit vlees niet worden gegarandeerd. Daarom is de NVWA op grond van wet- en regelgeving genoodzaakt het product als niet geschikt voor humane consumptie of diervoeder aan te merken. Op dit moment zijn er geen concrete aanwijzingen dat er een gevaar is voor de volksgezondheid.



Unsafety in horse scandal

- Development of problem definition Dutch authorities
- Phase 1: possible presence of phenylbutazone
 - EFSA/EMA risk assessed at 1:100.000.000
- Phase 2: possible unapproved horse carcasses
- Final phase: fraud → disrupted traceability
 - Also the safety of the beef is uncertain



Recall NL

- (How) can it fit in the GFL-framework?
- Unsafe within the meaning of Article 14 GFL
- Non-compliant within the meaning of Article 19 GFL



Recall

- GFL 19
- When?
 - Has reason to believe that a food is **not in compliance with food safety requirements**
- Two possible readings
 - In Art. 19 'food safety requirements' includes Article 18 GFL (traceability)
 - In Art. 19 'food safety requirements' exclusively refers to Art. 14 GFL



Regulation 178/2002

Article 14

Food safety requirements

1. Food shall not be placed on the market if it is unsafe.
2. Food shall be deemed to be unsafe if it is considered to be:
 - (a) injurious to health;
 - (b) unfit for human consumption.
3. In determining whether any food is unsafe, regard shall be had:
 - (a) to the normal conditions of use of the food by the consumer and at each stage of production, processing and distribution, and
 - (b) to the information provided to the consumer, including information on the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods.



(How) does fraud fit into Art. 14?

- Unfit for consumption?
- CJEU in Berger: food can be unfit without being injurious to health
 - C-636/11. ECLI:EU:C:2013:227



Enemy image GFL Art 3(14) hazards



Biological
Pathogenic



Chemical
Toxic



Physical
Radioactive

Blind spot of the GFL

Emerging enemy image in food law



Sanctions

- Effective, proportionate and dissuasive
- Italy: Maximum fine 10% of annual turnover
- NL
 - Current fines: € 1.000
 - New fines: € 4.500 => € 81.000 => € 810.000
 - Depending on size of FBO / seriousness of infringement



Thank you for
your kind
attention

Q&A

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