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## EXPLANATORY NOTE

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

1. These Regulations, which apply in relation to Wales, give effect to Commission Directive [2006/141/EC](#) on infant formula and follow-on formula and amending Directive [1999/21/EC](#) (OJNo. L401, 20.12.2006, p.1) and Council Directive [92/52/EEC](#) on infant formulae and follow-on formulae intended for export to third countries (OJ No. L179, 1.7.1992, p.129).

2. These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 ([1972 c. 68](#)) and references to Annex to Directive [2006/141/EC](#) are to be construed as references to that Annex as amended from time to time (regulation 2(6)).

3. These Regulations—

- (a) prohibit marketing of infant formula and follow-on formula which contravenes or fails to comply with specified regulations (regulation 3);
- (b) prohibit marketing or otherwise representing a product as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first months of life until the introduction of appropriate complementary feeding unless that product is infant formula (regulation 4);
- (c) provide that infant formula and follow-on formula must not contain any substance in such quantity as to endanger the health of infants and young children (regulation 5);
- (d) provide that infant formula must be manufactured from specified protein sources and other suitable food ingredients (regulation 6);
- (e) provide that follow-on formula must be manufactured from specified protein sources and other suitable food ingredients (regulation 7);
- (f) provide that infant formula must comply with specified compositional criteria (regulation 8);
- (g) provide that follow-on formula must comply with specified compositional criteria (regulation 9);
- (h) provide that in order to make infant formula or follow-on formula ready for use nothing more must be required than the addition of water (regulation 10);
- (i) provide that the use of food ingredients in infant formula and follow-on formula must observe specified prohibitions and limitations (regulation 11);
- (j) provide that only specified substances may be used in the manufacture of infant formula and follow-on formula in order to satisfy specified requirements of Directive [2006/141/EC](#) and that those substances must meet specified purity criteria (regulation 12);
- (k) prohibit a food business operator placing an infant formula on the market that has not yet been placed on the market in the United Kingdom unless that food business operator has given prior notice to the Food Standards Agency (regulation 13);
- (l) provide that infant formula and follow-on formula may not contain pesticide residues above specified levels (regulation 14);
- (m) provide that infant formula may only be sold under certain names (regulation 15);
- (n) provide that follow-on formula may only be sold under certain names (regulation 16);
- (o) provide for the labelling of infant formula (regulation 17);

*Status: This is the original version (as it was originally made).*

- (p) provide for the labelling of follow-on formula (regulation 18);
- (q) provide that infant formula and follow-on formula must be labelled to make a clear distinction between such products so as to avoid any risk of confusion between them (regulation 19);
- (r) apply the provisions of specified regulations to the presentation of infant formula and follow-on formula (regulation 20);
- (s) prohibit advertising of infant formula except in specified publications unless the advertisement complies with the provisions of specified regulations (regulation 21(1));
- (t) impose restrictions on the content of advertisements for infant formula (regulation 21(2) and (3));
- (u) prohibit advertising of follow-on formula where the advertisement contravenes or fails to comply with the provisions of specified regulations (regulation 22);
- (v) impose restrictions on the promotion of infant formula (regulation 23);
- (w) impose restrictions on the production or publication of informational or educational material dealing with the feeding of infants and intended to reach pregnant women and mothers of infants and young children (regulation 24(1), (2) and (3));
- (x) prohibit donation of informational or educational equipment or materials by manufacturers or distributors of infant formula unless certain conditions are met (regulation 24(4));
- (y) impose restrictions on what an institution or organisation may do with infant formula that it has received free of charge or at a reduced rate (regulation 25);
- (z) prohibit export to a third country of infant formula which contravenes or fails to comply with specified regulations, a specified international standard or the Food (Lot Marking) Regulations (S.I.1996/1502) (regulation 26(1));
- (aa) prohibit export to a third country of a product represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first four to six months of life unless that product is infant formula (regulation 26(2));
- (bb) prohibit export to a third country of follow-on formula which contravenes or fails to comply with specified regulations, a specified international standard or the Food (Lot Marketing) Regulations 1996 (regulation 27);
- (cc) provide that a person who contravenes or fails to comply with specified regulations is guilty of an offence and provide a penalty for contravening or failing to comply with those regulations (regulation 28(1));
- (dd) provide that each food authority must enforce and execute these Regulations within its area (regulation 28(2));
- (ee) apply specified provisions of the Food Safety Act 1990 (1990 c. 16) with modifications (regulation 29);
- (ff) amend the Medical Food (Wales) Regulations (S.I. 2000/1866 (W.25)) (regulation 30); and
- (gg) revoke the Infant Formula and Follow-on Formula Regulations (S.I. 1995/77) in so far as they apply in relation to Wales (S.I. 1995/77 applies in relation to the whole of Great Britain) and provide transitional arrangements with regard to S.I. 1995/77 (regulation 31).

4. A full regulatory impact assessment of the effect that this instrument will have has been prepared. Copies may be obtained from the Food Standards Agency, 11th Floor, Southgate House, Wood Street, Cardiff, CF10 1EW.