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WELSH STATUTORY INSTRUMENTS

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**2003 No. 3229**

**The Collagen and Gelatine (Intra-Community Trade) (Wales) Regulations 2003**

**Authorisation of establishments producing collagen intended for human consumption**

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

- (a) the proprietor of the establishment carries out checks to ensure that —
  - (i) critical 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 points are established and are acceptable to the food authority,
  - (iii) samples are taken for the purposes of checking cleaning and disinfection methods and compliance with the standards prescribed in accordance with the Commission Decision [2003/721/EC](#),
  - (iv) such samples are analysed as appropriate in a laboratory acceptable to the food authority,
  - (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, those products which are obtained in technologically similar conditions and are likely to present the same risk, are withdrawn from the market;
- (b) the proprietor of the establishment has a system in place for ensuring that a record is made in permanent form in respect of the matters specified in divisions (i) to (iii) of paragraph (a) and the results of the analysis referred to in division (iv) of that paragraph, and that it is kept for a period of at least two years and is made available to the food authority upon request;
- (c) the proprietor of the establishment has arranged or established a staff training programme to enable staff engaged in the production of collagen intended for human consumption, and who do not already have qualifications which are adequate and relevant for that purpose, to comply with the conditions of hygienic production appropriate to their duties; and
- (d) the food authority has all the information it requires to notify the Agency of an authorisation in accordance with regulation 9(2)(a).

(2) When granting an authorisation under this regulation, the food authority shall allocate a unique identification number to the establishment concerned.

(3) The proprietor of the business carried on at any establishment authorised under this regulation shall give notice immediately 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.