

Attachment 4.4 Capacity

4.4.1 EPA and EU Classifications

Identify the relevant activities in the First Schedule of the EPA Act 1992, as amended, to which the activity relates:

Class 5.16

Production of Pharmaceutical Products including intermediates.

Production, for the purposes of the activities mentioned in paragraph 5.12 to 5.17, means the production on an industrial scale by chemical or biological processing of substances or groups of substances mentioned in any of those paragraphs. The regulations do not define what is meant by 'industrial scale' however the proposed facility will be an industrial use.

Specify which category/categories of industrial activity referred to in Annex I of the Industrial Emissions Directive (2010/75/EU) is/are to be carried out at the installation:

Category 4.5

Production of Pharmaceutical Products including intermediates.

The regulations state that the Commission shall provide guidance on the interpretation of the term 'industrial scale' regarding the description of chemical industry activities described in (Annex I). The EU Commission website therefore provides the following classification (<http://ec.europa.eu>):

"Production on an industrial scale"

Annex I Section 4 ("chemical industry") contains no quantitative capacity thresholds but only a reference to "production on an industrial scale". The scale of chemical manufacture can vary from a few grams of a highly specialised product to many tonnes of a bulk chemical product, yet both scales may correspond to "industrial scale" for that particular activity. If the activity is carried out for "commercial purposes", it should be considered as production on an industrial scale, even if the material is an intermediate product and therefore not itself traded. By contrast, other activities producing chemicals exclusively for their own consumption - for example domestic, academic or laboratory activities - would not be covered.

As the proposed facility is a commercial pharmaceutical operation, the term industrial applies.

4.4.2 Planning Permissions

There is no restriction on production capacity outlined in the proposed determination (Planning Application: 18185)

4.4.3 Other Restrictions

There are no restrictions based on Disability Access Certificates and Fire Safety Certificates or other legislation controlling site procedures for the pharmaceutical production.

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