

Regulation on Mutual Recognition (EC) No 764/2008

Summer School of Food Law

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FOOD LAW CONSULTANTS

“[T]he articles of the Treaty relating to the free movement of goods (...) are fundamental Community provisions and any restriction, even minor, of that freedom is prohibited”

CJEU, Case C- 49/89 Corsica Ferries France [1989] ECR 4441, paragraph 8

Introduction

- ▶ The **food sector** is often subject of incorrect application of the Mutual Recognition Principle
- ▶ **65% of the notifications** pursuant to Decision 3052/95 related to food supplements
- ▶ From “**Cassis de Dijon**” to “**Douwe Egberts**”, the main CJEU cases relate to foods

Outline

- I. Mutual Recognition in Principle
- II. Why Mutual Recognition is not working in practice
- III. Analysis of Regulation 764/2008
- IV. Case-studies

Mutual Recognition in Principle

- ▶ Stems from Art. 34-36 TFUE and CJEU case law
- ▶ MS may not prohibit the sale on their territory of products which are **lawfully produced and/or marketed in another MS**, even if those products are manufactured in accordance with **technical rules different from those to which domestic products are subject**
- ▶ Only exception: restrictions justified on the grounds of **Art. 36 TFUE** or **overriding reasons of public interest**

Mutual Recognition in Principle

- ▶ Applies to **products not subject to EU harmonization**, or for which harmonization remains **incomplete**, e.g.:
 - ▶ Processing aids
 - ▶ Enzymes
 - ▶ Flavoring substances
 - ▶ Food supplements containing other substances (e.g. botanicals, aminoacids, taurine, etc.)
- ▶ And which are **lawfully manufactured and/or marketed** in another MS

Practical obstacles to Mutual Recognition

- ▶ **Lack of awareness** of MS and business operators
- ▶ **Widespread legal uncertainty as to the scope and burden of proof**
- ▶ **Risk of business operators:** difficult anticipation of whether and how mutual recognition will be applied in the MS of import
- ▶ **Absence of dialogue** between national authorities

Analysis of Regulation No. 764/2008

- ▶ **Innovations of the Regulation**
 - ▶ Procedure for **denial of Mutual Recognition** with tight deadlines
 - ▶ Establishment of **Product Contact Points**
 - ▶ Non-exhaustive **list of products** subject to Mutual Recognition
 - ▶ Repeal of Decision No 3052/95/EC

Analysis of Regulation No. 764/2008

▶ Objectives of the Regulation

- ▶ To strengthen the functioning of the internal market by **improving the free movement of goods**
- ▶ Ensuring a correct application of the mutual recognition principle **in individual cases** (complements Dir. 98/34)



Denial = exception

Analysis of Regulation No. 764/2008

▶ **Scope of application**

▶ **Administrative decisions**

▶ **Addressed to an economic operator**

▶ **On the basis of a national technical rule**

▶ **Direct or indirect consequence:**

▶ Prohibition of placing on the market

▶ Withdrawal from the market

▶ Modification of characteristics (e.g. labeling) or additional testing

▶ **For any product lawfully marketed in another MS**

Analysis of Regulation No. 764/2008

▶ A technical rule is:

- ▶ Any provision of a law, regulation or other administrative provision
- ▶ Not subject of **harmonization at EU level**
- ▶ Which either **prohibits** the marketing of a product or **needs to be complied with** to market the said product
- ▶ And lays down the **characteristics** required for the product (e.g. labeling) or other requirements affecting its life-cycle

Analysis of Regulation No. 764/2008

▶ A technical rule is not:

- ▶ An obligation to use **the official language** of the country of import (Rec. 10)
- ▶ A requirement for **prior-authorization of the product** (Rec. 12)
- ▶ As to food supplements:
 - ▶ the obligation to submit food supplements for prior authorization
 - ▶ decisions to re-classify as medicinal products, when these are performed on a case-by-case assessment (i.e. not on the basis of a technical rule)

Analysis of Regulation No. 764/2008

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Analysis of Regulation No. 764/2008

- ▶ **The Regulation does not apply to:**
 - ▶ **Emergency measures** notified to the Rapid Alert System (Art. 50(3)(a) Reg 178/2002)
 - ▶ **Interim protective measures** (Art. 54 Reg 178/2002)
 - ▶ **Measures taken in case of non-compliance with food and feed law** (Art. 54 Reg 882/2004)

Analysis of Regulation No. 764/2008

- ▶ **The Regulation does not apply to:**
 - ▶ Temporary bans on the marketing of **products that could be dangerous** (Art. 8(1)(d) of GPSD)
 - ▶ Ban and withdrawals of **dangerous products** (Art. 8(1)(e) of GPSD)
 - ▶ Prior conditions for the marketing of **products posing a serious risk** or requirement of warnings to be marked (Art. 8(3) of GPSD)

Analysis of Regulation No. 764/2008

▶ Procedure for denial of Mutual Recognition

▶ STEP 1: written notice to the operator

- ▶ Notice of the **intention** to apply a technical rule
- ▶ Specifying the **technical rule**
- ▶ Setting out **technical and scientific evidence** to the effect that the decision is
 - i. Justified on grounds of public interest
 - ii. Proportionate to its objective

Analysis of Regulation No. 764/2008

- ▶ **Procedure for denial of Mutual Recognition**
- ▶ **To what extent are MS required to justify their intended decision?**
 - ▶ Risk should be *serious* and *sufficiently established*
 - ▶ Not *purely hypothetical*
 - ▶ *Not founded on mere suppositions, which are not scientifically verified*
 - ▶ Level of justification depends on **degree of the obstacle**
 - ▶ *The absence of nutritional need is not sufficient*

Analysis of Regulation No. 764/2008

- ▶ **Procedure for denial of Mutual Recognition**
 - ▶ **STEP 2: period for comments**
 - ▶ The **operator** may submit comments
 - ▶ Time limit: at **minimum 20 days** upon receipt of the notice
 - ▶ Obliges MS to **rebut the arguments of the operator** to adopt the decision

Analysis of Regulation No. 764/2008

▶ Procedure for denial of Mutual Recognition

▶ STEP 3: decision of the Member State

- ▶ MS has **20 working days to adopt & notify the decision** to the operator and the European Commission (extendable once)
- ▶ The decision must state:
 - i. The grounds on which it is based
 - ii. The evidence to its justification and proportionality
 - iii. The remedies available
- ▶ If not adopted, the MS must **inform the operator**

Analysis of Regulation No. 764/2008

▶ **Rights of the Member State**

- ▶ May request relevant information on the **characteristics** of the product
- ▶ May request relevant and readily available information on the **lawful marketing** of the product in another Member State

Analysis of Regulation No. 764/2008

▶ **Rights of the economic operator**

- ▶ *“When the competent authority fails to notify the economic operator of a decision (...), the product shall be deemed to be lawfully marketed in that Member State insofar as the application of its technical rule (...) is concerned”*

Article 6(4) Regulation No. 764/2008

Analysis of Regulation No. 764/2008

▶ **Rights of the economic operator**

- ▶ The product may remain on the market during the procedure unless:
 - ▶ The MS proves that it poses a serious risk to the safety and health of users, or
 - ▶ The product is prohibited in a MS on grounds of morality or public security
- ▶ May challenge the decision to apply the technical rule or suspend the marketing of the product

Analysis of Regulation No. 764/2008

C 185/6

EN

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NOTICES FROM MEMBER STATES

List of Product Contact Points nominated by the Member States to deal with procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State ⁽¹⁾

(2009/C 185/07)

Member State Product Contact Point	Product Contact Point
BELGIUM	SPF Économie, PME, Classes Moyennes et Énergie. Direction générale Qualité et Sécurité. Division Qualité et Innovation. Service Normalisation et Compétitivité/ c/o FOD Economie, KMO, Middenstand en Énergie. Algemene Directie Kwaliteit en Veiligheid. Afdeling Kwaliteit en Innovatie. Dienst Normalisatie en Competitiviteit WTCIII Boulevard Simon Bolivar/Simon Bolivarlaan 30 1000 Bruxelles/Brussel BELGIQUE/BELGIË

Analysis of Regulation No. 764/2008

▶ **Product Contact Points**

- ▶ Provide information about **the technical rules applicable**
- ▶ Advise whether the product is subject to **prior authorization**
- ▶ Give contact details of the competent authorities
- ▶ Detail the **remedies generally available** in the event of a dispute between competent authorities and the economic operator

**Is the Mutual Recognition
Regulation the answer to our
prayers?**

Case-study 1

Borderlines

Case-study 2

Labeling & Health claims

Case-study 3

Novel Foods

Case-study 4

Other Substances

Conclusion

- ▶ The Regulation has the merit to **clarify the rights and obligations** of business operators and Member States
- ▶ Mutual Recognition does not apply automatically in the food sector, as the **protection of public health** plays a major role in the marketing of foods
- ▶ The trade of foodstuffs is often hampered by measures **falling out of the scope** of the Mutual Recognition Regulation

Thank you

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