DRAFT

MEMO

TO:	Board of Directors	**FROM:**	Brian Donlon
CC:		**DATE:**	17 November, 2004

SUBJECT : Sterile Technologies Ireland Ltd.- Technical Committee Report on Objection to Proposed Decision - Reg. No. 55-1

Application details

Event	Issue Date(s)	Reminder(s)	Response Date(s)
Application received	25 August 1998		
Article 14 (2) (b) (ii)	Not applicable		
Article 14 (2) (a)	10 November 1998		
Article 16	2 February 1999 1 April 1999	Not applicable	3 March 1999 9 April 1999
Proposed decision	28 July 1999		
Objections received	24 August 1999		
Article 25(1) Circulation of objections	30 August 1999		
Article 25(2) - Submissions on objections	29 September 1999		

Objections received

Objection by Applicant	None
Objection by third party/parties	Three
Submission in relation to Objection	Two

1. **Rosbeg Partners Limited**, 520 Beech Road, Western Industrial Estate, Naas Road, Dublin 12.
2. **Jim Coady & Associates,** Trinity House, Charleston Road, Dublin 6.
3. **Fehily Timoney and Company (on behalf of Gleneaden Trading Ltd.)**, Centre Park House, Centre Park Road, Cork.

Two valid submissions in relation to the Objections were made on 28th Sept. 1999 by:

1. **McHugh Consultants, 16 Herbert place, Dublin 2** (on behalf of Sterile Technologies Ireland Ltd).
2. **Rosbeg Partners Limited**, 520 Beech Road, Western Industrial Estate, Naas Road, Dublin 12.

A Technical Committee was established to consider the objections.

The Technical Committee included;

Brian Donlon, Chairperson
Donal Howley, Inspector
Margaret Keegan, Inspector

This is the Technical Committee's report on the objection.

Oral hearing

Rosbeg Partners Ltd. and Fehily Timoney and Company Ltd. requested an oral hearing.

Technical Committee's evaluation

The Technical Committee considers that the request is not warranted or justified.

Objection by Rosbeg Partners Ltd

Ground 1: (ref. Submission 7 in Inspector's Report)

1.1. The objection is of the opinion that the concerns set out in Rosbeg Partners' original submission dated 25/6/99 were not adequately dealt with.

Technical Committee's evaluation

The Technical Committee notes the concerns raised and the response detailed in the Inspector's Report. The Technical Committee notes that Condition 5.14.1 of the PD requires a 6 $\log_{10}$ reduction of spore forming micro-organisms, which is accepted to be the highest level of treatment (Level IV inactivation) required in the *State and Territorial Association on Alternate Treatment Technologies (STAATT) report* - April 1994. It should be borne in mind that the biological inactivation requirements of the Joint Waste Management Tender contract for Ireland requires a minimum of 4$\log_{10}$ reduction of spore formers which equates to Level III inactivation of the STAATT report. Level III inactivation was the level of inactivation required in waste licence (38-1).

The response to Ground 6 relates to the concern regarding the potential release of pathogenic micro-organisms.

Recommendation

No change.

Ground 2: (ref. Item 1)

2.1. The objection states that the State and Territorial Association on Alternate Treatment Technologies (STAATT) report requires the use of Bacillus stearothermophilus.

Technical Committee's evaluation

The Technical Committee notes that on pages 8-10 of the STAATT Report either of the two spore formers - *B. stearothermophilus* and *B. subtilis* - is considered acceptable.

Recommendation

No change.

Ground 3: (ref. Item 2)

3.1. The objection is concerned with the use of sodium hypochlorite (NaOCl) in the test procedure and also with the incubation period to be used in carrying out the challenge tests.

Technical Committee's evaluation

The Technical Committee notes that the tests carried out in the US did, according to the description of the protocols followed, use a ten minute immersion to simulate the treatment process. However, Condition 5.14.2 requires that "microbiological inactivation of healthcare risk waste shall be proved in the absence of applied sodium hypochlorite solution".

A procedure for the daily monitoring of spore inactivation at the facility was submitted as part of the application (MP5). The procedure did not take account of the number of spore strips to be used, the incubation period was 3 days at 55^{o}C. In the medical health care industry shorter incubation time periods (less than 2 days) to illustrate spore inactivation are routinely used. The Technical Committee considers that an alternate procedure to MP5 is required to be submitted to the Agency for agreement detailing the number of spore strips, the incubation time and temperature. This may result in treated waste being held on-site for shorter time periods following verification of test results.

Recommendation

Insert a new Condition 5.14.5 **Note 2: Prior to the commencement of operations the licensee shall submit to the Agency, for its agreement, a procedure for challenge tests for spore forming organisms.** Table F.3.2 change Note 2 to the following; **As specified in Condition 5.14.5**

Ground 4: (ref. Item 3)

4.1. The objection questions (i) the calculation of kill rates and (ii)the manner in which samples are taken and processed.

Technical Committee's evaluation

The Technical Committee notes that on examining the results it is evident that a 7 $\log_{10}$ reduction is achieved. The Technical Committee also notes Condition 5.13.2 which requires that all analytical results obtained during the commissioning tests be submitted to the Agency along with a concise interpretation.
The Technical Committee notes the need for competent practitioners and laboratories to be used in carrying out the monitoring and analyses.

Recommendation

Insert a new condition 9.8 as follows;
Condition 9.8 *All monitoring and analyses shall be carried out by competent practitioners and in competent laboratories to be agreed with the Agency.*

Ground 5: (ref. Item 4)

5.1. The objection questions the ability of the system to achieve the standards required by Condition 5.14.1(b). The objection contends that commissioning tests should reflect a worst case scenario.

Technical Committee's evaluation

The Technical Committee notes that the ability of the equipment to achieve the standards will be determined during the commissioning tests. The applicant has stated in their Article 16 response (Feb 1999) that they intend commissioning the plant using healthcare risk waste at maximum hourly throughput. Condition 5.3 limits the amount of waste that can be processed to one tonne per hour, while Condition 5.13 details the operating parameters to be tested in the commissioning tests.

Recommendation

No change.

Ground 6: (ref. Item 5)

6.1. The objection states "that there is evidence to suggest that a system which incorporates a pre-shredder has been the cause of TB infection in operators in the US. There is no safety interlock or other system to prevent pressure "blow back" noted in the submission".

Technical Committee's evaluation

The Technical Committee notes that it is proposed to pull air from the shredder area through a HEPA (high efficiency particulate air) filter prior to discharging it to

atmosphere. The applicant states, and this is borne out in manufacturers' literature, that HEPA filters are capable of achieving 99.95% removal efficiency for particles of 0.3 µm and greater. M. tuberculosis will be removed from the air flow if it is present by the proposed system. Schedule F.4 of the PD requires the applicant to carry out microbiological testing on the HEPA discharge monthly for the first six months of operation and at six monthly intervals thereafter.

The objection is also concerned with the potential for the movement of aerosols from inside the shredder hopper to outside the hopper, i.e. at the operators' station. Pages 6-7 of attachment D.2 describe the system which is intended to counter this possibility. Firstly, negative pressure must exist inside the hopper prior to it being opened. In addition, a sliding door located between the hopper and the shredder prevents any backflow of air while the hopper door is open. Finally, the hopper door is closed prior to the shredder commencing to run, preventing the egress of any aerosols generated during shredding.

Recommendation

No change.

Ground 7: (ref. Item 6)

7.1 The objection contends that a system to prevent moist air reaching the HEPA filter must be employed.

Technical Committee's evaluation

The Technical Committee notes that demisting filters are proposed in section 11 - *Maintenance Schedule* of the Operations and Maintenance Manual, received as Article 16 further information on 3rd March 1999. The Technical Committee considers that control of the abatement treatment system should be covered in the licence.

Recommendation

The following tables should be inserted into Schedule F.4

Abatement /Treatment Control

Table F.4.3 Monitoring at A1, A2

Monitoring to be carried out	Monitoring	Monitoring Equipment
Set point pressure levels Filter Integrity Filter Integrity	Daily check on pressure Daily "sniff test" Visual Weekly Check	Magnahelic gauges Not applicable Not applicable

Table F.4.4 Equipment

Equipment	Equipment Maintenance	Equipment backup
Air Abatement Equipment	See Note 1	Spares held on site

Note 1: Preventative maintenance as per manufacturers instructions

Ground 8: (ref. Item 7)

8.1. This objection states that tamper proofing has not been conditioned in the PD.

Technical Committee's evaluation

The Technical Committee notes that Condition 5.6 of the PD states that "all waste ... shall be processed as detailed in the application". The application states that tamper proof settings will be set on the processing unit to prevent unauthorised tampering with the time and temperature set points. In addition, Condition 5.13.2 requires that the parameter settings be reported to the EPA after commissioning and at least annually thereafter (Condition 5.14.4). The STAATT report states that tamper proof settings must be integral to the machine control.

Recommendation

Insert new subcondition 5.13.4 as follows;

Condition 5.13.4 *Subject to Condition 5.14.4, the parameter settings which control residence time and temperature shall be tamper proof and, once established during the commissioning tests, shall be subsequently modified only with the prior agreement of the Agency.*

Ground 9: (ref. Item 8)

9.1. The objection contends that the requirement of Condition 5.18 for a four week retention period of process control parameter records is inadequate.

Technical Committee's evaluation

The Technical Committee considers that the four week period for the retention of paper records is reasonable. However, electronic records of process control parameters may be required over a longer period. The Technical Committee notes that Condition 9.4 allows for modifications to record keeping requirements, on the written instruction of the Agency.

Recommendation

After the second last line of Condition 5.18, insert the following line;

"Electronic records of these parameters shall be maintained for a minimum period of six months".

Objection by Jim Coady & Associates

Ground 10: (ref. Condition 5.13)

10.1. The objection is concerned that no independent supervision or confirmation of the commissioning tests will be carried out.

Technical Committee's evaluation

The Technical Committee notes that commissioning tests will be reported upon to the Agency. Condition 5.13.2(b) requires that all analytical results be reported upon, including failures. Daily testing by the licensee and auditing and sampling by the Agency will be carried out.

Recommendation

No change.

Ground 11: (ref. Waste Acceptance and Handling)

11.1 The objection restates the point made in a submission that it is inevitable that blood products will be processed at the facility, notwithstanding the fact that Sterile Technologies Ireland Ltd. are prohibited from accepting blood products by the Joint Waste Management Board contract.

Technical Committee's evaluation

Five categories of clinical/healthcare risk waste are unsuited for treatment by the process. These include: (i) waste cytotoxic drugs, (ii) hazardous chemicals, (iii) pharmaceuticals, (iv) identifiable body parts and (v) blood products. This objection deals specifically with blood products and the Department of Health and Children has clarified that the Joint Waste Management Board tender, Section 4 exclusion on blood products, applies to "processed blood products, specifically from the BTSB". It is also confirmed by the Department that the BTSB is the only source of such processed blood products (i.e. plasma) in the State and that all the blood plasma generated by them is exported to Scandinavia for treatment.

Only 4 clinical / healthcare risk waste categories are acceptable at the facility under Condition 5.2. These include: (i) sharps, (ii) potentially infectious healthcare waste, (iii) autoclaved lab waste and (iv) potentially offensive material Healthcare waste generators are contractually bound to ensure proper waste segregation procedures are in place to the satisfaction of Sterile Technologies Ireland Ltd. The Technical Committee considers that a written declaration by the licensee and all healthcare waste generators using the facility

that they are aware of the requirements of this licence, in particular Condition 5.2 with regards to waste segregation.

Recommendation

Amend Condition 3.10, to include a new subsection (e) as follows;	
Condition 3.10(e)	declaration by the licensee and each waste producer using the facility that they have been made aware of the conditions of this licence and in particular Condition 5.2 with regards to waste segregation.

Objection by Fehily Timoney and Company Ltd.

Ground 12: (ref. Efficacy of sodium hypochlorite (NaOCl) as a disinfectant)

12.1 The objection is concerned with operator safety (exposure to micro-organisms) and the consumption of NaOCl by ammonium compounds.

Technical Committee's evaluation

Operator safety in terms of machine maintenance is a health and safety consideration. Sterile Technologies Ireland Ltd. have procedures in place for the entry of operators to the shredder area for emergency maintenance, e.g. to clear blockages. The procedures include disinfecting the area manually and waiting a certain period before entering.

The exposure of waste to NaOCl should be minimal. In the event of small quantities of waste remaining inside the hopper and shredder assemblies, during the cleaning operation, any ammonium compounds which may neutralise the NaOCl would probably be consumed leaving sufficient residual to disinfect the area as normal.

Recommendation

No change.

Ground 13: (ref. Worker safety as a consequence of using sodium hypochlorite)

13.1 The objection is concerned with operator safety (liberation of chlorine gas)

Technical Committee's evaluation

The small quantity of dilute hypochlorite and the limited opportunities that could arise whereby any dilute hypochlorite would come into contact with the waste stream would ensure that that there is no material risk of chlorine gas liberation.

Recommendation

No change.

Ground 14: (ref. Generation and release of organic halides into the environment)

14.1 The objection is concerned with the emission of organic halides into the atmosphere.

Technical Committee's evaluation

Schedule G.2 sets out the emission limit values for total volatile organic compounds. Any excedance will constitute a non-compliance of the licence. Page 4 of Attachment H.1 states that in the event of VOC emissions from the HEPA vent being high, VOC abatement will be installed if required. This is confirmed by Sterile Technologies Ireland

Ltd.'s response to this objection. In addition, Condition 7.4.6 requires Sterile Technologies Ireland Ltd. to investigate VOC abatement technologies other than activated carbon for use on both the HEPA and steam vents.

Recommendation

No change.

Ground 15: (ref. Landfill disposal of treated waste)

15.1 The objection is concerned that the processed healthcare risk waste may not be suitable for disposal to landfill and that no consideration has been given to its potential to generate leachate.

Technical Committee's evaluation

The decision to accept the processed waste at a landfill is to be made by the landfill operator. This is beyond the scope of the waste licence. Condition 5.21 requires that all processed healthcare risk waste shall be accompanied by a consignment note and shall be certified by a technically competent person from the testing laboratory, such that a facility operator considering the acceptability of the waste can make an informed decision.

Recommendation

No change.

Ground 16: (ref. Adequacy of challenge test for spore-forming organisms)

16.1 The objection contends that the challenge tests proposed in the PD are inadequate.

Technical Committee's evaluation

This issue is dealt with under Ground 2.

Recommendation

No change.

Ground 17: (ref. HEPA filter efficacy)

17.1 The objection contends that the operation of the HEPA will be upset by the presence of moisture in the off-gas.

Technical Committee's evaluation

This issue is dealt with under Ground 7.

Recommendation

See response to Ground 7.

Ground 18: (ref. tamper proofing of process settings)

18.1 The objection is concerned that tamper proofing has not been conditioned.

Technical Committee's evaluation

This issue has been dealt with under Ground 8.

Recommendation

See response to Ground 8

Additional Comments

Having considered the objections the Technical Committee would make the following additional comments;

i) typographical errors in Table F.4.2 (A1 should read A2 and vice versa)
ii) in Table D.2 reference is made to quarterly reporting on air emission monitoring, whereas air emission monitoring is bi-annual.

Recommendation

That the typographical errors outlined above be corrected.

iii) monitoring charges were originally costed as £600.

The first set of independent testing performed in relation to microbiological testing at the Cork University Hospital facility (38-1) was £780. It is the view of the Technical Committee that the cost be increased to £1000 to cover expenses likely to be incurred at this facility.

Recommendation

11.1.1 Annual contribution of £8,255 to be increased to £8,655

Signed: _____

Brian Donlon
Technical Committee Chairperson