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Programme Manager Frank Clinton
Signed: *N. Keavey* Date: *2/11/12*
OFFICE OF ENVIRONMENTAL
LICENSING & RESOURCE USE

INSPECTOR'S REPORT ON A TECHNICAL AMENDMENT REQUEST	
TO:	DIRECTORS
FROM:	Patrick Byrne Environmental Licensing Programme
DATE:	22 nd November 2012
RE:	Technical Amendment Request in relation to three IPPC licensed rendering installations (Dublin Products Limited, P0041-03, College Proteins, P0037-03 and Anglo Beef Processors Ireland T/A ABP Proteins Waterford, P0040-02) received from Department of Agriculture, Food and the Marine.

Background

The Department of Agriculture, Food and the Marine (DAFM) had a meeting with the Agency (Office of Environmental Enforcement (OEE) and Environmental Licensing Programme (ELP)) on 2nd February 2012 to discuss the rendering of BSE positive carcasses at Category 1 rendering plants. The Agency confirmed that processing/rendering of BSE positive carcasses was not permitted by the existing IPPC licences held by the Category 1 Rendering Plants and that processing of BSE positive carcasses could not be agreed under the terms of the licences.

The following three Category 1 rendering installations identified by the DAFM hold IPPC licences from the Agency:

1. Dublin Products Limited, Dunlavin, Co. Wicklow, P0041-03;
2. College Proteins, College Road, Nobber, Co. Meath, P0037-03; and
3. Anglo Beef Processors Ireland T/A ABP Proteins Waterford, Christendom, Ferrybank, Waterford, P0040-02.

In addition Eco-safe Systems Limited, Unit 1a Allied Industrial Estate, Kylemore Road, Ballyfermot, Dublin 10 holds a Waste Licence (W0054-02) issued by the Agency. Eco-safe Systems Limited is authorised by DAFM as a Category 1 processing plant but deals exclusively with animal by-product diagnostic and research samples and would be unsuitable for rendering BSE positive carcasses.

DAFM identified that the processing (rendering) of BSE positive carcasses represents a minimal monetary return for the rendering plants, however access to a means of disposal within Ireland is of significant importance to DAFM and the food sector. To date, the Category 1 rendering installation have not requested a review/technical amendment of their IPPC licence to process BSE positive material despite efforts by DAFM to encourage the licensees to make such requests to the Agency.

DAFM have provided written correspondence in relation to this issue, letter received by the Agency 18th June 2012, which requests that the Agency examine the possibility of technically

amending the IPPC licences granted to these installations and provide for the rendering of BSE positive carcasses.

Bovine Spongiform Encephalopathy (BSE) is considered to be a zoonotic¹ prion disease of bovines. At the height of the BSE epidemic in Ireland (2002) there were 333 new cases diagnosed among cattle. Eradication measures have been successful and 2 new cases were diagnosed in 2010 and 3 new cases were diagnosed in 2011. While the disease is virtually eradicated from the cattle population modelling predicts there will be a continuing small number of cases each year for a number of years to come due to the long incubation period of the disease.

DAFM identifies that Regulation (EC) No. 1069/2009² (Animal By-Products Regulation) and Commission Regulation (EU) No. 142/2011³ (Implementing Regulation) provide for the legal disposal of the carcasses of BSE positive cases via rendering (defined as 'Processing Method 1' in the Animal By-Product Regulation and associated Implementing Regulation) with subsequent disposal/recovery of Meat and Bonemeal by incineration/co-incineration.

DAFM states that carcasses from BSE positive cases were transported to Northern Ireland to be disposed of by incineration by the Agri-Food and Biosciences Institute (AFBI, state laboratory), however this was only an interim solution provided by the Department of Agriculture, Fisheries and Rural Development Northern Ireland. DAFM states that the AFBI incinerator facility is currently unavailable which leaves DAFM with no alternative contingency plan to dispose of suspect BSE carcasses.

DAFM describes their applicable protocols in relation to BSE positive carcasses under the following headings:

- Measures employed during collection and transport of a BSE positive carcass from knackery, slaughter plant or Regional Veterinary Laboratory to ensure negligible risk to both animal and public health; and
- Protocol Employed at Category 1 Processing Plants Minimising Risks Posed By Rendering of BSE Positive Carcasses.

Collection and Transport Protocol:

The protocol identifies the responsibilities of the Veterinary Inspector (VI) in relation to organising for BSE positive carcass collection, inspection of the carcass, arranging removal of the head (applicable to BSE rapid test positive/inconclusive carcasses), documentation, cleaning and disinfection of equipment and storage areas, collection and disposal of contaminated run-off and carcasses/animal by-products that were in contact with the BSE positive carcass at a category 1 rendering plant.

Category 1 Rendering (Processing) Plants Protocol:

All category 1 rendering plants utilise Processing Method 1 rendering (specified temperature, residence times, pressure, etc., to cook and sterilise the raw material and produce tallow

¹ Transmissible to humans

² Regulation (EC) No. 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002, OJEU No. L 300/1, 14 November 2009.

³ Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive, OJEU No. L 54/1, 26 February 2011.

and meat and bonemeal). Meat and Bonemeal is marked with a permanent marker, and disposed/recovered by means of incineration/co-incineration. Each meat and bonemeal consignment is accompanied by commercial documentation and ultimate disposal/recovery is reconciled by the rendering plants. Tallow is used as fuel in thermal boilers either on-site or at another DAFM approved plant or processed at a DAFM approved biodiesel plant. All waste water from rendering plants is re-circulated back into the rendering process. Gases produced from cooking and sterilisation are treated in thermal oxidisers prior to discharge. All category 1 plants are required to implement bio-security protocols.

Request:

DAFM requests that the Agency allow the processing of BSE positive carcasses at approved Category 1 Processing (Rendering) plants on the basis of the above protocols, the significantly reduced number of cases of BSE compared to the numbers confirmed at the height of the BSE epidemic, and all three identified category 1 processing (rendering) plants have been designed and are operated and controlled by DAFM so as to mitigate risks both to public and animal health in accordance with relevant Animal By-Products Regulation.

Consideration:

The Category 1 (Processing) Rendering installations identified by DAFM are licensed by the Agency. The three installations have broadly similar conditions within their licences which do not permit the processing of BSE positive carcasses, see Appendix A for details of specific conditions applicable to each licence.

OEE have informed the licensees that their licences do not permit the rendering of BSE positive carcasses and that a technical amendment/licence review is the appropriate means by which the Agency could consider a proposal to process BSE positive carcasses.

One of the category 1 rendering installations (Dublin Products Limited) was issued a revised IPPC licence in July 2012, following an assessment of their licence in accordance with the European Communities Environmental Objectives (Surface Waters) and (Groundwater) Regulations 2009 and 2010; however, the review was limited and did not consider all licence conditions.

The Animal By-Products Regulation classifies "animals suspected of being infected by a TSE⁴ in accordance with Regulation (EC) No 999/2001 or in which the presence of a TSE has been officially confirmed" as Category 1 Material (Article 8 of the Animal By Products Regulation). Article 12 of the Animal By-Products Regulation, Disposal and Use of Category 1 Material, includes the following options in relation to category 1 material:

- (a) Disposed of as waste by incineration, following processing, by pressure sterilization if the competent authority so requires, and permanent marking of the resultant material; or
- (b) Recovered or disposed of by co-incineration, if the category 1 material is waste following processing, by pressure sterilization if the competent authority so requires, and permanent marking of the resultant material.

The rendering process, as operated by the Category 1 Rendering installations in accordance with Animal By-Products Regulation and Implementing Regulation, reduces the level of infectivity associated with BSE. The prions associated with BSE are very difficult to destroy, and the rendering process is not capable of completely destroying the infectivity. However, the resulting meat and bonemeal is incinerated/co-incinerated and tallow is combusted in

⁴ All transmissible spongiform encephalopathies with the exception of those occurring in humans.

DAFM authorised thermal oxidisers and boilers. DAFM considers that there is a negligible risk to both animal and public health associated with the rendering of BSE positive carcasses at any of the three identified Category 1 Rendering installations.

Section 96(1)(c) states that: *'The Agency may amend a licence or revised licence for the purposes of – (c) otherwise facilitating the operation of the licence and the making of the amendment does not result in the relevant requirements of section 83(5) ceasing to be satisfied.'*

I am satisfied that the processing of limited numbers of BSE positive carcasses, in accordance with the conditions and schedules of the IPPC licenses and Animal By Product Regulations, will not result in the requirements of section 83(5) of the EPA Acts ceasing to be satisfied.

Recommendation:

The IPPC licences issued to the Category 1 rendering installations include limitations in relation to the treatment of BSE positive carcasses. Such limitations were included at the height of the BSE epidemic in Ireland. The eradication measures implemented have reduced the known occurrence of BSE cases in the national cattle herd to 2 new cases in 2010 and 3 new cases in 2011.

The Animal By-Products Regulation and Implementing Regulation provide for the rendering and subsequent disposal by incineration or recovery/disposal by co-incineration of the resulting material. The regulations specify health rules based on scientific advice to minimise the health risks associated with the disposal, recovery and use of animal by-products.

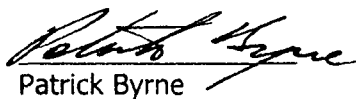
It is recommended that the IPPC licences issued to the three Category 1 rendering Installations identified be technically amended, in accordance with Section 96(1)(c) of the EPA Acts 1992 to 2012, to provide for the rendering of BSE positive carcasses.

The necessary amendments to the licences are identified in Appendix B below, subject to any submissions that may be received from the licensees.

The Agency shall, prior to issue of these recommended technical amendments, in accordance with Section 96(2)⁵ of the EPA Acts 1992 to 2012 write to the licensees informing them of the Agency's intention to provide for the rendering of BSE positive carcasses by means of a technical amendment on the basis of a request received from DAFM. The letter should include a copy of the request from DAFM and invite comments from the licensees within 4 weeks of the date of the letter; please find attached as Appendix C a draft letter to issue to the three licensees.

If a technical amendment is issued to the three identified Category 1 rendering installations the Agency shall, in accordance with Section 96(3) notify particulars of the amendment effected by that exercise to each person who made an objection to the Agency under Section 87(5) in relation to any exercise of the powers under section 83 or 90 as respects the licence or revised licence concerned.

Signed


Patrick Byrne

⁵ None of the requirements of section 90 or of any other provision of this Part shall apply to the exercise of the power under subsection (1) but the Agency shall, where appropriate, consult with the licensee before exercising the power

Appendix A:
Relevant Conditions from the Category 1 Rendering Plants licenced by the Agency

P0041-03, Dublin Products Limited

Condition 8.10 states:

“No bovine animal or animal products, which have been tested positive for BSE, shall be processed at this installation.”

Condition 8.11 states:

“All bovine animals arising from depopulated herds or cohorts of BSE infected animals shall be tested for the presence of the abnormal protease-resistant form of a normal host protein, prior to arrival at the site for processing. Only those carcasses and associated animal by-products which have tested negative shall be admitted to the site for processing. Whole bovine animal carcasses arising from depopulated herds or cohorts of BSE infected animals arriving at the site for processing shall be treated as if they were fallen animals (see Conditions 8.21 - 8.25 below).”

Condition 8.20 states:

“Whole fallen animals; suspect BSE animals/by-products or SRM, depopulated herds or cohorts of BSE infected animals; animals or by-products arising from a disease outbreak listed under the Diseases of Animals Act, 1966, Part III Diseases of Animals and Poultry, Class A and/or Class B; shall be processed only with the prior written approval of the Agency.”

Condition 8.22 states:

“No fallen bovine animal shall be processed at the facility without having first been tested negative for the presence of the abnormal protease-resistant form of a normal host protein.”
Schedule A: Limitations includes the statement under ‘Limitations’ that: “No bovine animal or animal products, which have been tested positive for BSE, shall be processed at this installation.”

P0037-03, College Proteins

Condition 7.13 states:

“Whole fallen animals; suspect BSE animals/by-products, depopulated herds or cohorts of BSE infected animals; animals or by-products arising from a disease outbreak listed under the Diseases of Animals Act, 1966, Part III Diseases of Animals and Poultry, Class A and/or Class B; shall only be processed with the prior written approval of the Agency.”

P0040-02, Anglo Beef Processors Ireland t/a ABP Proteins Waterford

Conditions 7.1 states:

“No bovine animal or animal parts/products, which have been tested positive for BSE, shall be processed at this facility.”

Condition 7.11 states:

“Animal by-products or SRM arising from depopulated herds or cohorts of BSE infected animals; animal by-products or SRM arising from a disease outbreak listed under the Diseases of Animals Act, 1966, Part III Diseases of Animals and Poultry, Class A and/or

Class B; shall not be processed at the facility, except with the written prior agreement of the Agency.”

Condition 8.3 states:

“The licensee shall prior to

- (a) receiving fallen animals for processing, provide the Agency with full details of the measures to be adopted for the disposal off-site of BSE positive material which may arise from on-site testing,
- (b) the removal of meat and bone meal and/or tallow oil off-site for disposal, provide full details to the Agency relating to the disposal/recovery of this material.

Schedule 3(i) states:

Schedule 3(i) High Risk/Hazardous Wastes for Disposal/Recovery

Waste Materials	Further Treatment Recovery/Recycling On-Site <small>Note 1</small>	On-Site Reuse <small>Note 1</small>	Method of Disposal/Recovery <small>Note 2</small>
Meat & bone meal and tallow oil	None	None	To be agreed with the Agency.
Suspect/positive BSE material	None	None	To be agreed with the Agency.
Fluorescent tubes	None	None	To be agreed with the Agency.
Other <small>Note 3</small>			

Note 1: The licensee may treat, reuse, recycle or recover waste subject to the prior written agreement of the Agency.

Note 2: Any variation from those contractors named in the IPC Licence application, or subsequent agreements, must have the prior written agreement of the Agency. In cases where a previously agreed waste contractor is considered by the Agency not to exercise due care in respect of the transport and disposal of the licensees waste, the Agency may at any time instruct a licensee to stop using this contractor.

Note 3: No other high risk/hazardous waste shall be disposed of/recovered off-site or on-site without prior notice to, and prior written agreement of the Agency.

Appendix B:
Recommended Amendments to provide for Rendering (Processing) of BSE Positive Carcasses

P0041-03, Dublin Products

Delete Condition 8.10 which states:

“No bovine animal or animal products, which have been tested positive for BSE, shall be processed at this installation.”

Amend Condition 8.11 to read as follows:

“Whole bovine animal carcasses arising from depopulated herds or cohorts of BSE infected animals arriving at the site for processing shall be treated as if they were fallen animals (see Conditions 8.21 - 8.25 below).”

Amend Condition 8.20 to read as follows:

“Whole fallen animals; animals or by-products arising from a disease outbreak listed under the Diseases of Animals Act, 1966, Part III Diseases of Animals and Poultry, Class A and/or Class B; shall be processed only with the prior written approval of the Agency.”

Delete Condition 8.22 which states:

“No fallen bovine animal shall be processed at the facility without having first been tested negative for the presence of the abnormal protease-resistant form of a normal host protein.”

Delete Limitations, under Schedule A: Limitations, which states:

“No bovine animal or animal products, which have been tested positive for BSE, shall be processed at this installation.”

P0037-03, College Proteins

Amend Condition 7.13 to read as follows:

“Whole fallen animals; animals or by-products arising from a disease outbreak listed under the Diseases of Animals Act, 1966, Part III Diseases of Animals and Poultry, Class A and/or Class B; shall only be processed with the prior written approval of the Agency.”

P0040-02, Anglo Beef Processors Ireland t/a ABP Proteins Waterford

Delete Conditions 7.1 which states:

“No bovine animal or animal parts/products, which have been tested positive for BSE, shall be processed at this facility.”

Amend Condition 7.11 to read as follows:

“Animal by-products or SRM arising from a disease outbreak listed under the Diseases of Animals Act, 1966, Part III Diseases of Animals and Poultry, Class A and/or Class B; shall not be processed at the facility, except with the written prior agreement of the Agency.”

Amend Condition 8.3 to read as follows:

“The licensee shall prior to

(a) the removal of meat and bone meal and/or tallow oil off-site for disposal, provide full details to the Agency relating to the disposal/recovery of this material.

Amend Schedule 3(i) to read as follows:

Schedule 3(i) High Risk/Hazardous Wastes for Disposal/Recovery

Waste Materials	Further Treatment, Recovery/Recycling On-Site <small>Note 1</small>	On-Site Reuse <small>Note 1</small>	Method of Disposal/Recovery <small>Note 2</small>
Meat & bone meal and tallow oil	None	None	To be agreed with the Agency.
Fluorescent tubes	None	None	To be agreed with the Agency.
Other <small>Note 3</small>			

Note 1: The licensee may treat, reuse, recycle or recover waste subject to the prior written agreement of the Agency.

Note 2: Any variation from those contractors named in the IPC Licence application, or subsequent agreements, must have the prior written agreement of the Agency. In cases where a previously agreed waste contractor is considered by the Agency not to exercise due care in respect of the transport and disposal of the licensee's waste, the Agency may at any time instruct a licensee to stop using this contractor.

Note 3: No other high risk/hazardous waste shall be disposed of/recovered off-site or on-site without prior notice to, and prior written agreement of the Agency.

Appendix C:

Draft letter to licensees inviting comments

Licensee

Date:

Reg. No: P0

Dear

I wish to advise that the Agency intends to technically amend your existing licence Reg. No. Pxxx-xx, under section 96(1)(c) of the EPA Acts 1992 to 2012 in response to a request (copy attached for your information) from the Department of Agriculture, Food and the Marine to provide for the rendering of BSE positive carcasses at Category 1 rendering (processing) installations.

Any comments in relation to the Agency's proposal to amend your licence, must be received within four weeks of the date of this letter. If no response is received the Agency will proceed with the initiation of a technical amendment to your existing licence.

If you have any further queries please contact Inspector Pat Byrne of the Environmental Licensing Programme, Office of Climate Licensing and Resource Use, at telephone no. 01-2680100.

Yours sincerely

Programme Officer

Office of Climate, Licensing & Resource Use