

Environment Agency permitting decisions

Variation of a bespoke permit

We have decided to issue the variation for Wrexham Pharmaceutical Works operated by Ipsen Biopharm Ltd.

The variation number is EPR/SP3030LZ/V002

We consider in reaching that decision we have taken into account all relevant considerations and legal requirements and that the permit will ensure that the appropriate level of environmental protection is provided.

Purpose of this document

This decision document:

- explains how the application has been determined
- provides a record of the decision-making process
- shows how all relevant factors have been taken into account
- justifies the specific conditions in the permit other than those in our generic permit template.

Unless the decision document specifies otherwise we have accepted the applicant's proposals.

Structure of this document

- Key issues
- Annex 1 the decision checklist

Key issues of the decision

Introduction

The variation is for a new secondary manufacturing facility in Unit 12 with two associated natural gas boiler emission points (A11 & A12), a new Biotech Pilot Suite in Unit 9 with associated emission points (A13 & A14), introduction of a biofill suite to Unit 9, and acquisition of Unit 8 for storage and office space [with associated domestic natural gas boiler emission points (A15 & A16)] to be included in the Installation Boundary-

Annex 1: decision checklist

This document should be read in conjunction with the Duly Making checklist, the application and supporting information and permit / notice.

Aspect considered	Justification / Detail	Criteria met
		Yes
Operator		
Control of the facility	We are satisfied that the operator is the person who will have control over the minor changes to the facility. The decision was taken in accordance with EPR RGN 1 Understanding the meaning of operator.	✓
The facility		
The regulated facility	The installation boundary has increased to include Unit 8, used as storage and office space. The Unit is a Directly Associated Activity with a technical link to the main operation As such, the site plan in Schedule 2 of the Permit has been amended to show the new installation boundary. Minor changes to directly associated activities include additional boilers, an additional emergency diesel powered generator and the associated activity of product verification. These have been incorporated into Schedule 1 Table S1.1 to reflect recent site changes and development since initial permit application.	✓
European Directives		
Applicable Directives	All applicable European Directives have been considered in the determination of the application.	✓
The site		
Extent of the site of the facility	The operator has provided a plan which we consider is satisfactory, showing the increased extent of the site (see above). Six additional emission points have been added to Schedule 4 Table S4.1. These are for emissions to air associated with the natural gas boilers for Unit 12 (A11 & A12), the new BPS (Biotech Pilot Suite) in Unit 9 (A13 & A14) and the domestic natural gas boilers for Unit 8 (A15 & A16). Two additional discharge locations to the Industrial Estate Surface Water system previously missed off have been	✓

Aspect considered	Justification / Detail	Criteria met
		Yes
	added to Schedule 4 Table S4.2. These are marked as W3 and W4 and take clean surface water run-off from areas of hard-standing and roofs with no associated increased impact. The Site Drainage Plan and Emissions Point Drawings have been revised to reflect these changes.	
Site condition report	The operator has provided a description of the condition of the additional area of land to be included in the installation boundary (Unit 8). We consider this description is satisfactory. The decision was taken in accordance with our guidance on site condition reports – guidance and templates (H5). The area of land in question has already gone through a recent permit surrender by another operator (Duracell/Gillette).	✓
Environmental Risk Assessment and operating techniques		
Environmental risk	We have reviewed the operator's assessment of the environmental risk from the facility. The main change has involved the addition of emission points A13 and A14 from the BPS Room Heating Ventilation & Air Conditioning (HVAC) and Microbiological Safety Cabinet (MSC) exhaust. Validation testing of fumigations and development of the fumigation process have all shown the concentrations of Formaldehyde to be insignificant. The concentrations of Formaldehyde in the room following fumigation and prior to venting meet occupational health standards and benchmarks for the sector. Fumigation is undertaken by a contractor who has his own Standard Operating Procedure approved by Ipsen Biopharm prior to fumigation. This methodology is included in Table S1.2 Operating Techniques (see also additional information received 14/08/12). All manufacturing and verification areas have no floor drains and are sealed. All effluent from primary manufacturing areas is heat treated. These emissions are categorised as environmentally insignificant.	✓

Aspect considered	Justification / Detail	Criteria met
		Yes
Operating techniques	We have reviewed the techniques used by the operator and compared these with guidance in EPR 4.02 Speciality Organic Chemicals. . The proposed techniques / emission levels for priorities for control are in line with the benchmark levels contained in the guidance and we consider them to represent appropriate techniques for the facility.	✓
The permit conditions		
Incorporating the application	We have specified that the applicant must operate the permit in accordance with descriptions in the application, including all additional information received as part of the determination process. These descriptions are specified in the Operating Techniques table in the permit (Table S1.2).	✓
Emission limits	We have decided that emission limits should be set for the parameters listed in the permit. We have imposed a mass emission limit to Table S4.4. This is to ensure that the usage of Formaldehyde is controlled. We have also required reporting against this annual limit in Table S5.1.	✓
Reporting	The only change is the requirement to report annual usage of formaldehyde as described above.	✓
Operator Competence		
Environment Management System	There is no known reason to consider that the operator will not have the management systems to enable it to comply with the permit conditions. The decision was taken in accordance with EPR RGN 5 on Operator Competence. The Operator has now achieved Level 3 Green Dragon Award and Phase 3 of BS8555.	✓
Relevant convictions	The National Enforcement Database has been checked to ensure that all relevant convictions have been declared. No relevant convictions were found.	✓

Aspect considered	Justification / Detail	Criteria met
		Yes
	The operator satisfies the criteria in EPR RGN 5 on Operator Competence.	
Financial provision	There is no known reason to consider that the operator will not be financially able to comply with the permit conditions. The decision was taken in accordance with EPR RGN 5 on Operator Competence.	✓