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Phase 2 of the Impact Assessment of Proposals for a Revised IPPC Directive

Part 2: Biological Processing for Chemical Production Final report

June 2008



Llywodraeth Cynulliad Cymru
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Executive Summary

Introduction

The Commission published its proposal and an impact assessment for a Directive on industrial emissions (Industrial Emissions Integrated Pollution Prevention and Control, IE(IPPC)D¹) on 21st December 2007. This consolidates seven existing Directives related to industrial emissions into “a single clear and coherent legislative instrument” and includes a number of changes related to new and existing activities. The main objective of this report is to assess, in outline, the likely impacts of the proposal in relation to inclusion of biological processing for chemical production.

Proposed Changes

The Commission has proposed the following amendment to Section 4 of Annex of the IPPC Directive:

“Production within the meaning of the categories of activities contained in this section means the production on an industrial scale by chemical **or biological** processing of substances or groups of substances listed in points 4.1 to 4.7.”

The purpose of including the reference to biological processing is to clarify interpretation issues and harmonise permitting practices across the Member States. Biological processing of basic pharmaceutical processes was explicitly covered within the IPPC Directive, but not in relation to other chemicals.

Costs & Benefits

Installations

Due to Environment Agency interpretation of chemical processing, no installations have been identified in the UK where the proposed changes to the Directive will cause any amendment of the current regulatory regime applied at that site. Installations using biological processing for chemical production are believed to already be subject to the regulatory costs under Part A of

¹ “Proposal for a Directive of the European Parliament and of the Council on industrial emissions (integrated pollution prevention and control) (recast)”. European Commission, Brussels, 21st December 2007. Available from: <http://ec.europa.eu/environment/ippc/proposal.htm>

the EPR/PPC Regulations, and therefore no additional costs are expected as a result of the proposed Directive changes.

There are no expected emissions reductions associated with the proposed changes to the IPPC Directive as the sector is already covered under IPPC and applying BAT. It is expected that there will be no additional benefits for the industry, beyond some standardisation and clarification of the regulatory structure.

Limitations/Uncertainties

The main limitation and uncertainty that should be noted with the approach applied and input data available is that it is difficult to determine the extent to which the Environment Agency interpretation of Schedule 1 activities has been applied to installations across the UK.

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1. Introduction

1.1 This Report

The overall aim of this work package is to provide support to Defra in response to the publication of the European Commission's proposal for a new Directive on industrial emissions. This work has been undertaken under Entec's framework contract with Defra on "*The Preparation of Regulatory Environmental Impact Assessments in Relation to Proposals for Air Quality Legislation*" contract (RIA). The main objective of this report is to assess the likely impacts of the proposal in relation to off-site industrial waste water treatment within the UK, building and commenting on as well as extending the Commission's Impact Assessment (IA), where appropriate. In particular, this report focuses on the proposed changes relating to the inclusion of biological processing for chemical production.

The project team has consulted with the following stakeholders to support the development of this report:

- Environment Agency for England & Wales (EA);
- Scottish Environmental Protection Agency (SEPA);
- Environment and Heritage Services (Northern Ireland) (EHS (NI));
- Chemical Industry Association (CIA);
- Chemical Business Association (CBA);
- British Association of Chemical Specialities (BACS)
- Bioindustry Association (BIA).

1.2 What is the Issue?

1.2.1 Overview of Revised IPPC Directive

The Commission published its proposal and an impact assessment for a Directive on industrial emissions (Industrial Emissions (Integrated Pollution Prevention and Control)), henceforth cited

as “IE(IPPC)D”²⁾ 21st December 2007. This consolidates seven existing Directives related to industrial emissions into a “single clear and coherent legislative instrument”. These existing Directives include titanium dioxide industry related directives (78/176/EEC, 82/883/EEC, 92/112/EEC), the IPPC Directive (2008/01/EC), the Solvent Emission Directive (1999/13/EC), the Waste Incineration Directive (2000/76/EC) and the Large Combustion Plants Directive (2001/80/EC). The Commission’s Impact Assessment (IA)³⁾ identified a number of problems related “(1) to shortcomings in the current legislation that lead to unsatisfactory implementation and difficulties in Community enforcement actions and, thereby, to loss of health and environmental benefits and (2) to the complexity and lack of coherence of parts of the current legal framework.”

The Commission has provided an indicative timeline for discussion and implementation of the proposals. It is important to note that this is dependent on the length of time it will take to discuss and agree the proposed directive within the co-decision procedure. The initial timetable is set out below in.

²⁾ “Proposal for a Directive of the European Parliament and of the Council on industrial emissions (integrated pollution prevention and control) (recast)”. European Commission, Brussels, 21st December 2007. Available from: <http://ec.europa.eu/environment/ippc/proposal.htm>

³⁾ “Commission Staff Working Document: Accompanying document to the Proposal for a Directive of the European Parliament and of the Council on industrial emissions (integrated pollution prevention and control) (recast). Impact Assessment.” European Commission, Brussels, 21st December 2007. Available from: <http://ec.europa.eu/environment/ippc/proposal.htm>

Table 1.1 Key Dates for the Discussion and Implementation of the Proposed IE(IPPC)D

Date	Description
12/2007	The Commission adopts its proposal for a Directive on industrial emissions as well as issuing its Communication 'Towards an improved policy on industrial emissions'
01/2009	First reading in the European Parliament and political agreement in Council.
12/2010	Completion of the co-decision process and publication of the Directive on industrial emissions within the Official Journal.
07/2012	Member States fully transpose the new Directive (18 months after entry into force). The Directive applies to all new installations from this date onwards.
01/2014	All existing installations previously subject to IPPC, Waste Incineration, Solvent Emissions and Titanium Dioxide Directives must meet the requirements of the new Directive. Large Combustion Plants do not yet need to meet the new Emission Limit Values (ELVs) prescribed within the Directive
07/2015	The newly prescribed activities such as additional poultry installations, smaller combustion units and wood preservation activities must meet the requirements of the new Directive.
01/2016	Large Combustion Plants must meet the requirements set out in Chapter 2 of the new Directive, as well as the ELVs set out in Annex V

1.2.2 Proposed Changes:

The Commission has proposed the following amendment to Section 4 of Annex of the IPPC Directive:

“Production within the meaning of the categories of activities contained in this section means the production on an industrial scale by chemical **or biological** processing of substances or groups of substances listed in points 4.1 to 4.7.”

The purpose of including the reference to biological processing, is to clarify interpretation issues and harmonise permitting practices across the Member States. Biological processing of basic pharmaceutical processes was explicitly covered within the IPPC Directive, but not in relation to other chemicals.

What are the Objectives and Intended Effects?

The main drivers for the revision of industrial emissions legislation are described in the IA undertaken by the Commission:

- The Lisbon Strategy and the EU Sustainable Development Strategy; this strategy stresses the role of environmental technologies in having “*significant economic, environmental and employment potential*”;
- the different Thematic Strategies (Air Pollution, Soil Protection, etc.) set objectives to protect human health and the environment from key air pollutants. Industrial emissions regulation has a major role in meeting these objectives;
- the need for “Better Regulation” and designing laws and legislation in a more coherent way and with minimum administrative burden; and
- experience in the implementation of the IPPC Directive in the last 10 years and ways to improve the legal framework to ensure that its objectives are met.

The Commission’s proposals aim to address the issues identified via a number of amendments to the existing legislation including the following:

- Clarification and strengthening of the concept of BAT;
- revision of the minimum ELVs for some sectors (for example, large combustion plants) to bring them into line with BAT standards;
- introduction of provisions on inspection and environmental improvements;
- stimulating innovation and the development and deployment of new techniques;
- simplifying and clarifying certain provisions on issuing permits, monitoring and reporting to cut unnecessary administrative burdens; and
- extending and clarifying the scope and provisions of the legislation to better contribute to the objectives of the Thematic Strategies.

For this particular amendment, the main objectives are to clear up the legal uncertainty when dealing with the biological processing for chemical production.

In addition, the proposed changes should provide a positive environmental and social impact through the implementation of BAT already established in existing BREFs for those installations not currently covered by the IPPC Directive.

2. Policy Options

This section presents the policy options considered in this report for the proposed inclusion of biological treatment for chemical production within the IPPC Directive. This was discussed and agreed with Defra at the inception meeting (8th April 2008).

2.1 Biological Processing for Chemical Production

The following two options have been considered for installations using biological processing for the production of chemicals:

1. No change.
2. As included in the proposed IE(IPPC)D.

3. Who is Affected?

This section presents a list of those stakeholders likely to be affected by the proposed changes for inclusion of biological processing for production of chemicals.

- Operators of biochemical works; and
- competent authorities e.g. Environment Agency, SEPA and EHS (NI)

4. Baseline Definition

4.1 Approach

This section outlines the approach that has been taken to define the baseline, for the relevant installations and/or activities and their associated emissions that may be affected by the proposed changes to the Directive.

4.2 Proposed Installations

4.2.1 Number of Installations

Biological processing (industrial biotechnology) in the production of chemicals refers to processes that use live micro-organisms or their purified enzymes as biocatalysts to bring about chemical reactions. The UK has in the region of 300 companies involved in industrial biotechnology which includes the development and use of biocatalysts for a wide spectrum of manufacturing processes, the production of biomass for biopolymers and biofuels and the manufacture of biocleaning agents.⁴

The impact of the proposed amendments to the Directive in relation to biofuels (in particular the production of bioethanol through the biological process of fermentation) has been covered within a separate impact assessment and is therefore not included within this assessment report⁵. Biological processing of basic pharmaceutical chemicals was explicitly covered within the IPPC Directive, but not in relation to other chemicals listed in Section 4, Annex 1 of the Directive.

Therefore this study focuses on industrial biotechnology companies, excluding pharmaceuticals and biofuels, and may include companies which manufacture flavours and fragrances, detergents, enzymes, bio-based polymers, and fine organic chemicals (i.e. acetic, citric, lactic, fumaric and gluconic acid). The total number of such companies in the UK however is unclear.

⁴ UK Trade and Investment (<http://www.ukinvest.gov.uk/United-Kingdom/10441/en-GB.html?page=1>)

⁵ Task III: A review of the potential impacts on the chemical sector (production of biofuels) in the UK resulting from proposed revisions to the IPPC Directive.

The Environment Agency, interpreted within their PPC guidance document⁶ “that a “chemical” means an individual substance or related substance obtained by, or used in, chemical processing including biochemical and electrochemical processes”. Specifically the guidance provides an example of a regulated process:

Example 1: The fermentation of sugar products or the growing of bacteria or fungi in fermenters, followed by the separation and extraction of protein of a specific compound (e.g. penicillin or alcohol) is considered production of “a chemical”.

The view of the Environment Agency⁷ is that this guidance should mean that all installations that produce chemicals through use of biological processes in England and Wales should already be permitted. Interpretation by SEPA and EHS (NI) is reported to be in line with Environment Agency guidance therefore the same principle applies in Scotland and Northern Ireland.

Due to the nature of chemical companies generally using a mix of chemical and biological processing it is difficult to determine the extent to which this has been applied.

There are currently very few, if any companies solely manufacturing chemicals in the UK using biological processes. One company which manufactured citric acid in the UK using fermentation did operate under an IPPC permit prior to being closed down.

Discussions with the stakeholders outlined in Section 1.1 have not identified any members with installations in the UK which are likely to be affected by the proposed changes to the IPPC Directive.⁸

Environmental Impacts

Compared to conventional chemical processing, biological processes are generally more efficient and less energy-intensive. However, there are emissions associated with biological processes which have been summarised in Table 4.1 below.

⁶ Environmental Permitting Regulations (England & Wales) 2007, Regulatory Guidance Series No. EPR 2, Understanding the meaning of regulated facility, Issue 1, V1.0, March 2008

⁷ Discussion with Environment Agency, May 2008

⁸ Based on response from BIA, CIA and BCA

Table 4.1 Potential Impact of Biological Processing for Chemical Production

Environmental Compartment	Potential Effect/Emission
Water	<ul style="list-style-type: none"> • Large volumes of waste water streams which may have high organic and nutrient loads.
Waste	<ul style="list-style-type: none"> • Biomass, possibly containing precipitation auxiliaries. Biomass may be classed as hazardous
Air	<ul style="list-style-type: none"> • Exhaust gases from seed and fermentation stages, containing broth aerosol, possibly malodorous • Steam emissions causing visual impact • Heat and steam generation resulting in direct air emissions from combustion processes • VOC from solvent use

4.3 Overview of Current Legislation

4.3.1 Environmental Permitting (England and Wales) Regulations (EPR)

The IPPC Directive explicitly mentions the biological processing of pharmaceuticals products as a listed activity, while the rest of Section 4 of Annex 1 refers only to chemical processing and this has been enacted within the EPR Regulations.

The EPR Regulations specifically mention “chemical processing” however as mentioned in Section 4.2.1, the EA interpreted within their PPC guidance document⁹ “that a “chemical” means an individual substance or related substance obtained by, or used in, chemical processing including biochemical and electrochemical processes”.

Industrial biotechnology companies within England and Wales are likely to fall under the following sub-sections of the EPR Regulations.

⁹ Environmental Permitting Regulations (England & Wales) 2007, Regulatory Guidance Series No. EPR 2, Understanding the meaning of regulated facility, Issue 1, V1.0, March

Table 4.2 Organic Chemical Sub-Sectors under EPR

4.1 sub-section	Column Heading	Industrial biotechnology products
i)	Hydrocarbons (linear or cyclic, saturated, aliphatic or aromatic)	
ii)	Organic compounds containing oxygen, such as alcohols, aldehydes, ketones, carboxylic acids, esters, peroxides, phenol, epoxy resins;	Organic chemicals (such as citric acid, acetic acid etc.), flavours and fragrances
iii)	Organic compounds containing sulphur, such as sulphides, mercaptans, sulphonic acids, sulphonates, sulphates and sulphones and sulphur heterocyclics;	
iv)	Organic compounds containing nitrogen, such as amines, amides, nitrous-, nitro- or azo-compounds, nitrates, nitriles, nitrogen heterocyclics, cyanates, isocyanates, di-isocyanates and di-isocyanate polymers	
v)	Organic compounds containing phosphorous, such as substituted phosphines and phosphate esters	
vi)	Organic compounds containing halogens, such as halocarbons, halogenated aromatic compounds and acid halides	
vii)	Organometallic compounds, such as lead alkyls, Grignard reagents and lithium alkyls;	
viii)	Plastic materials, such as polymers, synthetic fibres and cellulose-based fibres;	Bio-based polymers, bio-plastics
ix)	Synthetic rubbers;	
x)	Dyes and pigments	
xi)	Surface-active agents	Bio-cleaners

4.3.2 Pollution Prevention Control (PPC) Regulations (Scotland and Northern Ireland)

The PPC Regulations in Scotland and in Northern Ireland enact the existing IPPC directive. These regulations specifically mention “chemical processing” only, except in relation to pharmaceuticals.

Both SEPA and EHS (NI) have reported that the interpretation of chemical treatment is deemed to be broadly similar to interpretation by the Environment Agency within their PPC guidance document⁹.

4.4 Summary

The existing PPC regulatory framework within England and Wales already captures those installations that produce chemicals for commercial or industrial purposes, using biological processing. It is therefore assumed that the addition into the preamble of Section 4 of Annex 1 of the IPPC Directive would not bring any additional installations located in England and Wales into the PPC regime.

In order to determine the potential impact of the proposed changes to the IPPC Directive on installations in Scotland and Northern Ireland, we require confirmation that the Competent Authorities’ interpretation of chemicals includes those produced through biological methods.

5. Costs

5.1 Compliance Costs

It is not expected that there will be any additional costs to the industry as the affected installations in the UK are already covered by Part A of the EPR/ PPC Regulations and are already applying BAT. Any modifications to BREF notes or UK guidance may have future implications for the industry.

5.2 Administrative Costs

5.2.1 Operators

As all sites are already permitted under Part A, there should be no additional administrative costs beyond those already being incurred.

5.2.2 Regulators

It is assumed that the subsistence fee paid by operators will be sufficient to cover any ongoing cost burden on the regulators.

5.3 Results

Installations using biological processing for chemical production are already subject to the regulatory costs under Part A of the EPR/ PPC Regulations, and therefore no additional costs are expected as a result of the proposed Directive changes.

6. Benefits

There are no expected emissions reductions associated with the proposed changes to the IPPC Directive as the sector is already covered under IPPC and applying BAT. It is expected that there will be no additional benefits for the industry, beyond some standardisation and clarification of the regulatory structure.

7. Competition Assessment

The competition guidelines (August 2007)¹⁰ set out four main questions in order to ascertain whether the proposed policy (revisions in the IPPC Directive) would affect the market by:

1. Directly limiting the number or range of suppliers?
2. Indirectly limiting the number or range of suppliers?
3. Limiting the ability of suppliers to compete?
4. Reducing suppliers' incentives to compete vigorously?

A brief summary of the four questions are presented in Table 7.1 and for those where the answer to one of the questions is "Yes", then an explanation is provided in the following sections.

The results should be included in the "Evidence Base" within the Impact Assessment template.

Table 7.1 Summary of the Competition Test

Question	Biological Processing for Chemical Production
Q1. Directly limit the number or range of suppliers?	No
Q2. Indirectly limit the range of suppliers?	No
Q3. Limit the ability of suppliers to compete?	No
Q4. Reduce suppliers' incentives to compete vigorously?	No

¹⁰ http://www.offt.gov.uk/shared_offt/reports/comp_policy/oft876.pdf

Given industrial biotechnology installations are already covered under IPPC and applying BAT, it is expected that there will be no additional costs for the industry and therefore it is unlikely that there will be any significant competition effects to note. The proposed revisions to the IPPC Directive may reduce market distortions in the EU with more consistent regulation (and coverage) between Member States. However, given that the proposed revisions will not come into effect until 2015, it is unlikely that this will give UK installations a competitive advantage other those installations currently outside of the scope of IPPC; due in part to the fact that these installations will have sufficient time to comply with the directive at least cost.

8. Distributional Impacts on Different Sized Installations

Given industrial biotechnology installations are already covered under IPPC and applying BAT, it is expected that there will be no additional costs for the industry. Therefore it is unlikely that there will be any significant burden to any single installation in the industry.

