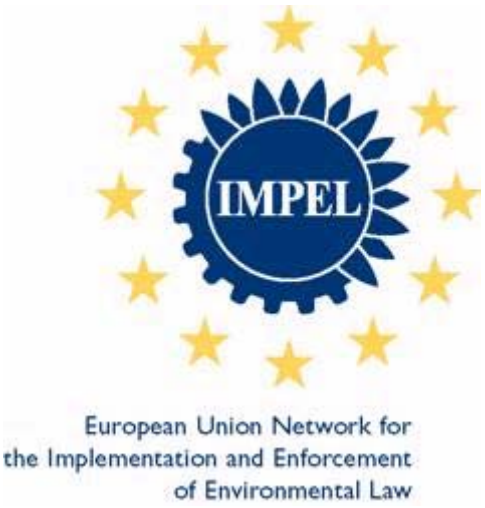

Consideration of Human Health through IPPC:

A Good Practice Guide

Foreword

The European Union Network for the Implementation and Enforcement of Environmental Law is an informal network of the environmental authorities of EU Member States, acceding and candidate countries, and Norway. The European Commission is also a member of IMPEL and shares the chairmanship of its Plenary Meetings.

The network is commonly known as the IMPEL Network

The expertise and experience of the participants within IMPEL make the network uniquely qualified to work on certain of the technical and regulatory aspects of EU environmental legislation. The Network's objective is to create the necessary impetus in the European Community to make progress on ensuring a more effective application of environmental legislation. It promotes the exchange of information and experience and the development of greater consistency of approach in the implementation, application and enforcement of environmental legislation, with special emphasis on Community environmental legislation. It provides a framework for policy makers, environmental inspectors and enforcement officers to exchange ideas, and encourages the development of enforcement structures and best practices.

Information on the IMPEL Network is also available through its web site at:
http://europa.eu.int/comm/environment/impel

Project Summary

Title Report Consideration of Human Health Through IPPC	**Number report:** 2004/10
Project Manager/Authors Project Manager: Anthony Parsons and Terence Shears, Environment Agency Authors: Jenny Kirton and Sarah Horrocks, Atkins	**Report adopted at IMPEL** **Plenary Meeting:** 30th November-2nd December 2005, Cardiff, UK
Project Group Members See Annex 3	**Number of pages:** Report: 33; Annexes: 42

Executive Summary

This project was undertaken to prepare a report on how human health effects are taken into account in the various stages involved in permitting within the Integrated Pollution Prevention and Control (IPPC) Directive. By considering the current varied approaches of Member States to this issue a good practice guide has been developed. This guide will assist Member States by identifying common principles and procedures which they can consider in their implementation of the IPPC Directive. IPPC provides a stronger emphasis than any earlier legislation on protecting human health through environmental regulation. The project identified that in most European Member States (MS) the responsibilities for health protection and environmental protection do not rest with the same body. Implementing IPPC is therefore challenging and requires significant co-operation.

The key findings of this project are:

- Applicants should be provided with guidance for the assessment of health through IPPC.
- Strict compliance with ambient health based Environmental Quality Standards (EQSs) is necessary to ensure health protection.
- Local sensitive receptors can justify more in depth assessments even if health based EQSs are not being exceeded.
- Where domestic EQSs are being exceeded then a maximum of 12 months should be allowed for improvements to secure compliance.
- There should be a statutory health consultee who is consulted on the draft permit as well as the application.
- The permitting authority should provide a clear indication of how the permitting decision was reached.

The good practice guide will act as a useful influencing tool to positively challenge how MS approach the implementation of IPPC. The UK will hold a national workshop in early 2006 to present the good practice guide to stakeholders and explore improvements that can be made. Other MS should be encouraged to revisit their approach to the consideration of health through IPPC in the light of this good practice guide. The EU should consider the conclusions and recommendations of this good practice guide and review whether actions at the EU level would be beneficial.

This project has highlighted that protection of human health is an integral part of environmental protection. There are inconsistencies in how this is managed across Member States and this good practice guide addresses these issues. The network established by the project is a valuable resource to both IMPEL and the EU and it should continue to share on-

going experiences and good practice relating to health through IPPC.

Disclaimer

This report on the consideration of human health through IPPC is the result of a project within the IMPEL Network. The content does not necessarily represent the view of the national administrations or the Commission.

CONTENTS

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1. INTRODUCTION

The European Community (EC) Directive 96/61/EC on Integrated Pollution Prevention and Control (the "IPPC" Directive) aims to achieve integrated prevention and control arising from certain activities across the European Union (EU), albeit with subsidiarity being applied. It lays down measures designed to prevent or, where that is not practicable, to reduce emissions to the air, water and land from these activities, including measures concerning waste, in order to achieve a high level of protection of the environment taken as a whole. The definition of 'pollution' within this Directive is:

> *'the direct or indirect introduction as a result of human activity, of substances, vibrations, heat or noise into the air, water or land which may be harmful to human health or the quality of the environment.'*

This means that regulators must set permit conditions so as to achieve a high level of protection for the environment as a whole, including human health. The Directive requires emission limit values (ELVs) to be set in permits – along with other relevant conditions – for any pollutant likely to be emitted in significant quantities from the installations it covers. Owing to the linkage with human health in its definition of "pollution", the Directive provides a stronger emphasis than any earlier legislation on protecting human health through environmental regulation. However, the process of considering potential effects of emissions on human health is complex and can be very costly and time consuming.

The IPPC Directive has recently been amended by Directive 2000/35/EC providing for public participation in respect of the drawing up of certain plans and programmes relating to the environment and amending with regard to public participation and access to justice Council Directives 85/337/EEC and 96/61/EC (the "PP" Directive). The PP Directive is intended to develop the public participation process and to provide the public with greater opportunities to influence permitting decisions. Experience already suggests that concerns about health effects will be a significant feature of the greater public participation which is being encouraged by the PP Directive.

In many Member States, the primary responsibilities for health protection and environmental protection do not rest within the same body. Consideration of ELVs and other permit conditions in fulfilment of the IPPC Directive is therefore challenging and requires significant co-operation.

The objective of the IMPEL project is therefore to develop a good practice guide on the consideration of human health under the IPPC Directive, by looking at the various current approaches of Member States[1]. It should be emphasised that this guide is limited to the consideration of health in relation to IPPC installations; it does not address public health in the general sense. The World Health Organisation (WHO) defines health as a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity. However, within this good practice guide a more narrow definition is employed.

Good practice is defined within this guide as an approach that demonstrates that human health has been adequately considered during the assessment of an IPPC application. It is intended that this guide will allow Member States to assess their current practice, to identify common principles and procedures, and to converge on a common approach through the EU. The guide includes examples of good practice that have been provided by some Member States. It should however be emphasised that other Member States may have similar examples of good practice that have not been provided in the guide.

This IMPEL project was managed by Anthony Parsons and Terry Shears of the Environment Agency of England and Wales. Jenny Kirton and Sarah Horrocks of Atkins Environment acted as consultants to the project and were the principal authors of this report.

Annex 1 to this report contains the Terms of Reference for the project. The questionnaire sent to participating countries and a summary of the responses is provided in Annex 2. Workshop attendees are listed in Annex 3. Supporting information on the regulatory setting of IPPC in each of the consulted Member States is provided in Annex 4.

[1] The term Member State as used in this document includes both Member States and Candidate Countries.

2. HUMAN HEALTH THROUGH IPPC

All Member States consider human health under the IPPC Directive. This is because the protection of human health is an integral part of environmental protection, as reflected in the definition of pollution within the Directive.

Each Member State should aim for internal consistency in the consideration of human health through IPPC. Approaches that can be adopted within a Member State to aid consistency include:

- having a single organisation with responsibility for receiving and assessing applications and issuing permits;
- having a centralised system for issuing permits;
- restricting regulation to a small team;
- producing national guidance;
- ensuring regular exchange of information within the regulation team;
- providing internal training to the regulation team;
- ensuring regular exchange of information between regional organisations, including discussion meetings to address topics of interest.

3. INFORMATION REQUIRED IN AN IPPC APPLICATION

The simplest way to ensure that the required information for the consideration of human health is supplied in an IPPC application is to provide the applicant with guidance for the assessment of health through IPPC.

The issues to be considered in relation to health are broad ranging and should include:

- all substances that can affect health that are emitted from the installation;
- emissions of such substances to all environmental media;
- annoyance issues (including noise, vibration and odour);
- waste;
- accidents;
- long term and short term effects;
- potential cumulative effects (where there are other local sources of the same emissions);
- synergistic effects (only if there is a suitably developed assessment methodology and appropriately experienced personnel).

Experience has shown that the amount of information that is required in an application is proportional to the potential health effect of the installation. This information includes:

- nature and quantity of emissions from the installation, which may be obtained from emission monitoring, including both point source and fugitive emissions;
- release points for the emissions;
- the environmental media into which the emissions are released;
- concentrations / levels in environmental media arising from the emissions;
- data on background environmental quality;
- information on likely annoyance;

- location of sensitive receptors;
- possible source → pathway → receptor linkages;
- health based Environmental Quality Standards (EQSs).

4. ASSESSING AN APPLICATION

The first stage in the assessment of an application is to consider whether best available techniques (BAT) as discussed in the BAT reference (BREF) notes are being applied, by comparing the emissions from the installation with ELVs.

The simplest way to prevent unnecessary work during the further stages of assessment is to use a screening tool to establish whether the emissions from the installation are insignificant.

The H1 Screening Tool in the UK

The regulatory authorities in the UK have produced a Cross-sector Guidance Note "H1" containing a structured screening level methodology for carrying out an environmental assessment of the overall impact of emissions from an installation. This methodology is designed to confirm which emissions are acceptable (i.e. do not cause significant pollution) and to identify priority emissions or environmental risks for further improvement. It addresses emissions to air, water and land.

A software tool has also been developed to accompany the guidance, which can be used to input the data, perform calculations and present the environmental impact. The use of the software tool simplifies the process and ensures that information is provided in a consistent and transparent format.

In quantifying local impacts, the user is required to estimate the level of a substance in the environment after dispersion (process contribution) using simple formulae to screen out insignificant emissions that are unlikely to have a significant environmental impact (e.g. if process contribution is less than a certain percentage of an environmental benchmark). The guidelines set out in the document can be used to see if detailed dispersion modelling is required for emissions that are not insignificant and if so, the estimated process contributions can be refined.

The predicted environmental concentration (the sum of the process contribution plus the existing background concentration), can be compared against EQSs and other environmental benchmarks and a situation rejected for any releases which are unacceptable. The total impacts are then summarised, e.g. calculation of an environmental quotient for air, land, water etc. This environmental quotient is obtained by normalising the process contribution for each substance against the appropriate environmental benchmark and then summing these values for all substances.

The criterion for screening out long-term emissions is 1% of the relevant EQS or other environmental benchmark, while for the short-term emissions the screening level is 10% of the relevant EQS or environmental benchmark.

Screening tools may be specific to health effects.

Health Screening / Health Impact Assessment in the Netherlands

This example is taken from the Dutch Liveable Cities Project: A Dutch recipe for environmental policy and spatial planning in the City & Environment project. Although not currently employed within the IPPC framework, it is considered that certain modules, in particular those relating to businesses, may be useful in assessing the health effects within IPPC. This instrument also provides the opportunity to take background levels and emissions from several other activities into consideration. Use of calculations made with this instrument in the early stage of licensing might help to choose the most optimal scenario. Along with calculations in relation to the different technical options (BAT) it also gives direction on spatial aspects that might otherwise be overlooked.

One of the benefits for the City & Environment project is the particular attention paid to health issues. Right from the planning stage, the effects of construction plans on public health are taken into consideration. The Dutch government has developed two instruments for this purpose: qualitative and quantitative health-effects screenings. The qualitative screening determines in which environmental segments (e.g. noise, air quality) health problems may occur. The quantitative screening goes a step further, assessing the development plans according to the seriousness of their effects on public health, i.e. how serious are the effects and how many people are affected. These assessments are performed on different sources (businesses, rail traffic, water traffic and air traffic) with respect to five environmental issues (noise, odour, external safety, air quality and soil quality).

The seriousness of health effects are calculated and expressed in up to eight categories related to the maximum permissible level (1 death per million for each activity). On a local map these levels are presented in coloured zones from green to red according their seriousness. Further calculations are done for the future regarding the number of exposed people in each zone, taking into consideration vulnerable groups (young, sick and old people). This concise guideline including software for calculations and making of presentations is available for public health departments and the inspectorate for the environment (Dutch language).

The health-effects screening often results in changes to the urban development plan and hence a healthier layout of the city. Local authorities can add to their technical and environmental knowledge by using these instruments to obtain a clearer picture of the health opportunities and threats in the area. Until now the instrument has been validated and successfully used in several cases in The Netherlands.

For those emissions that are not insignificant the health effects should then be assessed, in conjunction with the significance of these effects. At this stage in the assessment emphasis should be placed on the source → pathway → receptor methodology. Experience has shown that the effort that is required in the further stages of assessment is proportional to the health effect that is involved.

The assessment should involve comparison of the total concentration / level in the environment (the sum of the concentration / level arising from the emissions plus the background concentration / level) with health based EQSs. Strict compliance with a health based EQS is necessary to ensure health protection.

Protection of Human Health in the German Framework of TA-Luft

Permitting and monitoring of installations are regulated in the German Federal Immission Control Act, Technical Instructions on Air Quality (TA Luft 2002). In TA Luft, the following definitions are used:

- Immissions - air pollutants affecting humans, animals, plants, soil, water, atmosphere, built heritage.
- Emissions - air pollutants originating from an installation.
- Immission indicators - describe the initial load, additional load or total load of the air pollutant:
  - Initial load - the pre-existing load of a pollutant.
  - Additional load - the concentrations which can be expected to be caused (by planned installations) or which are actually caused (by existing installations).
  - Total load - for planned installations, this is equal to the initial load plus the additional load indicators; for existing installations, it is equal to the initial load.

The protection against hazards for human health due to SO_2, NO_2, benzene, tetrachloroethane, PM_{10}, lead and inorganic lead compounds is ensured if the total load does not exceed the relevant immission values at any assessment point. If the total load of one of these air pollutants exceeds the immission value at any assessment point, a permit may not be refused, provided that, with regard to the respective pollutant:

a) the indicator for the additional load caused by emissions from the installation at this point does not exceed 3% of the annual immission value and if it is ensured by imposed conditions that further measures for clean-air maintenance, including measures which go beyond state of the art techniques, are carried out; or

b) it is ensured by imposed condition that, as a rule no later than 12 months after the installation has been put into operation, rehabilitation measures (dismantling, closing down, alteration) or other measures which ensure the compliance with the above mentioned immission values are carried out at existing installations of the applicant or third parties.

Where immission values have not been established in the TA Luft for a particular air pollutant, it is necessary to examine whether harmful effects on the environment may be caused if sufficient evidence suggests this may be the case. Such examination shall serve the purpose of:

a) establishing what impacts the air pollution originating from the installation may cause in the evaluation area; type and extent of such an assessment are governed by the principle of proportionality; and

b) evaluating whether such impacts are to be deemed as hazards, significant disadvantages or significant nuisances to the general public or the neighbourhood; such evaluation shall be based upon the state of the art and general experience of life.

Hazards to human health shall always be considered significant. Even where immission values are not exceeded there is a requirement that human health is not affected. For instance, a special-case examination has to be carried out if an installation shall be permitted in the vicinity of a sanatorium for people with respiratory diseases.

Where there are no available health based EQSs, other health based environmental quality criteria need to be derived. A standard approach to this derivation should be agreed with the public health body in the Member State. The health based environmental quality criteria need to address both short term and long term effects.

Denmark – Health based assessment criteria

The Environmental Protection Agency in Denmark (DEPA) has set health-based quality criteria for chemical substances in soil, drinking water and ambient air. These health-based criteria are derived by dividing the tolerable daily intake of a substance by the standard exposure rate for each media (e.g. average daily volume of air intake). In regards to drinking water, other health factors may be taken into account, such as odour, discoloration and taste. Furthermore, economic or political administrative factors may also be taken into account when deciding upon the final guidance values.

With respect to the air environment, the health-based criteria used are known as C-values (contribution values), that is the maximum allowable contribution of a given substance from a facility to the ambient air concentration of the substance. In environmental permit conditions on C-values are always applied on top of ELVs for the emissions set according to the principle of BAT. The emissions to air from all outlets at an activity should as such in the first place comply with the ELVs. Secondly, and to comply with the C-values, the emissions should not cause the C-value to be exceeded for more than 1% of the time (i.e. the C-value can be exceeded up to 7 hours per month). The C-values only relate to the contribution from the activity and do not take background levels into account. Although the quality criteria are guidance values, from which deviations can be made in specific cases e.g. where human health would not be compromised, the local and regional environmental authorities only very rarely deviate from the C-values when setting conditions in environmental permits.

DEPA's guideline (no. 1, 2002) for Air Emission Regulation covers a range of substances released to air from Danish industries and other activities. In section 3.1.4 of the guideline is a short description of the C-value, as Chapter 4 describes how the C-values are used in connection with calculation of outlet heights. C-values have been set for more than 400 substances or groups of substances.

If an EQS is exceeded, this means that an unacceptable environmental effect would result from the application of BAT as discussed in the BREF notes. In this situation site-specific BAT will need to be defined at the installation level with associated ELVs. This may require additional abatement equipment to be fitted at the installation. Where the EQS is set out in EC legislation then compliance with that EQS should be in line with that legislation. Where the EQS is a domestic requirement then a 12 month period is considered to be a suitable timescale for the installation to comply with the required improvements. In addition, the installation may be requested to supply ambient monitoring data.

Approaches that can be adopted for considering the significance of the health effect include:

- comparison of the total concentration / level in the environment with an absolute value of an EQS or a range of values centred on the value of the EQS;
- consideration of dose-response relationships;
- seeking advice from the health consultee or a toxicologist.

5. HEALTH RISK ASSESSMENT

A more detailed assessment of the health effects may be carried out using the technique of health risk assessment, which considers exposure via all pathways i.e. inhalation of contaminated air, ingestion of contaminated water, soil and food, and dermal exposure.

The various stages in health risk assessment are as follows:

- Consideration of the health effects that can arise from the emissions from the installation;
- Identification of exposure pathways and assessment of exposure via all pathways;
- Comparison of exposure with exposure limits;
- Consideration of all the previous stages of the health risk assessment to provide an overview of the health risk.

Exposure limits that can be used include:

- Tolerable daily intakes (TDIs) such as those specified by the WHO – for non-carcinogenic effects;
- Risk limits – for carcinogenic (non-threshold) effects.

In the case of risk limits, an annual incremental risk of death for an individual of 1 in 1,000,000 or $1x10^{-6}$ can be taken to be an acceptable upper limit. For a lesser health effect, such as respiratory disease, 1 in 100,000 or $1x10^{-5}$ on an annual basis for an individual would be acceptable.

Guidelines for health risk assessment of noise in the Czech Republic

The objective of the Czech Republic methodological guidelines for health risk assessment of noise in a non-occupational environment is to unify procedures used by public health protection authorities to assess the health risk for humans exposed to noise in a non-occupational environment. The guidelines are based on methodological procedures assessing health risk (Health Risk Assessment) designed by the United States Environmental Protection Agency (US EPA). These methodological procedures are primarily set to assess risk factors of chemical substances in the environment. Nevertheless it is possible to apply the methods to physical factors as well.

The general procedure of health risk assessment for noise consists of the four following steps:

- Hazard identification. This phase includes identification of factors to be assessed, their description (especially of the aspects posing a risk to humans) and characterization of the conditions under which they can emerge, i.e. description of possible adverse effects of noise on human health in particular.

- Hazard characterization or relation between exposure and effect respectively. This phase includes identification of the relationship between exposure level and risk level. In this particular case authorities try to establish reference levels of noise exposure for the main adverse noise effects on human health or establish quantitative relationships between exposure level to excessive noise and probability of health impairment in average sensitive individuals of the exposed population. It is necessary to consider different aspects of the noise effect and therefore it is recommended to carry out both steps described above together.

- Exposure assessment. This phase is usually the most difficult in the whole process. It should cover many of the variable quantities in intensity of the affecting factor as well as describe social status and monitor the behaviour of individuals in the exposed population. Adverse effects of noise exposure on human health depend (unlike in the case of exposure to chemical substances) on various economic, social and psychological aspects and circumstances. Exposure assessment is based either on noise measurement results or on data from model calculations. Noise measurement procedures in non-occupational environments are set by the methodological guidelines of the Chief Public Health Officer of the Czech Republic. The model calculations should be validated against background measurements. Such measurements should be made under standard conditions for a few days. For more detailed risk estimation it is necessary to know the particular number of individuals exposed to particular noise levels and more details about exposure conditions such as the type of buildings, orientation of windows, age profile of the population exposed and duration of noise exposure.

- Risk characterization. This final phase includes qualitative or quantitative assessment of the level of health risk in the exposed population i.e. integration of information about the affecting factor hazard level and an evaluation of a particular exposure level. For instance: in case of long-term exposure of a number of citizens to continuous city traffic noise, the standard outcome of this procedure is the number of citizens expected to suffer from adverse noise effects (e.g. subjective feelings of annoyance or poor sleep as well as objective symptoms of health impairment and increased morbidity).

6. PRODUCING THE PERMIT AND ENFORCEMENT

An integrated approach should be adopted when producing the permit, as health is only one of the issues that need to be considered. In order to ensure that health is adequately addressed during the production of the permit the permitting authority needs to keep abreast of the health risks arising from pollutants. The basic approach for issuing a permit is:

- If there are no concerns, issue a permit;
- If there are concerns that can be addressed (within appropriate timescales), issue a permit with conditions;
- If there are concerns that cannot be addressed, do not issue a permit.

Where potentially harmful effects to human health have been identified during the assessment of the application and scientific evaluation does not allow the risk to be determined with sufficient certainty, the precautionary principle should be applied when setting permit conditions. The permit conditions may include:

- Requiring feedstock modifications;
- Requesting changes to the design of the installation;
- Specifying an additional abatement process to be fitted to the installation;
- Requesting changes to the operating conditions;
- Requiring monitoring in the vicinity of the installation.

In order to promote public confidence the permitting authority should provide a clear indication of how the permitting decision was reached.

Once the permit has been granted there is no guarantee of compliance by the operator of the installation. Therefore enforcement is an important process in the implementation of the IPPC Directive. Amendments to the permit can be made in response to:

- A public complaint;
- A health or annoyance concern;
- Evidence of a health effect or annoyance;
- New information about the health effects of a substance.

Review of permits in Denmark

According to the Environment Protection Act in Denmark, the environmental authorities can in general not issue new orders or conditions for an eight year period after the issuing of the first permit to an activity. If new information about the harmfulness of pollution from an activity emerges or if the pollution causes impacts that could not be foreseen at the time of issuing the permit the authorities can, however, issue an order containing new conditions for the operation of a given activity.

This implies that the authorities, within the eight year period, can issue an order to an activity about reducing the emissions of a given substance if new information, e.g. from research projects, reveals that the substance is more harmful for human health or the environment than was known at the time of issuing the permit. Similarly new conditions can be set within the eight year period if the emissions from an activity have impacts on the environment that could not have been foreseen at the time of issuing the permit, e.g. if new information about the water flow in a recipient stream has emerged showing that the stream is more vulnerable to the emission than expected.

An example on the use of this exception from the general eight year rule is the implementation of the regulations related to the Seveso Directive. The development in this area was that the risks for both humans and the environment arising from the activities covered by the directive were considered to be more serious than before. At the time of implementation of the directive in Danish law this development was considered to be sufficient for the authorities to tighten existing permit conditions for activities covered by the directive before the expiry of the eight year period.

At the same time it should be noted that the development of new production and pollution control technologies is, in general, not considered to be a sufficient basis for the setting of tightened permit conditions within the eight year period.

The amendments may include:

- Requiring feedstock modifications in order to reduce emissions;
- Requesting changes to the design of the installation in order to reduce emissions;
- Specifying an additional abatement process to be fitted to the installation in order to reduce emissions;
- Setting stricter operating conditions if a health effect or annoyance has occurred;
- Requiring monitoring in the vicinity of the installation if an EQS has been exceeded.

Enforcement and environmental quality standards in Belgium (Flanders)

In 1997, stack emission measurements ordered by the Flemish Environment Inspection Section (EIS) revealed a very high PCDD/F (dioxins and furans) emission at an iron sintering plant. The average flue gas concentration was about 13 ng TEQ/Nm³. This was equivalent to about 50% of the known total PCDD/F emission in the whole of the Flemish Region and at least an order of magnitude higher than the PCDD/F emission from all of the municipal waste incinerators. At that time, no ELVs for PCDD/F were mentioned in the licence of this plant or in the Flemish environmental legislation. However, this legislation states explicitly that, irrespective of the licence granted, the operator must always take the necessary measures to prevent damage and to avoid constituting a nuisance. The EIS based its further action on this prevention principle, particularly taking into account the risks for human health.

By the end of 1997, the EIS started to investigate the causes of the high PCDD/F emission and the possibilities to reduce it. This included several meetings with the plant management, visits to similar plants and officials in neighbouring countries and a literature research. The EIS assessed the potential health impact using the available PCDD/F deposition data and the PCDD/F concentration in cow's milk from surrounding farms. Dispersion model calculations helped to estimate the PCDD/F deposition due to the measured emission. The model output was compared to limit values, derived from the WHO TDIs. From the available data and calculations, the EIS concluded that the dioxin emission from the sintering plants was causing a risk for nuisance or damage to man or the environment. An important argument was the fact that the Belgian Minister of Agriculture meanwhile had decided to prohibit the consumption of milk with a PCDD/F content of more than 5 pg TEQ/g fat. This meant that the milk from several farms around the iron sintering plants could no longer be marketed and had to be destroyed. From the measurements and calculations, the EIS concluded that, in order to prevent further nuisance and damage, an emission concentration of less than 0.5 ng TEQ/Nm³ had to be reached as soon as possible. Therefore, the steel plant management was pressed by the EIS to immediately start a clean-up programme, in order to reach as soon as possible an emission level that would no longer cause a risk for nuisance and damage to man and the environment.

This programme was split up into two phases. Within one year (end of 1998), an intermediate emission level (less than 2.5 ng TEQ/Nm³) had to be obtained, while the target of 0.5 ng TEQ/Nm³ had to be reached within two years (end of 1999). In order to ensure a permanent follow up of the emission levels and their impact on the surroundings, the EIS also ordered a strict emission measurement scheme, and additional dioxin deposition measurements at two sites just outside the plant. By rigorously following up the measures taken by the plant and the emission measurement results, the EIS kept an eye on the emission reduction process. Through research, process modifications, application of an efficient end-of-pipe dioxin removal technique and very frequent emission monitoring, the plant operators managed to reach an emission reduction of over 95% within three years.

The effects of this emission reduction were quickly reflected in decreasing contamination of the neighbourhood of the plant, both in the deposition measurements and in the cow's milk from surrounding farms. After new analyses of the cow's milk had shown that the dioxin content was below the limit values, it could be marketed again for human consumption.

7. CONSULTATION WITH PUBLIC HEALTH ORGANISATIONS

Consultation with a public health organisation must be carried out where the permitting authority does not have health related expertise. However, there should always be the option for the permitting authority to consult with a public health organisation. The benefits of such consultation include:

- Access to information on local sensitive receptors and vulnerable groups;
- Access to information on specific health issues associated with the installation;
- Access to an expert opinion on the likely heath effects of the installation;
- Access to statistics on the incidence of disease in the local area and disease clusters;
- Access to information on the incidence of complaints relating to health issues;
- Developing partnerships;
- Improving working relationships;
- Aiding meaningful consultation;
- Adding value to the permitting process.

Consultation should be carried out when the application is being assessed and when the draft permit is being produced. Pre-application consultation is advisable for certain sectors, for example incinerators, and in certain site-specific circumstances, for example where there is evidence of a health effect or annoyance. Public health organisations with an affiliation to a university often gain an enhanced level of trust from the general public.

Providing guidance for health consultees ensures that maximum value can be obtained from the consultation process. It also aids consistency of responses from the health consultees. The guidance should impress upon the consultees that they have a responsibility to provide the response as part of their public heath duty. Allowing the applicant to have access to the guidance ensures they are fully aware of all information.

Provision of guidance to health consultees in England and Wales

The Health Protection Agency (HPA) in England and Wales has published guidance for the statutory health consultees (the Primary Care Trusts (PCTs) and Local Health Boards (LHBs)) whom they advise and support during the IPPC permitting process. Volume 1 of the guidance provides a background to IPPC and explains the role and responsibilities of the statutory consultee. Volume 2 is written for those involved in the actual response, be it PCTs or LHBs and/or their consultants. It sets out the core competencies needed to review IPPC applications, the basic elements of a response and suggests a format for the final response.

As a statutory consultee, the National Health Service (of which the PCTs and LHBs are a part) is formally involved in the process of environmental regulation. This process is considered to offer an opportunity to influence the management of the environment to minimise or prevent adverse health effects. It is an important responsibility with major implications for the public, consultee, Regulator and industry alike. As a result National Health Service input must be both appropriate and add value to the process. PCTs and LHBs are uniquely placed to offer expertise, information and interpretation not available to the Regulators. To maximise the value of this resource, the HPA's guidance aims to help PCTs and LHBs recognise the limits of their competence and be able to assess the complex material presented to them for comment. The guidance reflects a consensus between the key agencies and is offered by the HPA as a main part of the support available to PCTs and LHBs. It aims to encourage a consistent and appropriate response to all types of IPPC applications and will be updated and amended as all partners in IPPC learn more about the process and each other.

The guidance suggests that the statutory consultee response should consist of four key elements:

1 To offer a view on the potential health impact of emissions and activities of an installation (based on information provided in the application) and to place any risks into a local context, e.g. does the operator demonstrate a high level of protection for human health? This may include consideration of the level of a public health nuisance reported in relation to the installation.

2 To identify any existing local health issues that may be associated with the installation or its location, e.g. are there any local health problems that could be related to, or exacerbated by, the installation.

3 To identify any future health issues that could be associated with the installation or its location, e.g. are there any problems or issues on the horizon that the Regulator needs to take into consideration.

4 To provide reassurance to the local community, including reassurance that an installation will not present a significant risk to human health.

The document recommends that detailed examination of health data in relation to a specific site should only be considered where there is:

(i) Local intelligence on known or suspected excesses of disease in the local area, e.g. results available through routine surveillance work, complaints from local people or other sources such as epidemiological evidence.

(ii) Biological plausibility between the disease and the process emissions.

(iii) An exceedence of a relevant environmental standard or objective. Where environmental standards are unavailable, this may include exceedence of occupational standards or consideration of toxicological data.

If any of these criteria are lacking, it is likely that more detailed consideration of local health issues is not warranted. The criteria are designed so that the consultee is not required to use resources unnecessarily.

8. PUBLIC INVOLVEMENT

The United Nations Economic Commission for Europe (UNECE) Convention on Access to Information, Public Participation in Decision Making and Access to Justice in Environmental Matters was adopted in June 1998 in Aarhus in Denmark. The convention aims to strengthen the role of members of the public and environmental organisations in environmental protection issues, and provides for greater access to information held by public authorities. The convention came into force on 30 October 2001.

The PP Directive is one of two Directives that were adopted to enable ratification of the Convention. The PP Directive was due for implementation by 25 June 2005. In relation to the IPPC Directive the amendments introduced by the PP Directive reflect the need for the public to be given the opportunity to comment on permit applications and permit reviews.

Good communication with the public and transparency of decision making are very important factors in gaining public trust. This is particularly important in relation to health and IPPC, as public concerns about health effects will be a significant feature of the greater public participation that is being encouraged by the PP Directive.

Public Participation in France

The permitting process in France allows the public to participate and express its concerns, through a public meeting. In the final stage of the permitting process the application and the draft permit are also reviewed by the local committee for environment and technological risks which includes representatives from the health authorities and the local authorities, as well as from NGOs dealing with the protection of the environment. To help achieve transparency, the Member State's authorities initiate a process to systematically place permits on the internet, in conjunction with the report of the permitting authority used to make its decision.

A good participative process with stakeholders and gaining of public trust mainly relies on two types of structure:

- local committees for information and supervision (CLIS)
- permanent secretariat for the prevention of industrial pollution (SPPPI)

CLIS are official structures composed of representatives of local authorities, the permitting and enforcement authority, representatives of neighbours of the facility or NGOs and the Director of the facility itself. They are obligatory by law for certain types of undertakings (for example waste treatment facilities) but can also be created by the state authority if necessary, often in cases where the local circumstances have created a situation of conflict or mistrust between the authorities and the public.

SPPPI are more informal structures, of which there are 12 in the Member State. They were created in industrial areas where specific environmental problems required all stakeholders to work together, for example, in the case of severe water pollution a reduction programme including several industries was launched and followed by the SPPPI. Such structures are considered to be very useful to create public trust as they enable all stakeholders to give their opinion and to communicate directly with industry, so establishing very productive contacts. In many cases those structures are the ideal support for global health studies in a specific industrial zone. Such studies, which aim to evaluate air pollutants in the zone, establish a reduction programme, detect critical problems, or simply establish priorities for action, are conducted by the SPPPI.

Solving odour problems during the enforcement process in Belgium (Flanders).

Environmental enforcement plays an important role in achieving the objectives of the IPPC directive, both compliance with the general principle of integrated pollution prevention and control and public participation. This is illustrated here with an example of solving odour problems in the Flemish Region of Belgium through active public participation during the IPPC enforcement process.

In the Flemish Region, the Environment Inspection Section (EIS) of the Ministry of the Flemish Community is responsible for the enforcement of the environmental health legislation. It obliges plant operators to take all measures to prevent damage and nuisance; this also applies to odour nuisance. The EIS has a number of administrative and criminal instruments to promote and/or force the plant operator to reduce odour emissions. In general action is taken after receiving complaints. Along with noise pollution, odour pollution remains one of the most common forms of environmental nuisance. However, in the absence of clear criteria regarding the acceptability of odour pollution, the assessment of odour problems remains a subjective issue, and the extent to which the odour pollution is "a nuisance" can vary considerably from person to person.

The EIS always tries to identify the source first through its own field observations. Generally, this requires "sniffing team" measurements in the surroundings and a thorough inspection of the possible odour sources. The EIS usually talks with the complainants in order to obtain more information about the odour. Sometimes, clear arrangements are made with the neighbours to inform the EIS immediately in case of odour nuisance. Through its findings, the EIS determines if the odour is acceptable or not and evaluates whether the company has taken all possible measures to reduce its emission. If necessary, the EIS will impose additional measures or insist on a quick clean-up. On occasions, the company will be forced to perform an odour study. In some cases, the EIS will engage an official expert, e.g. when odour emission measurements are necessary or when a technical evaluation of the process or advice on adequate odour-emission limiting measures is needed. Also, in cases the EIS cannot univocally assess who or what causes the odour pollution, an extended odour investigation is commissioned.

Since odour investigations consist of various parts, they provide a very complete overview of the odour situation. The key question however is whether the investigated odour pollution is acceptable for the neighbourhood or not. By relying on the active participation of the public concerned, the odour investigation avoids the problems of the absence of odour criteria and the subjective nature of the issue, as tailor made odour criteria are deduced and the odour assessment is objectified. Based on the conclusions of such odour investigations, in particular the acceptability of the odour, the EIS determines its further attitude towards the company causing the odour nuisance. Often, professional negotiations between the EIS and the company are required in order to solve the problem. These are formalised by the EIS in an odour clean-up plan with binding and realistic implementation terms. The entire clean-up process is closely monitored by the EIS and adjusted if necessary. Often, permit conditions are updated in accordance with the conclusions of the odour investigations.

In addition, the EIS communicates the results of the odour investigation and the odour clean-up plan negotiated with the company to the neighbourhood. Later on, feedback is given about the evolution of the clean-up process. The approach of the odour investigation and the communication afterwards offers the opportunity to the neighbourhood to get involved in solving the odour nuisance problem. Furthermore, the odour investigation conclusion is more easily accepted by the plant operator and the neighbourhood because of its objective/rational character. By acting vigorously on the basis of an expert odour examination with participation of the public involved, the EIS succeeded in solving a number of lingering odour problems.

Examples of good practice in relation to public involvement include:

- Early provision of information to the public;
- Placing information relating to the permit application on the internet;
- Advertising permit applications in the local press;
- Publishing the reasons for permit conditions and the issue of the permit;
- Providing the results of real time monitoring data to the public.
- Open discussion surgeries attended by public health authorities who can answer health related questions directly;
- Public access to an independent person to provide advice;

The following additional measures may also be beneficial for potentially contentious applications:

- Arranging visits for the public to the installation under consideration;
- Establishing consultative groups involving the public, industry and regulators;
- Public meetings with the local authority and the Non Governmental Organisations (NGOs) on the application / draft permit;

9. CONCLUSIONS AND RECOMMENDATIONS

The key issues relating to the consideration of human health through IPPC are as follows:

- Protection of human health is an integral part of environmental protection;
- Member States should aim for internal consistency in their consideration of human health through IPPC;
- The simplest way to ensure that the required information for the consideration of human health is supplied in an IPPC application is to provide the applicant with guidance for the assessment of health through IPPC.
- The first stage in the assessment of an application is to consider whether BAT as specified in the BREF notes is being applied;
- The simplest way to prevent unnecessary work during the further stages of assessment is to use a screening tool to establish whether the emissions from the installation are insignificant;
- Strict compliance with a health based EQS is necessary to ensure health protection;
- Where there are no available health based EQSs, other health based environmental quality criteria need to be derived;
- An integrated approach should be adopted when producing a permit, as health is only one of the issues that need to be considered;
- Where potentially harmful effects to human health have been identified during the assessment of the application and scientific evaluation does not allow the risk to be determined with sufficient certainty, the precautionary principle should be applied when setting permit conditions;
- Consultation with a public health organisation must be carried out where the permitting authority does not have health related expertise;

- Consultation should be carried out when the application is being assessed and when the draft permit is being produced;

- Providing guidance for health consultees ensures that maximum value can be obtained from the consultation process;

- The decision document produced by the permitting authority should clearly indicate where and how the opinion of the health consultee has been taken into account in the permitting decision;

- Good communication with the public and transparency of decision making are very important factors in gaining public trust.

The following recommendations address both support for current good practice and the development of new areas of good practice. For clarity the recommendations are divided into groups dependent on the target organisation:

- Applicants should provide real time monitoring data to the public wherever possible;

- Applicants should consider establishing consultative groups (for high profile contentious applications only) involving themselves, the public and the regulators;

- Member States should revisit their approach to the consideration of health through IPPC in the light of this good practice guide;

- Member States should produce national guidance on the consideration of health through IPPC for both the applicant and the health consultees;

- Member States should develop partnerships with public health organisations where such partnerships are not already in place;

- Member States should ensure that, where appropriate, the precautionary principle is applied to the consideration of health through IPPC;

- Member States should invest in capacity building, for example to develop the understanding of health issues within environmental bodies;

- The EU should consider producing a BREF note addressing the assessment of health effects through IPPC;

- The EU should develop more EQSs, in particular to cover current gaps in current values, for example EQSs for soil;

- The EU should produce a standard approach to the derivation of environmental quality criteria where there are no EQSs available;

- IMPEL should use the established network to continue to share on-going experiences and good practice relating to health through IPPC.

Annexes

ANNEX 1 – PROJECT TERMS OF REFERENCE

1.1 Background	The system of Integrated Pollution Prevention and Control (IPPC) applies an integrated environmental approach to the regulation of certain industrial activities. This means that emissions to air, water and land along with a number of other environmental effects must be considered together. It also means that regulators must set permit conditions so as to achieve a high level of protection for the environment as a whole. IPPC aims to prevent emissions or where that is not practicable, reduce them to acceptable levels. The definition of 'pollution' includes emissions, which may be harmful to human health or the quality of the environment. The Integrated Pollution Prevention and Control Directive 96/61/EC requires emission limit values ("ELVs") to be set in permits – along with other relevant conditions - for any pollutant likely to be emitted in significant quantities from the installations it covers. Because of the linkage in its definition of "pollution", the Directive therefore provides a stronger emphasis than any earlier legislation on protecting human health through environmental regulation. However the process of considering potential effects of emissions on human health is complex and can be very costly and time consuming. There is a proposal to amend the IPPC Directive to strengthen public participation (Proposed Directive Providing for Public Participation in respect of the drawing up of certain plans and programmes relating to the environment and amending 96/61/EC) and provide the public with greater opportunities to influence permitting decisions. Experience already suggests that concerns about health effects will be a significant feature of the greater public participation which is thus being encouraged. In the UK the primary responsibilities for health protection and environmental protection do not rest with the same body. Consideration of ELVs and other permit conditions in fulfilment of the IPPC Directive is therefore challenging and requires significant co-operation. It is possible that regulators and advisory bodies elsewhere within Europe are finding similar challenges. It is almost certain that Member States will be duplicating effort on these matters and attempting to resolve the same issues as others. The exchange of information and experience through the IMPEL network would be invaluable in compiling good practice on this issue. A good practice guide would allow existing and prospective Member States to assess their current practice and to converge on a common approach throughout the EU. The EU's 6th Environmental Action Programme (6EAP) provides continuing support for IMPEL's exchange of information on implementation experience between Member States. In this

	capacity, the 6EAP notes that IMPEL can play an important role in improving the implementation of legislation.
1.2 Objective	The project is being undertaken to prepare a report on how human health effects are taken into account in setting ELVs and other permit conditions under the IPPC Directive. By considering the current varied approaches of Member States to this issue a good practice guide will be developed. This guide will assist Member States by identifying common principles and procedures.
1.3 Definition	The project would involve a series of steps as outlined below. 1. An introductory workshop of IMPEL experts. This would be to discuss the precise information sought from the project, and the production of a questionnaire to obtain that information. The workshop would take as a starting point presentations by a number of IMPEL partners on the challenges faced when applying permit conditions to protect human health through IPPC. The draft questionnaire would be scrutinised by all workshop attendees. 2. The questionnaire would be circulated to the designated people within the IMPEL Network. They would then liase with experts in the relevant areas within their own countries who may be either regulators or stakeholders in the regulatory process to complete the questionnaire. 3. Responses to the questionnaire would be analysed and common themes, problems and issues would be identified. This would provide the basis for the drafting of a report setting out the main areas of good practice, illustrated by practical examples taken from the IMPEL members' responses. 4. The draft report would be peer reviewed and finalised by an IMPEL Working Group at a workshop.
1.4 Product(s)	The project will produce a report reviewing the current methods and procedures through which human health effects are taken into account in setting ELVs and other permit conditions under the IPPC Directive, and identifying good practice for consideration by all Member States. The Report will be delivered to the IMPEL Plenary in June 2005 and subject to its approval will be ready for dissemination in July 2005. The target audience will be those responsible for regulating or advising under the IPPC Directive. The results of this work may also influence future revisions of relevant European legislation.

ANNEX 2 – METHODOLOGY

This IMPEL project was initiated through an introductory workshop of IMPEL experts, held in London, September 2004 and attended by participants from eleven countries. Appendix C lists all the project participants who took part in this first workshop and/or the second project workshop held in April 2005 in London.

At the first workshop the precise information sought from the project, and the production of a questionnaire to obtain that information, was discussed. The workshop took as a starting point presentations by a number of IMPEL partners on the challenges faced when applying permit conditions to protect human health through IPPC. The draft questionnaire was scrutinised by all workshop attendees.

The questionnaire was circulated to the designated people within the IMPEL Network. In completing the questionnaire, they were encouraged to liaise with experts in the relevant areas within their own countries who may be either regulators or stakeholders in the regulatory process.

Forty responses to the questionnaire were received, from representatives of the following Member States: Belgium, Czech Republic, Denmark, France, Germany, Republic of Ireland, Italy, the Netherlands, Slovakia, Spain, Sweden and the UK. A response was also provided by Bulgaria, a Candidate Country. Responses were provided by permitting authorities, enforcement officers, statutory consultees, policy makers and other advisory bodies.

Questionnaire responses were analysed and common themes, problems and issues were identified. The results of the questionnaire were summarised in a draft report setting out the main areas of good practice, illustrated by practical examples taken from the IMPEL members' responses. A presentation was given to the IMPEL Working Group at the second workshop and the draft report peer reviewed.

The outcome of the second workshop was a set of agreed principles of good practice and areas in which further examples of good practice should be obtained from participants.

The following sections of this Appendix contain:

- A copy of the blank questionnaire
- A summary of questionnaire responses to illustrate current practise in EU Member States.

COPY OF BLANK QUESTIONNAIRE

Consideration of Human Health Through IPPC

An IMPEL project is underway to identify how human health effects are taken into account in setting emission limit values and other permit conditions under the IPPC Directive. This questionnaire has been developed by an IMPEL workshop to collate information in support of the project objective. The intention is to use the results to produce a good practice guide on effective implementation of the human health requirements under IPPC.

This questionnaire has been sent to environmental regulatory authorities/Government bodies and agencies, and health organisations. Not all will be directly responsible for regulating under IPPC therefore some questions may not be directly relevant. Please answer those which apply to your area of responsibility.

Please take the time to complete this questionnaire, providing as many examples for your answers as possible. Please feel free to answer any of the questions on separate sheets by using tables, diagrams or providing examples of good practise (e.g. domestic guidance). These must be clearly labelled to show which question they refer to. A glossary of terms used is included as Annex 1 at the end for your information.

Which organisation do you represent?
What is the role of your organisation with respect to IPPC? e.g. responsible for permitting and/or enforcement, statutory consultee (eg. for health protection), or consulted organisation.

1) Do you consider health issues in carrying out the assessment of an IPPC application?
   - ☐ Yes
   - ☐ No

Please briefly discuss

_____

_____

_____

_____

2) Specify the range of issues that you consider as part of health within IPPC.

- ☐ Releases to air;
- ☐ Releases to land;
- ☐ Releases to surface water;
- ☐ Releases to groundwater;
- ☐ Health related effects/annoyance (noise/vibration, odour, visual impact);
- ☐ Exposure pathways;
- ☐ Cumulative impacts from multiple sites;
- ☐ Synergistic effects;
- ☐ Biologically active substances - pathogens/ allergens;
- ☐ Off site impacts of waste;
- ☐ Accidents;

any other (please list).

3) Do you provide health guidance to applicants? If so what does it contain?

- ☐ Yes
- ☐ No

4) What type of information with regard to health do you require in an IPPC application?		Yes / No	For every application? If not give an example of a situation when this information is required (eg for a specific industry sector)
Full health impact assessment;			
Substance specific health data eg toxicity, carcinogenicity, genotoxicity;			
Use of the source-pathway-receptor framework			
Comparison of the contribution to background / existing concentrations resulting from a given IPPC activity with health based ambient Environment Quality Standards (EQSs) for:	air		
	soil		
	surface water		
	groundwater		
Comparison of emission concentrations with health based Emission Limit Values (ELVs).			
Assessment of health related annoyance (noise/vibration, odour, visual impact);			
Exposure pathways;			
Background / existing environmental quality;			
Cumulative impacts from multiple sites;			
Synergistic effects;			
Information on biologically active substances-pathogens /allergens;			

Information on explosive substances;		
Information on locally exposed vulnerable groups (eg school children) or local environmental vulnerability (eg. drinking water supplies);		
Monitoring; emissions / environment / health, - please specify.		
Other (please list)		

5) How do you decide if the health risk is **significant**?		Yes / No	Example
Comparison of the background / existing concentrations resulting from a given IPPC activity with health based ambient Environment Quality Standards (EQSs) for: (please specify whether the absolute value of the EQS is used, or a range of values based around the absolute value of the EQS);	air		
	soil		
	surface water		
	groundwater		
Comparison of emission concentrations with health based Emission Limit Values (ELVs).			
Assessment of health related annoyance (noise/vibration, odour, visual impact);			
Exposure pathways;			
Use of substance specific health information;			
Consideration of background / existing environmental quality;			
Information on biologically active substances-pathogens /allergens;			
Information on explosive substances;			
Consideration of locally exposed vulnerable groups (eg school children) or local environmental vulnerability (eg. drinking water supplies);			
Seeking expert medical/health opinion;			
Use of predictive modelling;			
Use of risk screening;			
Use of monitoring; emissions / environment / health, -please specify.			
Other (please list)			

Local conditions

6) When considering significance, how do you take account of local environmental conditions and targets? Please specify and discuss.
   - ☐ Use of background concentrations of emitted pollutants;
   - ☐ Consideration of cumulative impacts of pollutants;
   - ☐ Consideration of annoyance;
   - ☐ Consideration of land use or planning restrictions;
   - ☐ Consideration of safety;

   any other (please list).

7) When considering significance, what local health information do you take into account?
   - ☐ Local prevalence or incidence of disease;
   - ☐ Clusters of disease;
   - ☐ Advice from local public health experts;
   - ☐ Complaints from local people concerning either annoyance or health issues;

   - any other (please list).

8) If you are the permitting authority:
   (a) do you possess health expertise?
   - ☐ Yes
   - ☐ No

   If so, please specify the areas of expertise
   - ☐ Toxicology;
   - ☐ Epidemiology;
   - ☐ Medical doctor;
   - ☐ Public health;

   - any other (please list).

   (b) As permitting is mainly carried out by environmental bodies are health professionals e.g. health authorities also involved in the permitting process. If so,
      i) Who is involved?

      ii) How are they involved?
   - ☐ As a statutory consultee, or
   - ☐ On a voluntary basis;
   - ☐ Other, please list

iii) When are they involved?

- ☐ Pre application,
- ☐ At the application stage or,
- ☐ At the stage of the draft permit?

iv) Who initiates their involvement?

- ☐ The applicant or,
- ☐ The permitting organisation.

v) What do you ask them to do?

- ☐ Review the application, or
- ☐ Provide further information on specific issues such as incidence of disease in the surrounding area;
- ☐ Other, please list

vi) Is it mandatory to consider the health professional's statement when making the permitting decision and if it is so, to what extent?

9) Has there ever been a public appeal or an objection to a permitting decision on health related issues in your Member State /Country/ area of jurisdiction? If so, please provide examples.

- ☐ Yes
- ☐ No

10)

(a) Have you ever refused an application on health grounds? If so, please provide examples.

- ☐ Yes
- ☐ No

(b) Did the applicant appeal against your decision?

- ☐ Yes
- ☐ No

(c) If so, what was the outcome?

11) Have you ever required changes to a process or set permit conditions specifically on health grounds (other than compliance with health based EQSs)? eg specifying that an abatement process is fitted. If so, please provide examples.
- ☐ Yes
- ☐ No

12) What criteria and methods do you use to decide whether to set health based permit conditions?		Yes / No	Example
Comparison of the contribution to background/existing concentrations resulting from a given IPPC activity with health based ambient Environment Quality Standards (EQSs) for: (please specify whether the absolute value of the EQS is used, or a range of values based around the absolute value of the EQS);	air		
	soil		
	surface water		
	groundwater		
Comparison of emission concentrations with health based Emission Limit Values (ELVs).			
Assessment of health related annoyance (noise/vibration, odour, visual impact);			
Use of exposure pathways;			
Consideration of cumulative impacts from multiple sites;			
Consideration of synergistic effects;			
Use of scientific evidence of health hazards;			
Use of health risk assessment;			
Health professional's statement;			
Local health policy;			
Public concern;			
Any other (please list).			

13) Does your enforcement and review process allow you to address health concerns arising from installations? If so, please provide examples.
- ☐ Yes
- ☐ No

14) How do you try to gain public trust on health issues during your permitting and enforcement process? Please provide examples. Examples of this may include the following:
- good communication with relevant authorities, other stakeholders and the public;
- transparency, public participation and risk communication strategies.

15) How do you ensure consistency within your Member State / Country / Area of jurisdiction when considering health aspects as required within the IPPC Directive? Please describe. Examples of this may include the following:
   - ☐ Use of national guidance;
   - ☐ Use of internal audits;
   - ☐ A system (formal/informal) for exchange of information on health based regulation of IPPC activities between government agencies (e.g. between local/regional branches of a central body or between local/regional authorities responsible for regulating IPPC activities);
   - ☐ other, please list

16) Do you think we need EU cross-cutting guidance for health issues within IPPC? Please give reasons why and (if yes) suggest what it might cover in broad outline.
   - ☐ Yes
   - ☐ No

17) Is there anything else that you think would help the process of implementing the aims of the IPPC Directive with respect to human health? Please describe. For example are there any other processes that you apply, or examples under other legislation or tools which would complement the goals of the Directive with respect to human health?

To assist in the summary of data and statistics could you please provide the following information if applicable:

How many IPPC permits has your organisation issued to date? _____
How many IPPC permits do you expect to issue (in total by 2007)? _____
How many IPPC applications have you assessed but not yet issued permits for? _____

SUMMARY OF QUESTIONNAIRE RESPONSES

This section summarises the results of the responses to the questionnaire to illustrate current practise in EU Member States with regard to the consideration of health within IPPC. It follows the structure of the questionnaire under these broader headings:

- Consideration of health under IPPC;
- Application for a permit;
- Permitting and enforcement;
- Public involvement;
- Other issues.

Consideration of Health

Questions 1 to 3 of the questionnaire looked at:

- Whether human health issues are considered in the assessment of an application;
- What issues are considered part of health within IPPC; and
- Whether any guidance is available to applicants.

Health issues

All questionnaire responses, from the permitting authority, statutory consultee and other observers of the IPPC application process, stated that human health is taken into consideration when carrying out the assessment or review of an application. This is through the assessment of BAT and the use of EQSs and ELVs. Several respondents noted that health is an integral part of IPPC and environmental protection. One respondent said that they considered IPPC to be a good tool in public health protection. Another response was that the consideration of health was a natural part of the permitting process and one of the most important issues.

The issues considered by Member States to be related to human health are broad ranging and cover all environmental media. Every respondent from the participating Member States stated that they consider releases to air and surface water in relation to health, and all but a few said they consider releases to soil and ground water. Health effects related to annoyance factors (noise and odour) are considered by all but one respondent. Two respondents stated

that they only consider one particular medium or issue (specifically, bathing water and noise); this would appear to be related to the particular local priorities and areas of expertise of the respective respondents.

Cumulative effects are considered to be important where relevant, that is, where there are other local sources of the same pollutants. However, it was suggested by one respondent that this is already taken into account through the consideration of background concentrations. Synergistic effects are an area that some Member States stated they would like to look at, although they also note that this is a difficult concept to take into account due to the lack of a scientific basis for assessment.

Exposure pathways, biologically active substances and accidents are considered by over half the respondents when assessing an application. Around a third of respondents also consider off-site impacts of waste. Additional areas considered to be part of health under IPPC by individual respondents include biocides, bathing water and non-ionising radiation.

Guidance

Although most Member States consider health issues under IPPC, there appears to be a lack of published guidance for applicants as to how the various issues should be addressed. There are a few exceptions, where national guidance has been issued, for instance where the permitting authority has produced a guide for the risk assessment of health for IPPC installations. Some Member States are currently giving consideration as to what advice should be provided by the permitting authority to staff, applicants and statutory consultees.

General advice, although not necessarily health related, appears to be provided by many organisations. Such advice may direct the operator towards associated technical guidance, for example on pollution abatement techniques and limit values, environmental impact assessment methods and protection of public health in general. In one Member State, the Environmental Protection Agency acts as an advisory body to the regional authorities that handle IPPC applications and often also to the applicants. The advice provided relates to the interpretation of legislation, regulations, health based guideline values and related quality criteria.

Application for a Permit

Questions 4 to 7 of the questionnaire looked at:

- What information the permitting authorities, statutory consultees etc. require when reviewing an application;

- How a decision is made on whether a health risk is significant;
- How local conditions and targets are taken account of.

Information required

When reviewing an IPPC application, the majority of consulted organisations stated that they request a range of data concerning the potential health risk. The amount of information required was noted by one permitting authority to be proportional to the likely potential impact of the installation. The information required by most includes background data on environmental quality, comparison of facility emissions with ELVs and facility contribution with EQSs, information regarding annoyance, location of vulnerable groups of people and emissions monitoring data.

There was a considerable amount of variation between the requirements of different Member States, and the organisations within them, about whether this information is necessary for every application. For instance, background environmental quality data and the calculation of the contribution from the facility to EQSs is commonly required for all applications, as is information on emission concentrations to compare with ELVs. Air and water emissions are generally taken into account, with emissions to soil considered to a lesser extent. The reasons for this include the absence of quality standards for soil, and the lack of a direct, quantifiable link between levels in soil and health effects.

Health based guidance values for the content of pollutants in soil are only used to examine whether pollution has already taken place. Apart from this, comparison of concentrations of pollutants in waste with guidance values can determine whether the waste can be put directly on the soil with out any pollution prevention measures. The comparison of emissions against criteria that have been explicitly set for the protection of human health is not common or standard practise. In one Member State, however, ambient quality criteria have been derived from health guidelines and are set for the specific contribution from the facility.

With regard to nuisance issues and health effects, noise, vibration and odour are commonly assessed; however some Member States noted that they do not take visual impact into account in terms of human health. In Italy, visual impact is only considered for new facilities, under Directive 85/337/CEE. Two thirds of respondents stated that background levels of pollutants are a factor that is considered when assessing an application. One Member State noted that they suffer from a lack of information on existing environmental quality.

Some organisations consider that, by adding the facility contribution to background environmental quality data, they are able to provide an assessment of cumulative effects without the need for further investigation. Synergistic effects are considered more difficult to

account for due to a lack of data available for effects at the environmental level concerned and lack of expertise from applicants in this area.

Substance specific data and safety data may be required for every application or only where specific issues have been identified. Information on explosive substances may be required with respect to production and storage details, where a risk has been identified in the assessment of accident potential, or where oxidising agents are concerned. In one Member State, emissions data on dangerous substances are compared with USEPA risk based criteria.

The supply of information on biologically active substances (pathogens and allergens) in some cases is always mandatory, in other cases only where considered appropriate (for example applications for landfills, intensive farming and the food and drinks industry), or may not be required at all.

Exposure pathways (source → pathway → receptor) are considered by a few organisations to be essential to every application. However, less than half of respondents stated that they require information on exposure pathways when assessing an application. Around one third of respondents stated that they require a health impact assessment to be undertaken. The location of receptors or vulnerable groups is relevant to this. In some cases this may not be considered by the permitting authority because facilities are located at a dedicated industrial site. In one Member State, exposure pathways are said to be normally taken into account during the planning process; however if there is a hospital for respiratory disease within the evaluation area, this is dealt with by "examination of a special case", for example where an ambient air quality standard for a particular pollutant does not exist, but where it could be expected that this pollutant will be released in relevant toxic concentrations. In another Member State, the exposure pathways are considered in the process of setting the health based quality criteria for soil, drinking water and air.

Monitoring data may be required by the authority assessing an application for an existing plant, where emissions to the environment are considered to be significant, for instance where an installation exceeds an ELV. In such a case, ambient monitoring may also be required to be undertaken, for instance in local towns. Monitoring of surface waters, ground waters and air quality is considered to be important by one Member State where the application is for a landfill or waste facility. One respondent stated that health data are not expected to be supplied by the applicant; this is considered to be the role of the health consultee.

Significance

A range of approaches are taken by Member States when deciding whether a health risk is significant. For example, this may involve comparing ambient concentrations (including the

facility contribution) to a range or an absolute value of an EQS, or looking at dose-response relationships to estimate the risk due to exposure to emitted compounds.

Published methods and guidance for the determination of significance are scarce. In one Member State, a methodology has been developed which provides a way of quantifying environmental impacts to all media and for determining BAT and significance of emissions through a comparison of facility emissions with absolute values of EQSs (for air, water etc.). This method also takes into account background levels of pollutants.

In many cases, the main condition for granting an IPPC permit is that emissions from the installation remain under the limit values. In these situations, a permit cannot be granted when the emissions exceed the ELV or when predicted environmental concentrations exceed an EQS, as this is assumed to imply a "significant" health risk and the permit must be refused.

In one Member State, the consulted organisation with health expertise carries out an exposure assessment (e.g. exposure to gaseous compounds in the atmosphere, or intake through drinking water or contaminated vegetables) using available background data and measured or modelled results for the facility. Existing scientific knowledge on exposure (dose)-response relationships is then used to estimate the number of people severely annoyed by noise, the number of additional cancer cases or the number of accidents that may occur due to the facility. However, in this country the determination of significance is left to those with a statutory role.

Standard criteria for the determination of significance were mentioned by some respondents as being used when looking at exposure pathways: for example an excess risk for non-threshold (carcinogenic) effects or a risk ratio for substances with a threshold. These values tend to be considered as target values rather than strict decision barriers. This approach is used in health risk assessment.

One respondent stated that the health risk is considered to be significant when there is the presence on site of explosive substances included in the Seveso Directive.

Local conditions

When determining the significance of the health risk, consideration must be given to local conditions (existing health status and pollution levels) and targets. Local background pollutant concentrations are almost always taken into account, as are the cumulative effects of pollutants and annoyance factors. Consideration is also given to land use or planning restrictions and safety, but to a lesser extent. However, in one instance it was noted that the local conditions are only considered in vulnerable areas since, for the most part, IPPC

facilities are located in industrial areas remote from any such vulnerable areas. A few Member States noted that permit conditions are not based on local environmental conditions, but are instead based on emissions and compliance with limit values.

The information required by the majority of respondents with respect to the local situation includes statistics on the local prevalence or incidence of disease and disease clusters. It appears that around half of those consulted take account of advice from public health experts where it is available. Other information widely used to assess the local situation is the incidence of complaints from local people concerning annoyance or health issues. This may be extended to looking at local administrative and official reports and public allegations, or it may mean asking locals about their experience of the facility, and evaluating the experience and results of the supervisory activities of the local environmental health authority.

Permitting

Questions 8 to 13 looked at all stages of permitting, from the review of the application, determination, appeals and refusals, to setting, enforcing and reviewing permit conditions:

- Whether the permitting authority possesses health expertise;
- Which health bodies are included in the permitting process and how;
- Whether any appeals or refusals have occurred on health grounds;
- What criteria and methods are used in setting health based permit conditions;
- Whether the enforcement and review process allows health to be addressed.

Health expertise

In all but one Member State, permitting authorities do not themselves possess health expertise. There was one reported exception where the permitting authority possesses in-house expertise in public health. One regional authority said that they would specifically like to have expertise in epidemiology and public health.

Typically, health bodies (ranging from local or regional health officers, regional experts in environmental toxicology, public health bodies, academic institutions, to the Ministry of Health) are involved as consultees during the permitting process. They are usually invited to participate by the permitting authority although a fifth of respondents stated that the applicant may contact the relevant health body. In one case the involvement of health experts was reported to be voluntary.

Health consultees' involvement may be at various stages in the process - most often during the application stage but also at the pre-application and draft permit stages. One respondent stated that the consultee is involved at all three stages. In one Member State, the regional health organisation may be involved at later stages of the permitting process, including control of operation after the permit has been issued, although the role is currently limited to the evaluation of only noise and vibration.

As well as reviewing the IPPC application from a health perspective and providing information on the incidence of disease in the local area, public health authorities may also be required to provide the permitting authority with information on local sensitive populations, an expert opinion on the likely health impact of the installation, a statement as to specific health or hygiene issues or formulate objections to the installation concerned.

Appeals and refusals

Several organisations reported situations where there have been public appeals or objections to permitting decisions on health grounds. These cases tend to relate to high profile applications for waste facilities (landfill, incineration), cement plants (where waste is to be burnt) and pulp and paper plants. Objections have mostly been raised due to nuisance issues (noise, odour and dust) as well as emissions to air of the pollutants: mercury, dioxins and VOCs.

There were only two reports of cases where an IPPC application has been refused on health grounds: in one case, an application was refused due to the lack of a health risk assessment; in the other case, the refusal was due to the exceedence of an EQS. In some Member States, applications may be resubmitted after advice from the permitting authority early on in the permitting process that the facility is unlikely to meet the relevant health criteria. In one Member State, the respondent stated that presently the permitting authority is not legally allowed to refuse an application on health grounds, but that several iterations could be required along the way to ensure that all necessary information has been obtained from the operator and that the facility will comply with permit conditions.

Several competent authorities across the EU reported having required changes to be made to a process on health grounds. The changes have typically been in relation to reducing emissions to air of toxic substances, acid gases, dust and odour. The changes have involved repeating air dispersion modelling with actual emissions data, and fitting abatement equipment. One Member State revealed that health considerations have influenced the specific design of processes, most typically for the incineration, petroleum and chemical sectors. There were also a few cases of changes being required in relation to noise, however in one of these cases, noise abatement was not considered to be specifically health related.

Permit conditions

The various permitting authorities were asked to specify the criteria and methods that are used in setting health based permit conditions. Responses were varied, for example one authority reported that none are used, whereas some authorities stated that they used the full range of criteria and methods listed (see Question 12 for full listing). However, as a matter of course, the determination of a permit will not be based solely on health risk; instead the ruling will be based on an integrated approach that cannot separate health from other pollution and risk aspects.

The majority of respondents use EQSs and ELVs to set permit requirements. In some Member States, if emissions from the facility are considered to impact negatively on ambient air quality, the permit could be used to set even more strict values than the ELVs. As noted by several organisations, the use of such criteria is based on the assumption that they offer some form of protection to human health.

An assessment of health related annoyance, in particular noise and odour, is often used to set permit requirements. Other factors used to determine permit requirements are: toxicity data, exposure pathways, health risk assessment, public concern, health professionals' statements and local health policy. Synergistic and cumulative effects are not often considered at this stage due to a lack of appropriate assessment methodology.

In one Member State region, each application is evaluated by the permitting authority for unusual emissions that entail a nuisance or risk. Standards are set for the relevant emissions to air, soil and water, based on EQSs, health standards or in a few specific cases by toxicity tests. A permit for a new installation may be rejected if the installation would endanger the environmental quality. Studies or other measures are imposed on existing installations to bring them into compliance with the required environmental quality.

Enforcement and review

The majority of respondents stated that their enforcement and review process allows health concerns to be addressed when such an issue is raised. Several examples of how this is achieved were provided, including: facility inspections following complaints from the public; requirement for (further) monitoring; review of permit conditions and setting of stricter conditions if serious health problems or nuisance are found to have occurred; setting monitoring requirements if EQSs are exceeded; requesting that the operator makes changes to the facility process to reduce emissions/nuisance. In some extreme cases facilities may be shut down due to unacceptable emissions, for example incinerators emitting high levels of dioxins.

Public Involvement

Question 14 looked at how the public are involved and how their trust may be gained on health issues during the permitting and enforcement process, including:

- Communication with local stakeholders and public participation;
- How transparency is maintained at this stage of the process.

The IPPC Directive has recently been amended by the Public Participation Directive (PP Directive) with the intention of developing the public participation process and providing the public with greater opportunities to influence permitting decisions. Experience already suggests that concerns about health effects will be a significant feature of the greater public participation which is thus being encouraged. However due to overlapping timeframes, the questionnaire responses may not fully reflect the impact of the PP Directive and the effect this may have on the IPPC public consultation process.

Good communication and transparency are recognised by all the questionnaire respondents as being very important factors in gaining public trust on health issues. Early provision of information, public meetings with the local community and NGOs, open discussion "surgeries", attended by public health authorities who can answer questions directly, and arranging visits for the public to the installation in question are good examples of how communication and transparency can be achieved.

The university hospital in Gothenburg, a consulted organisation in Sweden with expertise in health, reported that they have gained a satisfactory level of trust from the general public. They attribute this to their technical competence and affiliation to a university, as well as the high transparency in their review process (most of their evaluations are placed on the internet).

To keep the public informed during the permit review process, the relevant authority may wish to advertise permit applications in the local press, create a website where information pertaining to the permit application is stored, or hold public meetings on the application or draft permits. In some Member States, public consultation and communication are mandatory.

General issues

The final three questions of the questionnaire considered:

- How consistency is achieved within a Member State or Region;

- Whether EU cross-cutting guidance is considered to be required;
- What else may be required in order for successful implementation?

National guidance is a common method for ensuring consistency in the consideration of health aspects. To ensure consistency in the review process in one Member State, guidance has been produced for the public health consultees, describing how to review an application and what advice they should provide. The guidance can also be used by the applicants to ensure they are meeting the needs of the consultee.

Several permitting authorities have systems for the exchange of information. These include, for example, informal meetings for information exchange, between regional authorities or other countries (depending on the permitting structure), to discuss different topics under the "health and IPPC" banner. Examples of how consistency is achieved include internal training, having IPPC regulation carried out by a small team, or a centralised system of issuing permits, with one body responsible for receiving, assessing and granting permits.

With regard to the issue of whether EU cross-cutting guidance is required, many organisations felt that such guidance would be useful to ensure a consistent approach to the consideration of health effects across the Member States. Reasons given for developing such guidance included: the reduction of any competitive advantage to industry in different Member States, the improvement of public confidence in the review process, and the improvement of information exchange with the creation of a common knowledge on health issues. Suggestions for what the guidance could contain included: how to carry out health impact assessment, how to develop and use health based standards, how to determine significance, and good practise on the appropriate level/type of assessment required in different circumstances.

Conversely, some organisations felt that EU guidance was unnecessary and potentially inappropriate, as many topics would be dependent on the local situation and hence better based at a regional level. In one instance concern was expressed that specific guidance may mean that health protection is perceived as a specific issue in IPPC, as opposed to "just one of the reasons why there are regulations aimed at reducing emissions". However, this respondent believed that some form of general guidance would be beneficial.

Finally, the questionnaire asked respondents what they thought would help the aims of the IPPC Directive to be successfully implemented with respect to human health. Suggestions included holding conferences and information exchange activities to ensure a common education, installing a safety management system (similar to that under the Seveso Directive) to prevent risks, making it clear whether existing environmental standards cover health effects, provision of clear guidance on health input to IPPC and demonstration of how that health input is taken into account.

It was also suggested that the competent authorities should employ human health experts or have resources available to provide training to existing staff. The EIA process was recognised as being an example of good practise, and it was suggested that this process could include consideration of human health effects (for example with an assessment carried out by a competent body).

Glossary

Application	A submission made by an Operator to a regulator, for example to seek the grant of a Permit, surrender of a permit, variation of the conditions of a permit or transfer of a permit.
BAT	Best Available Techniques shall mean the most effective and advanced stage in the development of activities and their methods of operation which indicate the practical suitability of particular techniques for providing in principle the basis for emission limit values designed to prevent and, where that is not practicable, generally to reduce emissions and the impact on the environment as a whole.
Consultee	A body or person which the regulator may consult when determining an application for a permit.
Discussion surgery	An informal, open meeting between the public and health professionals where people can express concerns and discuss issues with those involved in the application/permitting process.
ELV	Emission Limit Value – the mass, concentration or level of an emission which may not be exceeded over a given period. Health based ELV's will be very low (e.g. requiring absolute filters) for substances with known serious potential health effects and more relaxed for less harmful substances.
Emission	The direct or indirect release of Substances, vibrations heat or noise from individual or diffuse sources in an installation into the air, water and land.
EQS	Environmental Quality Standard. The meaning, depending on the context, is either: a requirement which must be fulfilled at a given time by a given environment as set out in EC legislation; or a domestic requirement or objective
Exposure Pathway	The route a substance takes from its source (where it began) to its end point (where it ends), and how people can come into contact with (or get exposed to) it.
(Adverse) Health effect	A change in body function or cell structure that might lead to disease or health problems.
Health risk	The probability that something will cause injury or harm to human health.
Installation	A stationary technical unit where one or more activities (as specified) are carried out; and any other location on the same site where any other directly associated activities are carried out which have a technical connection with the activities carried out in the stationary technical unit and which could have an effect on pollution,

IPPC	Integrated Pollution Prevention and Control – a general term used to describe the Regulatory regime applied to installations which give effect to the IPPC Directive.
IPPC Directive	Directive 96/61/EC concerning Integrated Pollution Prevention and Control.
Source-Pathway-Receptor	Source - The place where a release comes from. Pathway - The route a release takes from its source (where it began) to its end point (where it ends) Receptor - People who could come into contact with the release
Statutory Consultee	A body which the regulator must consult when determining an application for a Permit.
Synergistic Effect	An interaction between two or more effects to produce an interaction, which is greater than the sum of the effects separately.

ANNEX 3 – PROJECT PARTICIPANTS

Country	**Representative**
Belgium	Mr Paul Bernaert
Bulgaria	Ms Krassimira Kazashka-Hristozova
Czech Republic	Lenka Ungermanova
Czech Republic	Dr. Magdalena Zimová
Denmark	Mikael Malinowski
France	Mr Thomas Joindot
Germany	Dr. Martin Kraft
Ireland	Padraic Larkin
Italy	Ms Luciana Sinisi
Italy	Antonio De Maio
Netherlands	Dr Cor van den Bogaard
Spain	Mª del Carmen García Alonso
Sweden	Mr Börje Andersson
Sweden	Ms Ulla Kujala
DG Environment	Alexandre Paquot
UK	Nigel Barraclough
UK	David Bell
UK	Dr Naima Bradley
UK	Paula Charleson
UK	Emma Hayes
UK	Andrew Kibble
UK	Jenny Kirton
UK	Lesley Ormerod
UK	Neil Goodlad
UK	Anthony Parsons
UK	Terry Shears
UK	Helen Smethurst
UK	Chris Smith
UK	Dr Derek Tinsley

ANNEX 4 – SUPPORTING INFORMATION

IMPLEMENTATION OF IPPC IN EUROPE

Belgium

No substantial changes have been made to Flemish legislation to meet the overall aim of achieving integrated prevention and control of the pollution arising from the activities listed in Annex I of the Directive. The integrated licence was established by decree of 28 June 1985 concerning environmental licences, hereinafter referred to as the environmental licence decree, bringing together various licensing systems in the form of a single licence with the overall aim of achieving integrated prevention and control of pollution in order to protect man and the environment.

In the first instance the permitting decision is taken by the Permanent Deputation of the province where the installation is sited (Art. 9 of the environmental licence decree). On appeal (second instance) the decision is taken by the Flemish minister responsible for the environment (Art. 23 of the environmental licence decree). During this process, an opinion is delivered by various authorities (Art. 20 of Title I of the Vlarem), both in the first instance and in the second instance. Some departments always deliver opinions, the department of environmental licenses and the department of town and country planning. Other authorities have to deliver an opinion, according to what is stated in Appendix I of the Vlarem. The municipal board also delivers opinions (Art.35, 3° b)).

Bulgaria

In Bulgaria, a candidate country, the IPPC permit will substitute the current environmental permits concerning the waste management and treatment and effluent discharging. The validity of the permit is termless but it has to be reviewed every 5 years.

The IPPC permit is issued by the Minister of Environment and Water although the Executive Environment Agency (EEA) is responsible for managing most of the stages within the procedure and preparing the draft version of the permit. The EEA, which is based also in Sofia is subsidiary to the Minister of Environment and Water, has a range of duties including the collection of national monitoring data and the provision of the information about the environmental situation to the public.

There are 15 Regional Inspectorates of Environment and Water (RIEW) within Bulgaria, which support the EEA by providing special technical and local knowledge concerning the facilities in the their region. The RIEW is also a competent authority for monitoring and enforcement of the permit conditions. There are 4 River Basin Directorates, which are

responsible for the issuing of permits for water use and waste water discharge. They are involved in the IPPC permitting procedures at almost all stages during the permit issuing and the follow enforcement activities.

Denmark

In Denmark the IPPC Directive was transposed into Danish legislation in 1999 through an amendment of the Consolidated Environmental Protection Act. Subsequently more detailed rules were laid down through an amendment of the Statutory Order on Approval of Listed Activities also in 1999.

The regulation covers both new and existing activities. Environmental permits already covered most of the activities that became "IPPC activities" as these were already included in the list of activities (the so-called "listed activities") that prior to establishment or in case of extensions of existing activities which may result in increased pollution, are obligated to obtain an environmental permit. If installations carrying out IPPC activities also carry out other activities for which the operator is obligated to obtain an environmental permit, the IPPC permit should also cover and apply to such activities. There are around 1250 individual IPPC activities in Denmark, all of which are now covered by environmental permits.

The Competent Authorities for granting the environmental permits are the District or County Councils. In cases relating to the establishment or major changes or extensions of IPPC activities, the Competent Authority shall give the public the opportunity to comment on the application before deciding on the granting of the permit, through a public announcement upon receipt of the application. For activities where the process of granting a permit includes an Environmental Impact Assessment, the mentioned public announcement according to the IPPC regulation may be omitted. Instead a draft permit must be issued together with the EIA document for public hearing. The period for hear-ing an EIA document is longer than that of an IPPC document.

Periodically and at least once every 10th year the Competent Authority shall reconsider the IPPC permits and, if necessary, change the conditions of the permit through an order pursuant to the Consolidated Environmental Act. If, on the other hand, the Competent Authority after reconsideration does not find reason to change the conditions of the permit, the competent authority shall publish a separate decision to this effect.

The Competent Authority shall conduct the first periodic reconsideration after 8 years from the date the permit was granted to an IPPC activity for the first time. This implies that at the latest by 2007 the process of reconsideration will have been initiated for all IPPC activities in Denmark. To provide the public with opportunity to present their views the Competent Authority shall make a public announcement at the start of the re-consideration process and

among other things inform the public of its right to comment on a draft decision based on the reconsideration.

The hearing and appeal system for environmental permits for IPPC activities follows the same regulations as for other listed activities. An appeal over the permit may be lodged with the Danish Environment Protection Agency (DEPA). The appeal must be received within four weeks of a public statement made by the Competent Authority informing that a decision has been made on giving an environmental permit to the operator of an IPPC activity. The operator, neighbours to the activity and certain institutions and non-governmental organisations can lodge the appeal.

The decision of DEPA may likewise be complained against within a four-week period. These appeals must be submitted to the Environmental Board of Appeal (EBA), which is an independent institution under the Ministry of the Environment. Except in relation to decisions of DEPA on IPPC activities the EBA decide themselves whether a given appeal over a decision of DEPA shall be taken into consideration and subsequently decided upon. As a last resort the question can be taken to a court of justice.Italy

France

All IPPC facilities are in France embedded in the system of “classified installations”. Installations that present more serious risks or dangers cannot operate without an authorisation from the “prefect”. All IPPC facilities fall within this definition. Thus, the prefect is responsible for implementing the regulations under the supervision of the Ministry for Environment. He is assisted by the inspectorate for classified installations, the inspectors belonging mostly to the regional service for Industry and Environment (DRIRE), for the inspection of industrial facilities, and the departmental direction of veterinarian services (DDSV), for the inspection of facilities related to agriculture (farming).

The classified installations regulations consider all the risks, pollution and nuisances that an installation can cause. This situation has the double advantage of giving the operator one main contact in the administration, the classified installations inspector, and of taking into account any transfers of pollution (waste from the treatment of water or fumes, gas washing water, etc.). This approach means that the impacts of the operation of an installation on health and the environment can be appreciated in a synthetic way. With the implementation of the IPPC Directive, this approach is now mandatory in all the member states of the European Union. However, the nomenclature of classified installations for the protection of the environment has a wider field of application for installations coming under the system of authorisation than that of Appendix I of the Directive, because it has lower thresholds of activity than those defined in that appendix.

Once the permit is issued, the classified installations inspectorate checks whether the technical prescriptions imposed on the installation are being respected. The inspectors also intervene if complaints have been made or accident or incidents have occurred. If the inspector finds that prescriptions are not suitable, he or she can propose that the prefect imposes additional prescriptions by decree. If the operator does not respect the prescriptions by which he or she is bound under the terms of the classified installations legislation, he or she is liable to administrative and penal sanctions. In penal terms, the offence must be formulated in a statement drawn up be an inspector of classified installations or an officer of the criminal investigation department.

The administrative punishments are set by the prefect, after the operator has been sent an enforcement order demanding that they respect, within a set time, the operating conditions that have been imposed. If, after this time, the operator has not complied, the prefect can oblige the operator to pay a sum corresponding to the cost of the work to be done, or have the prescribed measures executed by the public authorities, at the operator's cost, or, on advice from the departmental health and safety committee, suspend the operation of the installation until the conditions imposed have been executed. The sums deposited can be used to cover the costs of the work executed by the public authorities.

The prefect also has the possibility to modify the technical requirements of the permit. The departmental health and safety committee will be asked to give an opinion on it before the additional decree is signed and published. An common way to proceed consists of asking the operator to produce a study on a precise point which is considered by the inspectorate as subject to re-examination (for example impact on the river, or the efficiency of the abating process), and after that writing a second decree that will modify technical requirements applying to the installation. It should also be mentioned that the prefect always has the possibility to ask the operator to submit the documents he produces to the advice of a third-body expert, the choice of which will have to be approved by the administration. This process enables to build better and transparent decisions. Eventually, when significant changes to the way an installation is operated occur, a new complete permitting process has to be undertaken.

The operator and the third parties, private individuals or associations, have several means of appeal before the administrative or judicial jurisdictions. The administrative jurisdictions (civil service tribunals, administrative appeals court, Council of State) adjudicate on appeals directed against the decisions made by prefects in the matter of classified installations. These appeals may be made both by operators, for example, against a refusal of an authorisation decree or against requirements prescriptions deemed too strict, or by third parties, in the same way for reasons arising from the inadequateness or non-respect of those prescriptions. In the matter of classified installations, contrary to most other legislations, the hearing in front the civil service tribunal is "fully adversarial". Within this context, the administrative

jurisdictions have wide powers to void, modify or complete acts of the prefects. Moreover, they have the power to order the state to pay compensation to and to injured parties for damages caused by failure to monitor a classified installation. The appeals to the civil service tribunal, which can be made without the services of a lawyer, must specify the subject of the request and the judicial reason, i.e. the rule of law invoked to support the appeal. The judicial litigation concerning classified installations is divided into criminal litigation and civil litigation. The civil courts (magistrates' court and high court) can condemn an operator to compensate a third party to whom he or she has caused damage. The criminal courts (criminal court, magistrates' court dealing with criminal matters) inflict the penal punishments provided by the law at the request of the Public prosecutor, who receives the complaints from individuals. They can condemn the operator to compensate a third party when an infringement has caused damages.

As regards existing installations, the authorisation decree has to be re-examined and modified if necessary in order to match with the principle of using best available techniques. This process mostly relies on the 10-year report all IPPC operators have to make. A technical regulation of 29th June 2004 defines the content of this 10-year report and sets the calendar for the operators' obligation to give this report to the authority.

Germany

With the Law of 27 July 2001 transposing the EIA Directive, the IPPC Directive and other EC environmental protection Directives (Article Law [1]) through targeted changes to various sectoral laws, the IPPC Directive was transposed into German law. This integrated approach was achieved through the imposition of sectoral law conditions requiring the licensing procedure to be coordinated and steps to be taken to avoid simply shifting the problems to other environmental sectors.

Under the German legal system, the activities listed in Annex I to the Directive have been regulated through three sectoral laws, in particular. Accordingly, amendments have been made to the Federal Immission Control Act, the Federal Water Act and the Closed Substance Cycle Waste Management Act. In particular, amendments were made, in the substatutory body of rules, to the Licensable Installations Ordinance and to the Permit Procedure Ordinance. It should be pointed out that as a result of the Licensable Installations Ordinance a large number of additional types of installations (or activities) have become subject under German law to the full requirements of the IPPC Directive. In addition, very many of the activities referred to in Annex I to the IPPC Directive are also subject under German law to the requirements of the IPPC Directive, even at lower limit values. All of the activities listed in Annex I to the IPPC Directive (types of installation) (with the exception of landfills) require a permit pursuant to the Licensable Installations Ordinance. Accordingly, the central licensing authorities are the authorities responsible, under Land law, for pollution control.

The effects of the immission protection law permit are highly concentrated, insofar as the permit covers other decisions taken by the authorities in relation to the installation. The immission protection authority calls on other authorities whose sphere of operations is affected by the project to deliver an opinion. Prior to this, the application documentation is first distributed radially to the participating bodies. Consequently, this form of participation does not involve parallel licensing procedures but merely the canvassing of opinions.

The decision, as far as the applicant is concerned, is taken by a single authority. In such cases, the waste management authorities, the nature conservation authorities and, where appropriate, the monument protection authorities are frequently involved. On completion of this procedure, the authorities vested with responsibility under the Federal Water Act will also be involved, even in cases where the installation does not need an additional permit under that Act but where the interests of water protection are affected in some other way. In many Federal Länder, the authorities responsible for immission protection law permits also have collective responsibility for other areas such as waste management, soil protection, water management and nature conservation; in this way complete coordination is guaranteed.

Italy

In Italy the IPPC permit will replace all the current environmental authorizations and will have to be renewed every 5 years. If the installation is EMAS registered then the permit validity is extended up to 8 years. The Competent Authority for granting the permit is the Ministry of Environment, at national level and the Regional Administrations, at regional level, depending on the production capacity and typologies of plants (power plants, refineries etc. have to address to the national authority).

APAT (Agency for Environmental Protection and Technical Services) and ARPAs (Regional Environmental Protection Agencies) are responsible for data collection, controlling and monitoring. APAT also provides support to the Italian Ministry of Environment for IPPC issues. APAT is in the process of setting up, with financing from the Ministry of the Environment, an Observatory for monitoring the application of IPPC at the regional, national and EU level.

The decree 372/99 also regulates operational changes, within the period of validity of the permit, since the operator must report them to the authority (Ministry or Region) providing a description of the change and an evaluation of expected consequences in terms of emissions of pollutants of and risk for the environment. The authority will then judge on a “case by case” basis.

National guidelines for BAT selection have been prepared by an ad-hoc Interministerial Commission, set up in 2003, composed by representatives of three Ministries: Environment

and Territory, Industry, Health, working in technical groups, with the support of experts from industry, science and public administration.

Netherlands

Since 1992 industrial pollution in The Netherlands has been dealt with by the Netherlands Emission Guidelines for Air (NeR). The guidelines were meant to harmonise environmental permits regulating emissions to air. Best Available Techniques were the starting point for establishing the emission standards and the associated techniques that are combined in the NeR. Also the principle of ALARA (As Low As Reasonably Achievable) was applied within the risk criteria framework. It was a joint effort by public authorities and industry.

When the IPPC Directive came into existence in 1996, with the aim of integrated pollution prevention and control, offering a high level of protection and dealing with harmonisation within Europe, this was supported by the Netherlands. However The Netherlands were of the opinion that no changes in the laws were required as they were of the view that the NeR and other instruments used to regulate emissions from industrial activities already worked in line with this directive. The EU disagreed with this and the Netherlands were forced to change existing legislation in line with the IPPC Directive. The implementation of the IPPC Directive is supported by Infomil, a semi-governmental organisation that advises local governments. This organisation also contributes to developing the BREFs.

In The Netherlands, BREFs are implemented within the existing system of the Netherlands Emission Guidelines as special guidelines for specific processes. This is in order to bring guidelines for industrial and other activities under the IPPC regime and other activities outside this scope within the same framework. In the meantime environmental legislation has been adapted and the new law will come into force, most likely, in December 2005. In practice the new law is already followed as the Council of State directly applies this Directive.

Spain

Directive 96/61/EC concerning integrated pollution prevention and control (IPPC) was transposed into Spanish legislation in 2002 through a national law “Ley 16/2002, de 1 de Julio, de prevención y control integrados de la contaminación”.

The enforcement of the law is the responsibility of the regional governments. In the procedure to obtain an IPPC permit both local and regional authorities are involved (for some permits also the water authorities of the Central Government). In the first instance it is the local authority that evaluates the installation and the public is allowed to comment on the

application. The regional government (environmental authorities) takes the decision –issuing the permit- after other authorities/departments have delivered their opinion.

Sweden

An application for a permit for an environmentally hazardous activity is examined by an environmental court. The Government can prescribe that an application for a permit for certain types of activity is to be examined by the county administrative board. If the environmentally hazardous activity can be accepted as having little impact on the environment then the Government can prescribe that a municipal board examines issues regarding permits.

The Annexes to the Decree (1998:899) on Environmentally Hazardous Activities and Health Protection list the activities which are to be considered for permits by the environmental court (A activities), county administration (B activities) or municipal board (C activities). The activities covered by the IPPC Directive are so called A activities or B activities and are therefore examined by an environmental court or county administration.

It is stated in the Environmental Code that the Swedish Environmental Protection Agency, the Swedish Legal, Financial and Administrative Services Agency, the Swedish Rescue Services Agency and the county administration must, where necessary, be party to the case in order to look after environmental interests and other public interests. A municipality may, furthermore, be represented to safeguard environmental interests and other public interests within the municipality. The Swedish Board of Fisheries is also able to comment during the case under the conditions stated in the provision.

The decision on whether the application is complete, the implementation of the supplementary process, notification of the case, and the preparation of the case is usually carried out by the examining authority, which subsequently passes the issue of the permissibility of the activity over to the Government, along with their report. The Government decides on whether the activity should be allowed or not. This decision is then binding on the examining authority. The Government can also lay down certain conditions for the activity. The matter is then returned to the examining authority, which is then to continue dealing with the matter, to issue the final permit to begin the activity and communicate the conditions that apply to the activity. A decision on permissibility in accordance with Chapter 17 of the Environmental Code means that the Government has decided that the activity may take place. The decision that the operator may begin the planned activity is then made by the licensing authority. As stated above, this process is integrated even although various competent authorities are involved in the examination.

United Kingdom

In England, Wales and Scotland, power to make regulations providing for a new pollution control regime was conferred through the Pollution Prevention and Control Act 1999. In England and Wales, the IPPC Directive is implemented by means of The Pollution Prevention and Control (England and Wales) Regulations 2002. In Scotland, the IPPC Directive is implemented by The Pollution Prevention and Control (Scotland) Regulations 2003. In Northern Ireland, primary legislation to implement the Directive was made in December 2002 by means of The Environment (Northern Ireland) Order 2002 No. 31534. The Pollution Prevention and Control Regulations (Northern Ireland) 20035 were made on 31 January 2003 and came into effect on 31 March 2003. All three of these Regulations – collectively referred to as "the UK Regulations" – are very similar and will, in due course, replace the UK system of integrated pollution control ("IPC") of industrial processes which, in England and Wales and in Scotland, was implemented under the Environmental Protection Act 1990 and in Northern Ireland under the Industrial Pollution Control (Northern Ireland) Order 1997. Experience gained under IPC was fed into the development of the IPPC Directive and provides a sound basis for implementation of IPPC for regulators and for many industrial operators.

In England and Wales, the Environment Agency has responsibility for permitting about 85% of the IPPC installations. However, the relevant local authority - usually the district, London or metropolitan borough council in England and the county or borough council in Wales – has this responsibility in respect of the remainder, which are installations in some sectors whose activities are regarded as generally presenting a lower pollution potential. This arrangement also preserves regulatory continuity for most of the installations concerned. The Scottish Environment Protection Agency and the Northern Ireland Environment and Heritage Service are responsible for permitting IPPC installations in Scotland and Northern Ireland respectively. These bodies are referred to as "the regulator" or "regulators".

Throughout the UK, every installation subject to IPPC has a single, readily identifiable regulator which is solely responsible for the permitting procedure and the associated setting and enforcement of permit conditions. Although only one "competent authority" is thus involved, the UK Regulations all contain requirements for the relevant regulator to consult other statutory organisations about each IPPC permit application. These always include the relevant health authority, the Food Standards Agency, the relevant nature conservancy council and the local authority, with other organisations specified according to the nature of the activity or activities carried out at the installation. In determining whether to grant the IPPC permit application, and if so with what conditions, the regulator is required to consider any representations received from these or any other organisations or persons.

The UK Regulations place a duty on regulators to follow developments in BAT. Furthermore, the incorporation of Annex IV of the Directive into all the Regulations also has the effect of requiring regulators to do this since item 12 of the Annex refers to information on BAT developments. UK regulators play an active part in the work of the European IPPC Bureau on producing BREFs, in that way becoming familiar at an early stage with BAT developments. Furthermore, the regulators work with industry experts in developing national guidance and in contributing to the UK BREF process, thus creating additional fruitful means of identifying developments in BAT.

CONSULTATION OF HEALTH EXPERTS

A questionnaire was sent out to workshop attendees to describe the role of the health consultee in their respective Member States. The following questions were asked:

(i) Who is consulted?

(ii) How are they consulted?

(iii) What advice are they expected to provide (with regard to health)?

(iv) How are their comments taken on board?

(v) How long are they given to respond to the consultation process?

The responses are summarised below.

Belgium

In Belgium (Flanders Region), the Flemish public health administration is the health consultee. The consultation is both in writing and in a discussion process. The consultee is expected to provide a motivated judgment concerning the public health aspects of the planned activity as well as – where the activity is admissible from a health point of view – the terms under which the activity poses no unacceptable risk to human health.

In a discussion with other advisory groups an attempt is made to provide a consensus advice to the Government, which issues the permits. Consensus or majority and minority viewpoints are then given to the competent authority that makes the final decision. The consultation time varies between one (appeals) and two months

Bulgaria

In Bulgaria, the Ministry of Health, Ministry of Regional Development and Welfare and hygienic experts (epidemiological inspectorates) are consulted as statutory consultees. They are usually given a week or two to respond to the consultation process but not more than month.

If the case is important or/and difficult they are invited them to participate in the "consultation meeting" which is part of the procedure for issuing IPPC permits. At that meeting the terms and conditions within the permit are negotiated.

The consultees are expected to provide advice mainly connected with the conditions of the permit, concerning emissions from the installation (emissions to air, water, noise and odour emissions, diffuse emissions, waste generation and treatment) and the possible/approved environmental effect (including human health). If it concerns a new installation, the distance from the site of the enterprise and the residential area is very important.

All the comments are taken on board, but sometimes they are negotiated depending if the comments are based on a legislative document, expert's opinion, researches or analysis etc.

Czech Republic

In the Czech Republic the Regional Hygiene Officer (RHO) is consulted as a Statutory Consultee. The RHO has the following obligations:

- in procedures on granting an integrated permit, shall lay down the binding conditions for operation of a source of noise or vibrations if the hygiene limits cannot be met,
- from the standpoint of public health protection, shall control the integrated permit or operation of the installation at a time agreed with the inspection or, in case of the procedure pursuant to this act, at a time agreed with the Authority,
- shall limit or terminate the operation of an installation or part thereof, if futher operation thereof would or could cause serious damage to human health,
- shall impose fines pursuant.

Currently under the IPPC Act the competent authority lays down the binding conditions for the operation of a source of noise or vibration if the hygiene limits cannot be met. It depends on the authority if other special conditions for the protection of human health are taken. The competence of the RHO is limited to the issuing of mandatory instructions for public health protection concerning noise and vibration factors. However, in August 2005, an amendment to the Czech Republic's IPPC Act is to be issued, which will suggest that the competence of the RHO is longer limited to the issuing of mandatory instructions for public health protection concerning noise and vibration factors and will allow the RHO to assess all problems of health under IPPC.

The competent authority is obliged to include the health protection requirements into the integrated permit, that are set forth in the standpoint on health risk assessment pursuant to the Act on Public Health Protection.

The RHO is given a maximum of 30 days to respond to the consultation process after they receive the application. The response is provided in the form of a statement, which must contain in particular an evaluation of the proposal for binding conditions for operation of the installation and / or proposals for further binding conditions as appropriate, that it proposes should be included in the integrated permit

Denmark

The Regional Health Officer (RHO) from the Ministry of the Interior and Health is the health consultee in Denmark. The draft permit is sent to them for comments (part of the general hearing on the draft permit where also the applicant, the municipality, neighbours etc participates). The permitting authorities are allowed to contact the RHO if they have health related questions of a more general nature or questions that they need to clarify as part of a specific permitting process. In connection with a hearing of a draft permit the RHO is expected to give specific comments e.g. if they find that the facility in question to their view constitutes a health risk for the surroundings, why this is and, if possible, what should be done to minimise or remove the risk.

In some (rare) cases the Health Officers are asked to provide information in relation to possible health problems in areas around industries that are about to get a permit. In cases where it is already known that pollution of e.g. the soil has taken place e.g. due to the activities of an individual or maybe more industries the Health Officer can be asked to provide guidance to the public on how to act in relation to letting their children play on open soil or on how to handle vegetables grown in the soil.

The permitting authority will normally not issue a permit if the Health Officer has produced negative comments on the draft. A subsequent discussion between the authority and the health officer will often lead to changes in for example the conditions, after which changes the permit will be issued. The consultation period lasts between 3 and 8 weeks (the statutory hearing period implemented as a result of the PPD directive).

France

In France, the permitting authority consults the local Director for Health (i.e. the local body of the Ministry for Health) through a formal consultation process. After the application has been sent to the permitting authority and is complete, a copy of it is sent to this Director. The Health Directors are expected to give information about the potential toxicity of emitted substances, and the presence of particularly sensitive people around the future installation. However there is no regulation which defines precisely the scope if the advice.

The permitting authority decides whether it takes in account or not the advice, and in which way it considers it. In the final report made by the permitting authority however, the content of the advice should be reported and the authority has to justify the way it has taken the advice into account. As for all other bodies consulted in France, the Health Director is given 45 days to respond to the consultation process.

Germany

In the State of North-Rhine-Westphalia (Germany) the State Environment Agency (LUA) can be commissioned by the Licensing Agency (Staatliches Umweltamt, StUA). The State Agency has health physicians and toxicologists which give their assessments about possible effects of pollutants released by installations on the population, who are consulted via direct contact between the Licensing Agency and the State Agency.

The health experts are expected to provide advice to ensure the protection of the population which is possibly exposed to pollutants released by relevant installation. These comments have to be considered in the whole licensing process. The consultee is given a few weeks to respond to the consultation process.

Ireland

In assessing Licence applications, the Irish EPA will consult with Directors of Public Health where health may be a concern.

Netherlands

In the Netherlands consultation of health experts is not a regular part of licensing of industrial activities. In general the opinion is that once environmental emission values are followed there is no extra or unacceptable health risk involved. Under specific circumstances such as very big industrial activities or activities in an area where there is agitation within the population the licensing authority might decide to involve health experts. For extensive industrialactivities this might be because of the necessity of an Environmental Assessment Report. In this case most likely research institutes and agencies will be involved while the local or regional public health department is involved in an advising committee.

When there is strong involvement of the public or specific pressure groups, and an Environmental Assessment is not needed, often the public health department will be asked by the authorities either to do a risk assessment or to advise in this process. This health department would also be involved in communication with the public. One of the most important instruments available for health screening is the so called Health Impact Assessment. This instrument makes it possible both in a qualitative and a quantitative way to

give insight into the additional risks for the population within a certain area also in the light of the existing background exposure. All this has to be done in line with the licensing programme.

Sweden

In Sweden, the licensing authority consults experts on environmental medicine at a university or at a regional hospital if available. There is cooperation between these experts, even on regional level there is therefore access to competence at the university if necessary. The consultation period is normally one month, however if it is necessary more time can be requested (up to a few months).

When the application is completed according to the regulation the authority must publish information on the application in the local papers. The application is sent to a local office where everybody who is interested has the right to take part in the consultation. Regional and local authorities are at the same time asked to give their opinion on the application. If it is of importance the authority may also consult an expert on environmental medicine for his/her opinion.

The expert is expected to give their opinion on the environmental impact assessment (EIA), if the information in the EIA is correct, complete and relevant. In their answer they give an evaluation of the planned activity and if the emissions can be accepted, or if it is necessary to reduce the impact from the activity or even to refuse a permit. They also give advice about monitoring and if it is necessary to do an epidemiological study.

All the written opinions from different authorities and experts are communicated with the other parties and the applicant is asked to answer to the opinions put forward in them. The decision on the permit, restrictions and emission limit values are based on all this information.

United Kingdom

The consultees are the Primary Care Trusts (PCTs) in England, the Local Health Boards in Wales, the National Health Service Boards in Scotland and the Health Authority in Northern Ireland. A copy of the application is sent to the consultees asking for comment soon after the application is submitted to the permitting authority.

In England and Wales, the Health Protection Agency (HPA) supports PCTs and LHBs in fulfilling their responsibilities as Statutory Consultees within the IPPC regime. The HPA teams have access to a wide variety of expertise to help inform the public health response. The PCTs and LHBs are expected to offer their public health opinion of the installation,

based on information provided by the HPA together with their own knowledge particular local health problems they consider relevant, and the presence of sensitive subgroups within the local population.

In Scotland, the NHS Boards are supported by Health Protection Scotland (HPS, formerly SCIEH), which has produced guidance to assist in extracting information of interest from IPPC applications for Public Health purposes and in formulating a more detailed response to SEPA if desired. NHS Boards are however free to comment on any aspect relevant to the potential impact of an installation on the health of a local population. However, there is no statutory requirement in terms of the nature of the response required from a NHS Board.

The key areas on which the consultees are expected to provide advice include:

- Advice on any particular local health problems that they consider relevant.
- Consideration of the likely impact of releases and activities on human health (both acute and chronic).
- To provide the necessary local focus for professional comment on health risk.
- To be aware of the implied legal duty to make properly considered responses.
- To collect socio-demographic data in order to identify at risk groups in the community and advise the Regulator of specific health risks associated with vulnerable groups.
- To place risk into context and differentiate between hazard and risk.
- To communicate risk to the public in the context of other every day hazards.
- To assist the Regulator in setting permit conditions intended to safeguard health.
- To conduct dialogue with other consultees in order to obtain a holistic public health view and avoid duplication of effort.

Comments must be considered by the regulator and either reflected in relevant permit conditions or an explanation must be provided in the decision documents to explain why the comments were not taken into account. The consultees are given up to 28 days to respond to the consultation process, plus they are given the opportunity to feed in at any time prior or post permit issue.