

## ENVIRONMENTAL PROTECTION AGENCY ACTS 1992 AND 2003

### NOTIFICATION OF A PROPOSED DETERMINATION OF AN APPLICATION FOR AN INTEGRATED POLLUTION PREVENTION AND CONTROL LICENCE IN ACCORDANCE WITH SECTION 87(2) OF THE ENVIRONMENTAL PROTECTION AGENCY ACTS 1992 AND 2003.

In pursuance of the powers conferred on it by the above mentioned Acts the Agency proposes to determine the application by: TopChem Pharmaceuticals Limited, Ballymote Business Park, Carrownanty, Ballymote, County Sligo (Licence Register No. P0828-01), under Section 83 (1) of the said Acts in the following manner:

The applicant submitted the application, plans, documents and other particulars on 14 June 2007.

It is proposed, for the reasons hereinafter set out, to grant a licence to the above named applicant to carry on the following activity

- : 5.16: The use of a chemical or biological process for the production of basic pharmaceutical products

at Ballymote Business Park, Carrownanty, Ballymote, County Sligo subject to twelve Conditions.

A copy of the proposed determination accompanies this notification.

#### OBJECTIONS/ORAL HEARING REQUESTS

The applicant and any other person may object to the proposed determination, in accordance with section 87(5) of the EPA Acts 1992 and 2003. In accordance with section 87(12) and section 87(13) of the EPA Acts 1992 and 2003, objections must be received at any time no later than:

**4<sup>th</sup> January 2008**

A person making an objection may request an oral hearing of the objection, in accordance with section 87(6) of the EPA Acts 1992 and 2003 at any time no later than the date specified above.

It is important to note that any objection to the proposed determination/request for an oral hearing of the objection must be made either by sending it by prepaid post to the headquarters of the Agency, or by leaving it with an employee of the Agency **at the headquarters of the Agency in Wexford**, during office hours, i.e. 9.00am to 5.00pm Monday to Friday.

An objection against the proposed determination must include the grounds for the objection. An objection and a request for an oral hearing of an objection must **each** be accompanied by the appropriate fee, and be addressed to the Office of Climate, Licensing & Resource Use, EPA headquarters, P.O. Box 3000, Johnstown Castle Estate, County Wexford.

A valid objection/request for an oral hearing of the objection must be received at the headquarters of the Agency **no later than the applicable date above**.

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Note: The form and content of an objection is set out in the attached extract from the Environmental Protection Agency (Licensing) Regulations 1994 to 2004.

The fees for an objection and request for an oral hearing of the objection are as set out in the attached extract from the Environmental Protection Agency (Licensing Fees) Regulations 1994 to 2004.

In order to be considered valid, an objection and a request, each must also comply with the other statutory requirements in relation to objections and requests for oral hearings as set out in the EPA Acts 1992 and 2003, the EPA (Licensing) Regulations 1994 to 2004 and the EPA (Licensing Fees) Regulations 1994 to 2004. Extracts from the Acts and the Regulations accompany this notification.

In the event that:

- (a) no objection is taken against the proposed determination or
  - (b) an objection or objections is or are taken against the proposed determination and the objection or objections is or are withdrawn,
- the Agency will make its decision in accordance with the proposed determination and grant the licence as soon as may be thereafter.

A copy of the proposed determination may be obtained from the Office of Climate Change, Licensing & Resource Use, EPA headquarters, P.O. Box 3000, Johnstown Castle Estate, County Wexford.

Signed on behalf of the said Agency:

\_\_\_\_\_  
Dr. Thomas McLoughlin

Date of notification:

\_\_\_\_\_  
29<sup>th</sup> November 2007

## **Article 29 of the Environmental Protection Agency (Licensing) Regulations 1994 to 2004**

### **Form and content of objection**

- (1) An objection shall-
  - (a) be made in writing,
  - (b) state the name and address of the objector,
  - (c) state the reference number given under article 42(2) to the application or the review in the register of licences and the subject matter of the objection,
  - (d) state the grounds for the objection and the reasons, considerations and arguments on which they are based, and
  - (e) be accompanied by a fee specified in accordance with section 99A of the Act.
- (2) Without prejudice to article 31, an objector shall not be entitled to elaborate in writing upon, or make further submissions in writing in relation to, the grounds for the objection stated in the objection, or to submit further grounds of objection and any such elaboration, submission or further grounds for the objection that is or are received by the Agency shall not be considered by it.
- (3)
  - (a) An objection shall be accompanied by such documents, particulars or other information relating to the objection as the objector considers necessary or appropriate.
  - (b) Without prejudice to article 31, the Agency shall not consider any documents, particulars or other information submitted by an objector other than the documents, particulars or other information which accompanied the objection.
- (4) An objection shall be made -
  - (a) by sending the objection by prepaid post to the headquarters of the Agency, or
  - (b) by leaving the objection with an employee of the Agency at the headquarters of the Agency during office hours.
- (5) The Agency shall as soon as may be after receipt of an objection acknowledge such receipt

## **Sections 87(6) & (7) of the Environmental Protection Agency Acts 1992 to 2003**

**Section 87**  
Processing of  
applications for  
licences or reviews  
of licences

- (6) (a) A person making an objection under subsection (5) may request an oral hearing of the objection.
- (b) (i) A request for an oral hearing of an objection shall be made in writing to the Agency and shall be accompanied by such fee (if any) as may be payable in respect of such request in accordance with regulations under section 99A.
- (ii) A request for an oral hearing of an objection which is not accompanied by such fee (if any) as may be payable in respect of such request shall not be considered by the Agency.
- (c) A request for an oral hearing of an objection shall be made before the expiration of the appropriate period, and any request received by the Agency after the expiration of that period shall not be considered by it.
- (7) An objection, or a request for an oral hearing under subsection (6), shall be made-
- (a) by sending the objection or request by prepaid post to the headquarters of the Agency, or
- (b) by leaving the objection or request with an employee of the Agency, at the headquarters of the Agency, during office hours, or
- (c) by such other means as may be prescribed.

## Extract from EPA (Licensing Fees) Regulations 1994 to 2004

- Fees for an objection**
- 8** (1) A fee shall be paid to the Agency in respect of an objection.
- (2) Subject to sub-article (3), the fee payable under sub-article (1) shall be the amount indicated in column (3) of Part II of the Schedule opposite the appropriate mention of objection in column (2) of the said Part of the Schedule.
- (3) Where an objection is made to the Agency by -
- (a) a local authority,
  - (b) a planning authority
  - (c) a sanitary authority,
  - (d) the National Monuments Advisory Council,
  - (e) the Central Fisheries Board,
  - (f) Failte Eireann
  - (g) in the case of an activity any part of which is situate within the functional area of the Shannon Free Airport Development Company Ltd., that Company, and
  - (h) An Taisce - The National Trust for Ireland,
- the fee payable in respect of the objection shall be the amount indicated in column (3) of Part II of the Schedule opposite the mention of a reduced fee for an objection in column (2) of the said Part of the Schedule.
- Fee for request for an oral hearing**
- 7C** (1) Where a person making an objection under section 87(5) of the Act requests an oral hearing of the objection, a fee shall be paid to the Agency by the said person.

(1)	(2)	(3)
Article 8(2)	Objection by the applicant or licensee	€253
	Objection by any other person other than a person mentioned in Article 8(3)	€126
Article 8(3)	Reduced fee for an objection	€63
Article 7C(2)		€100