(2003/C 52 E/177)

WRITTEN QUESTION E-2394/02

by Ria Oomen-Ruijten (PPE-DE) to the Commission

(2 August 2002)

Subject: MPA hormone scandal

1. Wyeth Pharmaceuticals in Ireland disposes of its hormone waste via the processing firm of Cara Environmental Technology. Does the legislation on waste permit a pharmaceuticals firm to dispose of hormone waste without any control on what is done with the waste? Does the legislation on waste products make sufficiently clear with what rules a firm must comply in the processing and subsequent export of such waste? To what extent have the Irish authorities sufficiently checked what is happening to this waste and are all the export permits in order?

2. Is the Belgian firm of Bioland, which processed the MPA hormone, adequately monitored by the Belgian government and governmental bodies, in the light of the fact that this firm has been discredited on several occasions by its careless (to say the least) attitude to the rules?

3. How are the Dutch firms which processed this waste monitored in the animal feed chain?

4. Is it possible to give an account by Member State of the financial losses suffered by pig farmers as a result of export restrictions, the closure of numerous farms for several weeks, and the possible infertility of the herd?

5. To what extent can the European legislation on product liability offer a solution to the losses suffered by livestock farmers?

Supplementary answer
given by Mr Byrne on behalf of the Commission

(21 October 2002)

1. Community legislation on waste, in particular Articles 4 and 8 of the Waste Framework Directive 75/442/EEC of 15 July 1975 on Waste [1], establishes that Member States have to take the necessary measures to ensure that waste is recovered or disposed of without any harm to human health, animal health or the environment. Member States have to ensure that waste is handled by undertakings authorised for recovery or disposal. Council Regulation (EEC) No 259/93 on the supervision and control of shipments of waste within, into and out of the European Community [2] lays down the obligations to be fulfilled by all parties involved in the shipment of waste. This Regulation clearly establishes that the shipment of 'AD 010 waste [3] from the production and preparation of pharmaceutical products' (such as the waste concerned in this affair) has to follow a certain control procedure based on prior written notification and consent. It is the responsibility of the Member States to ensure that all parties fulfil these provisions.

The Commission has written to the competent authorities of Belgium and Ireland in order to obtain further information on the implementation of Community waste legislation in this particular case.

2. The Commission is informed that Bioland never held a license to process pharmaceutical waste. According to Council Regulation EEC No 259/93 'AD 010 waste from the production and preparation of pharmaceutical products' has to be classified as 'amber' waste. Thus shipments of pharmaceutical waste have to follow a certain control procedure based on prior written notification and consent.

According to the preliminary results of the investigations carried out by the competent authorities from Belgium and Ireland, the waste containing the MPA was incorrectly classified as 'green' waste (which is exempt from control procedures). Therefore, the competent local authorities in Belgium were not notified nor aware of the shipments.

The Commission is also informed that Bioland was not licensed for direct supply to the food industry. As a result, the firm was not known to the competent control agency. No licence is required to supply the feed industry.

3. Dutch feed producers and traders are subject to inspection of the Productschap Diervoeder (PDV), a statutory trade organisation. On behalf of the Dutch government, PDV is responsible for the implementation of Community feed control legislation. Its inspectorate, the Keuringsdienst Diervoedersector (KDD), is accredited under the relevant standard (EN45004).

Additional inspections are carried out by the Rijksdienst voor de Keuring van Vee en Vlees (RVV) and the Algemene Inspectie Dienst (AID).

In addition, the Dutch feed sector has set up its own quality assurance programme, the Good Manufacturing Practice (GMP) scheme. Companies participating in this programme commit themselves to a number of non-statutory obligations, such as to buy raw materials exclusively from raw-material suppliers recognised by the GMP scheme (or an equivalent scheme).

Unfortunately two GMP-certified undertakings bought raw materials from Bioland. Bioland was never recognised by the GMP scheme. In the meantime both companies have had their GMP status withdrawn.

4. The Netherlands is the Member State most affected by the incident. The authorities there have estimated the losses as follows: primary sector (farmers): EUR 43 million due to destruction of animals and loss of income; feed sector: EUR 33 million due to destruction and recall; slaughterhouses: EUR 25 to 50 million due to temporary decline in production and export limitations; the Dutch government: EUR 6 million due mainly to increased testing and surveillance. This amounts to a total loss of EUR 107 to EUR 132 million.

5. Council Directive 85/374/EC of 25 July 1985 on liability for defective products [4] foresees a common regime concerning compensation for material damage suffered by consumers due to defective products.

This Community regime does not cover damage or loss suffered by farmers who used 'defective' feedingstuffs (e.g. contaminated feedingstuffs), because this damage occurred in the framework of an economic activity and did not affect goods intended or used for private consumption.

(1) OJ L 194, 25.7.1975.
(2) OJ L 30, 6.2.1993.
(3) Waste which may contain either inorganic or organic constituents.
(4) OJ L 210, 7.8.1985.

(2003/C 52 E/178) **WRITTEN QUESTION E-2398/02**

by David Bowe (PSE) to the Commission

(5 August 2002)

Subject: Neuroscience

Does the Commission not think that a public debate over the ethical limits to new developments in neuroscience is long overdue? Would the Commission not agree that there is a case for the creation of an advisory body similar to the one that has been set up to advise on genetics issues to advise the Commission and others in the field of neuroscience? If not why not?