
SCOTTISH STATUTORY INSTRUMENTS

2003 No. 568

The Collagen and Gelatine (Intra-Community Trade) (Scotland) (No. 2) Regulations 2003

Authorisation of establishments producing collagen

5.—(1) A food authority shall, on application under this regulation, authorise an establishment producing collagen intended for human consumption if the food authority is satisfied that—

- (a) the establishment complies with the requirements set out in Chapters I, II, V, VI, VII, VIII, IX and X of Schedule 1 to the Food Safety (General Food Hygiene) Regulations 1995⁽¹⁾;
- (b) the proprietor of the establishment carries out that proprietor's own checks to ensure that—
 - (i) critical control points in the establishment relative to the production process used are identified and are acceptable to the food authority;
 - (ii) methods for monitoring and controlling such critical points are established and are acceptable to the food authority;
 - (iii) samples are taken for the purpose of checking cleaning and disinfection methods and for the purpose of checking compliance with the standards prescribed in accordance with Commission Decision [2003/721/EC](#) and are analysed as appropriate in a laboratory acceptable to the food authority;
 - (iv) a record in permanent form is kept and made available to a food authority upon request and is kept in respect of the matters specified in paragraphs (i) to (iii) for a period of at least two years from the date on which the record was made;
 - (v) the food authority is notified immediately when a laboratory examination of samples or any other information at the proprietor's disposal reveals a serious health risk; and
 - (vi) in the event of an imminent health risk, the quantity of products, obtained in technologically similar conditions and likely to present the same risk, is withdrawn from the market, and any quantity of products so withdrawn shall be held under the control and supervision of the food authority until it is destroyed, used for purposes other than human consumption or, after authorisation by the food authority, reprocessed in a manner appropriate to ensure it is fit for human consumption;
- (c) the proprietor of the establishment has arranged or established a staff training programme enabling workers to comply with the conditions of hygienic production appropriate to the tasks undertaken by such staff, unless such staff are able to show that they have adequate qualifications;
- (d) records of the sources of all incoming raw materials and of the destination of all outgoing products in relation to the establishment are made and then kept for a period of at least two years from the date on which the record was made;
- (e) a system is operated which makes it possible to link each production batch dispatched, the incoming raw material consignments, the production conditions and the time of production; and

(1) S.I.1995/1763, amended by S.I. [1995/2148](#) and [3205](#), [1996/1699](#), [1997/2537](#), [1998/994](#), [1999/1360](#) and [1540](#) and S.S.I. [2000/62](#) and [93](#).

- (f) the food authority has all the information it requires to notify the Agency of the authorisation in accordance with regulation 9(2)(a).
- (2) When granting an authorisation under this regulation, the food authority shall allocate a distinctive number to the establishment producing collagen concerned.
- (3) The proprietor of the business carried on at any establishment authorised under this regulation shall give notice to the food authority of—
 - (a) any change, or intended change, of the proprietorship of such business; or
 - (b) any material change, or intended material change in the operation of such business.