EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, which apply to England only, make provision to enforce Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No. 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding (O.J. No. L 25, 2.2.2016, p. 1, "Delegated Regulation 127").

These Regulations also amend the Food for Specific Groups (Information and Compositional Requirements) (England) Regulations 2016 (S.I. 2016/688) ("the 2016 Regulations") in order to provide for the enforcement in domestic law of the provisions of Commission Delegated Regulation (EU) 2016/128 of 25 September 2015 supplementing Regulation (EU) No. 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for food for special medical purposes developed to satisfy the nutritional requirements of infants (O.J. No. L 25, 2.2.2016, p. 30) ("the Delegated Regulation") (regulation 6 and Schedule 4).

These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 (c. 68) and references in them to provisions of Delegated Regulation 127 or to provisions of the Delegated Regulation are to be construed as references to such provisions as they are amended from time to time.

These Regulations also make amendments to correct drafting errors which occurred in the Food for Specific Groups (Information and Compositional Requirements) (England) (Amendment) Regulations 2017 (S.I. 2017/62) ("the 2017 Regulations") and reported on by the Joint Committee on Statutory Instruments in their 25th report for 2016-2017. Accordingly these Regulations are to be issued free of charge to all known recipients of the 2017 Regulations.

Part 2 provides for the enforcement of Delegated Regulation 127. In particular, regulation 3 provides that each food authority must execute and enforce Part 2 within its area. Regulation 2(1) contains a definition of "food authority".

Regulation 4 and Schedule 2 apply and modify provisions of the Food Safety Act 1990 (c. 16) for the purposes of Part 2 of these Regulations.

Regulation 5 and Schedule 3 make provision for revocations and savings as a consequence of Part 2 of these Regulations. The Infant Formula and Follow-on Formula (England) Regulations 2007 (S.I. 2007/3521) ("the 2007 Regulations") and the provisions which amend those Regulations are revoked. The 2007 Regulations implement Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC (O.J. No. L 401, 30.12.2006, p. 1) and Council Directive 92/52/EEC on infant formulae and follow-on formulae intended for export to third countries (O.J. No. L 179, 1.7.1992, p. 129). Article 13 of Delegated Regulation 127 repeals Directive 2006/141/EC with effect from 22nd February 2020, and from 22nd February 2021 in the case of infant formula and follow-on formula manufactured from protein hydrolysates.

Regulation 5 further provides for certain revocations to be saved for the purposes of the transitional arrangements in that regulation. Those transitional arrangements provide that where infant formula or follow-on formula which has been placed on the market or labelled prior to the date of application of Delegated Regulation 127 (22nd February 2020 or, in the case of infant formula or follow-on formula manufactured from protein hydrolysates, 22nd February 2021), it can continue to be marketed until stocks are exhausted, provided that certain requirements are met.

Regulation 6 and Schedule 4 make provision for the enforcement of the Delegated Regulation by amending the 2016 Regulations so that references in the 2016 Regulations to the Delegated

Regulation are to the Delegated Regulation as it applies to food for special medical purposes including that developed to satisfy the nutritional requirements of infants (paragraph 2 of Schedule 4).
Paragraph 3 of Schedule 4 substitutes a new regulation 8 of the 2016 Regulations to provide new transitional arrangements which ensure that stocks of food for special medical purposes which were labelled or placed on the market before the date of application of provisions of the Delegated Regulation can continue to be marketed until those stocks are exhausted.
Paragraph 4 of Schedule 4 amends the table in Schedule 1 to the 2016 Regulations to include further provisions in the definition of "specified EU requirement".
Regulation 7 and Schedule 5 correct the drafting errors in the 2017 Regulations. Schedule 5 amends the Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997 (S.I. 1997/2182), the Medical Food (England) Regulations 2000 (S.I. 2000/845) ("the 2000 Regulations"), the Processed Cereal-based Foods and Baby Foods for Infants and Young Children (England) Regulations 2003 (S.I. 2003/3207), the 2007 Regulations and the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) Regulations 2009 (S.I. 2009/3051).
Regulation 8 and Schedule 6 revoke the 2000 Regulations and provisions which amend them. The 2000 Regulations implement Commission Directive 1999/21/EC on dietary foods for special medical purposes (O.J. No. L 91, 7.4.1999, p. 29).
Regulation 8 further provides for the revocations to be saved for the purposes of the transitional provisions in regulation 8 of the 2016 Regulations as substituted by paragraph 3 of Schedule 4, and for the purposes of the transitional provisions in regulation 5.
Regulation 9 revokes regulation 4 of the 2017 Regulations which was defectively drafted.
Regulation 10 requires the Secretary of State to review the operation and effect of these Regulations and publish a report within five years after they come into force and within every five years after that. Following a review it will fall to the Secretary of State to consider whether the Regulations should remain as they are, or be revoked, or be amended. A further instrument would be needed to revoke the Regulations or to amend them.
A full impact assessment has not been produced for this instrument as no, or no significant, impact on the private, voluntary or public sector is foreseen.

Changes to legislation:
There are currently no known outstanding effects for the The Food for Specific Groups (Food for Special Medical Purposes for Infants, Infant Formula and Follow-on Formula) (Information and Compositional Requirements) (Amendment etc.) (England) Regulations 2020.