European Commission

Explanatory meeting on the EU acquis

The legislation on
Food for Specific Groups

These slides accompany the explanation of the acquis to Albania and North Macedonia and can only be used for that purpose. Their content is subject to further development of the acquis and interpretation by the Court of Justice of the European Union

DG SANTE, Unit E1

22 February 2019

Health and Food Safety

European Commission

Revision of the legislation

Directive 2009/39/EC on Foods for Particular Nutritional Uses
(PARNUTS or dietetic foods)

Regulation (EU) No 609/2013 on Food for Specific Groups
(FSG Regulation)

Entry into application: 20 July 2016

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Foods for particular nutritional uses (PARNUTS or dietetic foods)

Directive 2009/39/EC (Framework Directive) defines them as:

- Special composition or manufacturing process
- Distinguishable from "food for normal consumption"
- Suitable for claimed nutritional purpose
- Marketed in such a way to indicate such suitability
- Fulfilling the particular nutritional requirements of:
  - Persons with disturbed digestive processes or metabolism or
  - Persons in a special physiological condition or
  - Infants and young children in good health

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Directive 2009/39/EC

The Framework Directive:

- Set **general requirements** (e.g. composition and labelling)
- Listed **categories** of dietetic foods for which specific legislation will be adopted by the Commission
- Required the Commission to present a **report** on the necessity of specific rules for foods for people with diabetes
- Established a **notification procedure** for dietetic foods not listed

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Specific Implementing Directives adopted under 2009/39/EC

- **Infant and follow-on formulae**

(Commission Directive 2006/141/EC)

- **Processed cereal-based foods and baby foods**

(Commission Directive 2006/125/EC)

- **Energy-restricted diets for weight reduction (slimming foods)**

(Commission Directive 96/8/EC)

- **Dietary food for special medical purposes**

(Commission Directive 1999/21/EC)

- **Substances for nutritional uses**

(Commission Regulation (EC) No 953/2009)

- **Foodstuffs for people intolerant to gluten**

(Commission Regulation (EC) No 41/2009)

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Enforcement problems

- Number of products not belonging to one of the categories specifically mentioned in the Directive continued to increase
- Many products clearly not "dietetic foods"
- Interpretation of the definition varied among Member States and created problems with free circulation of products in the EU

<u>Need for the revision</u>

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Key elements of the new Regulation

- Concept of 'dietetic food' ➔ abolished
- Limited scope – vulnerable groups:
  - **Infant formula and follow-on formula**
  - **Processed cereal-based food and baby food**
  - **Food for special medical purposes**
  - **Total diet replacement for weight control**

➔ **Increased legal clarity**

- Definitions of the categories
- General composition and labelling requirements
- Single EU list of substances to be added to FSGs
- Empowerment to Commission to adopt specific rules (by 20 July 2015)

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Specific delegated acts adopted under Regulation 609/2013

- **Infant formula and follow-on formula**

(Commission Delegated Regulation (EU) 2016/127)

- **Food for Special Medical Purposes (FSMPs)**

(Commission Delegated Regulation (EU) 2016/128)

- **Total diet replacement for weight control (TDRs)**

(Commission Delegated Regulation (EU) 2017/1798)

- **Processed cereal-based foods and Baby foods**

*A Commission Delegated Regulation on processed cereal-based foods and baby foods- was **objected by EP** following adoption by Commission*

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Transition periods

- Directives adopted under 2009/39/EC continue to apply until the delegated acts have replaced them
- Early compliance with new rules

Delegated act	Date of application	Consequence
Delegated Regulation 2016/127 on IF and FoF	22 February 2020 (protein hydrolysates-22 February 2021), repeals: Directive 2006/141/EC	products in compliance with Directive 2006/141/EC **or** Regulation 2016/127 may coexist until 22 February 2020/2021
Delegated Regulation 2016/128 on FSMPs	22 February 2019 (FSMPs for infants- 22 February 2021) repeals: Directive 1999/21/EC	products in compliance with Directive 1999/21/EC **or** Regulation 2016/128 may coexist until 22 February 2019/2020
Delegated Regulation 2017/1798 on TDRs	27 October 2022 repeals: Directive 96/8/EC	products in compliance with Directive 96/8/EC **or** Regulation 2017/1798 may coexist until 27 October 2022

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Other elements of the new Regulation

Reports on:

- Milk-based drinks and similar products intended for young children ("growing up milks" or "young child formula") *(31 March 2016)*
- Foods intended for sports people *(15 June 2016)*

<u>No Need for specific rules</u>

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Other elements of the new Regulation

Transfers of existing rules:

- Rules on "gluten-free" and "very low gluten" (covered by Commission Regulation (EC) No 41/2009 in the past)

  ➔ under Regulation (EU) No 1169/2011 on the provision of food information to consumers (Impl.Regulation (EU) No 828/2014)

- Rules on 'meal replacement for weight control' (covered by Commission Directive 96/8/EC in the past)

  ➔ under Regulation (EC) No 1924/2006 on nutrition and health claims made on food (Commission Regulation (EU) 2016/1413)

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