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| **Kingdom of Belgium** |
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| **THE FEDERAL PUBLIC SERVICE FOR PUBLIC HEALTH, FOOD-CHAIN SAFETY AND THE ENVIRONMENT** |
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| **Royal decree amending the Royal Decree of 18 February 1991 concerning foodstuffs intended for particular nutritional uses** |
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| **PHILIPPE, King of the Belgians,** |
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| To all who now are and will be after, Our Greetings. |
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| Having regard to Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control, and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009; |
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| Having regard to Commission Regulation (EU) 2016/128 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council with regard to the specific compositional and information requirements relating to food for special medical purposes; |
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| Having regard to the Law of 24 January 1977 on the protection of the health of consumers with regard to foodstuffs and other products, as amended by the Law of 22 March 1989, Article 2, amended by the law of 22 March 1989; |
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| Having regard to the Royal Decree of 18 February 1991 on foodstuffs intended for particular nutritional uses; |
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| Having regard to the Communication to the European Commission, to ‘21 June 2021, applying the Article 5, part 1 of Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and rules on information society services; |
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| Having regard to the Opinion No 9371 of the Superior Council on Public Health adopted on 30 June 2017; |
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| Having regard to the opinion of the Inspector of Finance, issued on 22 December 2021; |
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| Having regard to the opinions No 71.064/3 and No 71.065/3 of the Council of State, issued on 18 March 2022, pursuant to the Article 84, § 1, first paragraph, point 2 of the laws of the Council of State, coordinated on 12 January 1973; |
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| On the recommendation of the minister of Health and the Minister of Agriculture, |
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| Hereby decrees the following: |
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| **Article 1.** Article 1, §1 of the Royal Decree of 18 February 1991 on foodstuffs intended for special nutrition, last amended by the Royal Decree of 19 November 2007, is supplemented by the provision under 11°, reading: |
| ‘11° Non-hospital services: the operators who, in the context of a medical treatment of a patient outside a hospital, install, maintain and/or remove medical devices related to enteral feeding by tube at the home of patients.’ |
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| **Art. 2.** The annex to the same decree is amended in accordance with the annex to this decree. |
| **Art. 3.** Each within his or her own scope of competence, the Minister of Public Health and the Minister of Agriculture shall be responsible for the implementation of this decree. |
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| ,Brussels 1 September 2022. |
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| By the King: |
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| The Minister for Public Health,  Frank VANDENBROUCKE |
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| The Minister for Agriculture,  David CLARINVAL |
| |  | | --- | |  |   **Annex to the royal decree amending the Royal Decree of 18 February 1991 on foodstuffs intended for particular nutritional uses**  ‘ Annex to the Royal Decree of 18 February 1991 on foodstuffs intended for particular nutritional uses’  The following amendments shall be made to the Annex to the Royal Decree of 18 February 1991 on foodstuffs intended for particular nutritional uses:  1 ° the words ‘diet foods for special medical purposes’ are replaced in Part 4 by the words ‘food for special medical purposes’;  2° point 4.2.4. is replaced by the following:  ‘4.2.4. Sales and/or delivery  4.2.4.1. The sale and/or delivery to the end-user of food intended for medical purposes shall be authorised only by:  1. dispensing chemist (pharmacist);  2. health care facilities recognised by one of the federated entities, provided that the food for medical purposes is provided on the basis of a medical prescription and only to institutionalised patients;  3. health care establishments approved by one of the federated entities and only to institutionalised patients for food for medical purposes administered by oral route and intended for adults and intended to meet with nutritional needs in case of:  malnutrition or risk of malnutrition not associated with other diseases or conditions; or  dehydration or risk of dehydration; or  swallowing problems;  4. the services registered outside a hospital in accordance with the Royal Decree of 15 November 2017 on the contact point for materiovigilance within hospitals and the registration of distributors of medical devices, provided that the food for medical use is the subject of a medical prescription;  5. retail, provided that the food for medical purposes is administered by oral route and intended for adults, and intended to meet nutritional needs in case of malnutrition or risk of malnutrition not associated with other diseases or conditions.  4.2.4.2. A technique for distance communication, sale and/or delivery to the end user of food intended for medical purposes shall be permitted only by:  1. dispensing chemist (pharmacist);  2. retail as described in point 4.2.4.1 of this annex.’  Having regard to our decision of 1 September 2022 amending the Royal Decree of 18 February 1991 on foodstuffs intended for particular nutritional uses.  On behalf of His Majesty:  The Minister for Public Health,  Frank VANDENBROUCKE  The minister of Agriculture,  David CLARINVAL |