## EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations revoke the Materials and Articles in Contact with Food (Scotland) Regulations (S.S.I. 2005/243) ("the 2005 Regulations") and re enact or re enact with amendments provisions contained in those Regulations. These Regulations provide for the enforcement of Regulation (EC) No.1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (O.J. No. L 338, 13.11.04, p.4) ("Regulation 1935/2004").

The Regulations also provide for the enforcement of Commission Regulation (EC) No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food (O.J. No. L 384, 29.12.06, p.75) ("Regulation 2023/2006"), and implement Commission Directive 2007/42/EC relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs (O.J. No. L 172, 30.6.07, p.71) ("Directive 2007/42"). This Directive repealed and consolidated Commission Directive 93/10/EEC (O.J. No. L 93, 17.4.93, p.27) as last amended by Commission Directive 2004/14/EC (O.J. No. L 27, 30.1.04, p.48).

## These Regulations-

- (a) provide that references to a certain EC instrument or specified parts of certain EC instruments are to be construed as references to the instrument or specified part of it as it may be amended from time to time (regulation 2(4));
- (b) do not apply to materials or articles outside the scope of Regulation 1935/2004(regulation 3);
- (c) contain provisions which make it an offence to contravene certain requirements of Regulation 1935/2004 (Regulation 1935/2004 being the principal framework Regulation on materials and articles in contact with food) (regulation 4), and of Regulation 2023/2006 (regulation 5);
- (d) provide for designation of the competent authorities for the various purposes identified in Regulations 1935/2004 and 2023/2006 (*regulations 6 and 7*);
- (e) re-enact, without substantive amendments, the provisions of the 2005 Regulations relating to vinyl chloride (*regulations 8 and 9*);
- (f) re-enact provisions of the 2005 Regulations relating to regenerated cellulose film ("RCF") with minor amendments to implement Directive 2007/42 (regulations 10 and 11).
- (g) in regulation 10-
  - (i) control which substances may be used in the manufacture of RCF, which may vary according to whether or not it is coated with plastics (paragraph (3));
  - (ii) regulate which substances may be used to manufacture plastic coatings for RCF, and under what conditions (paragraph (4));
  - (iii) create a conditional derogation from paragraph (3) in respect of substances used as colourants or adhesives in the manufacture of non plastic coated RCF (paragraph (5));
  - (iv) create offences in relation to the sale, import or business use of non compliant RCF (paragraphs (6) and (7)); and

- (v) create a requirement for RCF, when marketed prior to the retail stage, to be accompanied by a declaration of legislative compliance (paragraph (8)).
- (h) in regulation 11-

apply to plastic coated RCF the existing controls (derived from Commission Directive 2002/72/EC) on migration of constituents of plastic materials and articles into food, in particular by—

- (i) specifying overall migration limits for plastic coated RCF (paragraphs (1) and (2));
- (ii) applying to plastic coated RCF the specific migration limits applicable to certain substances used in the manufacture of plastic materials and articles (paragraphs (3) and (4)); and
- (iii) applying the prescribed methods and procedures for checking compliance with migration limits (paragraphs (5) and (6)).
- (i) include savings and transitional provisions which-
  - (i) preserve the defences available under the 2005 Regulations for any RCF manufactured before 29th April 1994 that may still be in circulation; and
  - (ii) preserve the defence in relation to RCF manufactured in or imported into the European Community before 29th January 2006 (regulation 12).
- (i) contain general administrative and enforcement provisions which—
  - (i) penalise contravention of these Regulations or obstruction of those enforcing them *(regulation 13)*;
  - (ii) provide for a defence of due diligence to an offence under these Regulations (regulation 14);
  - (iii) designate enforcement authorities for various functions under the Regulations (regulation 15);
  - (iv) specify the procedure to be followed when sending a sample for analysis (regulation 16);
  - (v) make provision for a sample to be analysed by the Government Chemist (regulation 17); and
  - (vi) apply certain provisions of the Food Safety Act 1990 (regulation 18).
- (k) make amendments and revocations by-
  - (i) amending regulation 8(2) to the Ceramic Articles in Contact with Food (Scotland) Regulations 2006 (S.S.I. 2006/230) (regulation 19).
  - (ii) making consequential amendments to the Plastic Materials and Articles in Contact with Food (Scotland) (No. 2) Regulations 2006 (S.S.I. 2006/517) and the Food Safety (Sampling and Qualifications) Regulations 1990 (S.I.1990/2463) (regulations 20 and 21); and
  - (iii) revoking the 2005 Regulations and subsequent amending legislation as well as a spent provision in the Food Safety Act 1990 (Consequential Modifications) (No. 2) (Great Britain) Order 1990 (S.I. 1990/2487) (regulation 22).

A full regulatory impact assessment of the effect that this instrument will have on business costs has been prepared and placed in the Scottish Parliament Information Centre. Copies may be obtained from the Food Standards Agency, 6th Floor, St Magnus House, 25 Guild Street, Aberdeen, AB11 6NJ.