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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations are made in consequence of the entry into force of new requirements in Commission Delegated Regulation (EU) 2016/128 of the European Parliament and of the Council as regards the specific compositional and information requirements for food for special medical purposes (“the Delegated Regulation”) on 22 February 2020.

Regulation 2 introduces schedule 1 of these Regulations, which amends the Foods for Specific Groups (Scotland) Regulations 2016 (“the 2016 Regulations”) to include reference to provisions of the Delegated Regulation which relate to food for special medical purposes developed to satisfy the nutritional requirements of infants. The amendments made by these Regulations to schedule 1 of the 2016 Regulations have the effect that it becomes a criminal offence not to comply with the requirements of the Delegated Regulation when such food is placed on the market, except where transitional arrangements apply.

The relevant transitional arrangements are inserted into the 2016 Regulations by paragraph 1(3) of schedule 1. These ensure that stocks of food for special medical purposes which were labelled or placed on the market prior to the date of application of provisions of the Delegated Regulation can continue to be marketed until those stocks are exhausted.

Schedule 1 of these Regulations also amends references in schedule 1 of the 2016 Regulations to provisions of Regulation (EU) No 609/2013 of the European Parliament and of the Council on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control. It will become a criminal offence to contravene article 15(1) of the EU Regulation (Union list), but will no longer be a criminal offence to breach article 4(1) (placing on the market) of that Regulation alone.

Regulation 3 amends the Vitamins, Minerals and Other Substances (Scotland) Regulations 2007 (“the 2007 Regulations”). Regulation 3(2) ensures that the definition of “the EC Regulation” includes a reference to, as it may be amended from time to time, Annex 3 of Regulation (EC) No 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods. Regulation 3(3) amends the 2007 Regulations with the effect that it becomes an offence to add a substance listed in Part A of Annex III of the EC Regulation to foods, or to use such a substance in the manufacture of foods. It also becomes an offence to add a substance listed in Part B of Annex III of the EC Regulation to foods, or to use such a substance in the manufacture of foods, unless that substance is added or used in accordance with the conditions specified in that Part.

Regulation 4 introduces the revocations in schedule 2, which relate to the Foods for Special Medical Purposes (Scotland) Regulations 2000 (“the 2000 Regulations”) and provisions which amend them. The 2000 Regulations implement Commission Directive 1999/21/EC on dietary foods for special medical purposes in respect of food for special medical purposes developed to satisfy the nutritional requirements of infants. Directive 1999/21/EC applies until 21 February 2020 in respect of such foods and thereafter is repealed by article 10 of the Delegated Regulation.