

**The application of toxicity-based  
criteria for the regulatory control  
of wastewater discharges.**

**RESPONSE COMPENDIUM**

March 1997



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**ENVIRONMENT AGENCY  
DIRECT TOXICITY ASSESSMENT NATIONAL CENTRE**

# **The application of toxicity-based criteria for the regulatory control of wastewater discharges.**

## **Response compendium**

**A compendium of consultees replies and the Agency's position on the issues raised in the consultation document 'The application of toxicity-based criteria for the regulatory control of wastewater discharges'.**

March 1997

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ENVIRONMENT AGENCY



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## **1. Executive Summary**

During July-October 1996 the Environment Agency conducted a consultation exercise on its proposals for 'the application of toxicity-based criteria for the regulatory control of wastewater discharges'. This provided industry and other interested parties with an opportunity to comment on the proposals and an opportunity to debate the major issues was provided at a meeting held at Torquay (29-31st October 1996). The consultation process was considered to be a successful and worthwhile exercise, by both the Agency and external participants. The Agency has considered all of the comments and replied to all those who responded.

The use of direct toxicity measures for effluent control and for environmental monitoring were generally seen as a positive move towards better environmental protection. Debate centred on how the measures should be implemented. In particular consultees wanted to see the introduction of DTA as action levels which trigger toxicity reduction measures within improvement plans rather than as pass/fail compliance limits within licences. Consultees also thought the DTA initiative should proceed via a demonstration programme. This would allow experience to be gained from 'real world application'. The programme will be scoped and managed by a joint industry (CIA, CBI, WSA) and regulator (Environment Agency, SEPA) steering group. The programme will consist of a number of projects in which a revised protocol will be tested. This protocol uses information on environmental impact to prioritise sites, takes into account costs and benefits and includes the use of action limits and improvement plans to achieve toxicity reduction. Information sheets will be produced during the course of the programme.

This document represents a summary of the comments on the proposals and the Agency's position on particular issues.

## **2. Introduction**

The Environment Agency is committed, through its R&D programme, to the development of effective 'tools' for pollution control which will help industry better target investment for environmental improvements. The Agency and the Scotland and Northern Ireland Forum for Environmental Research (SNIFFER) have sponsored collaborative programmes to test protocols to derive and monitor toxicity-based licence conditions. Research has been directed to select and develop suitable methods and towards the production of quality data. Proposals for the selection of candidate discharges; toxicity reduction; the determination of toxicity-based licence conditions; compliance monitoring; cost liabilities and the reporting of information; and the responsibilities of the regulator and regulated have also been developed.

The Agency believes toxicity-based measures can be used effectively to control toxic discharges and bring about environmental improvement. Much of the research effort has been directed at developing a consistent approach, protocols based on sound science and suitable methods and laboratory systems that deliver high quality data.

The proposals were outlined in a consultation document as part of a consultation exercise with industry and other interested parties. The exercise was supported by the Scottish Environmental Protection Agency (SEPA) and the Environment and Heritage Service of the Department of Environment-Northern Ireland.

## **3. The Consultation Exercise**

Proposals for toxicity-based licencing were launched by the Environment Agency at a Society of Environmental Toxicology and Chemistry (SETAC) conference at Luton University on the 15-16th July 1996. This conference was attended by over 200 people representing more than 110 organisations. A press release was also distributed on the 16th July and many periodicals covered the launch including:

Anglers Mail

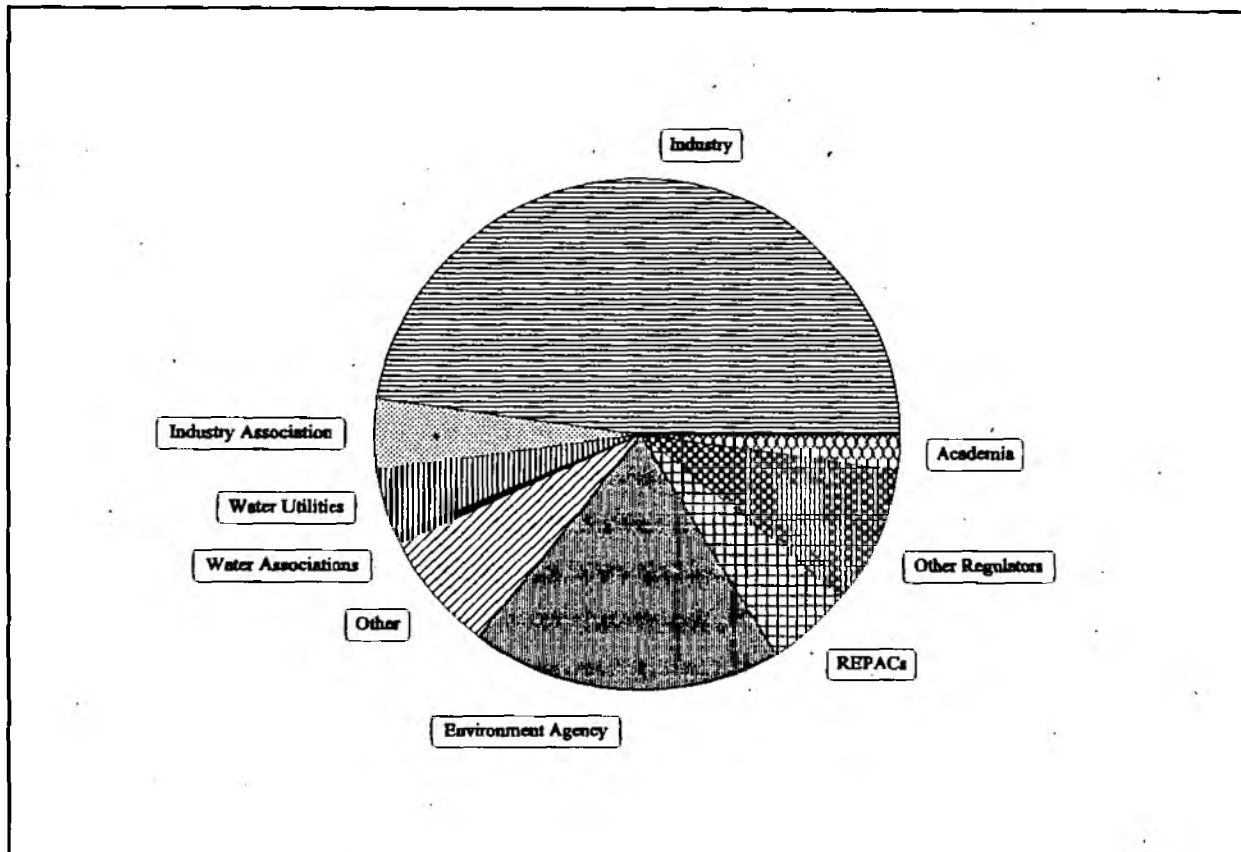
Paper Federation of GB- Newsletter No. 42

ENDs Report	Industrial Environmental Management
Environment Action	The Surveyor
Environment Business	Water and Effluent Treatment News
Environment Protection and Technology	Water Bulletin
Environmental Information Bulletin	Waste and Environment Today
Pollution-Environmental Policy and Technology	

Following the press release many requests were received for the consultation document. Potential consultees were also identified from various Environment Agency databases. Over 3000 consultation document packs were disseminated during the consultation period. The packs each contained:

- The consultation document: 'The application of toxicity-based criteria for the regulatory control of wastewater discharges';
- Support paper for the consultation document;
- Guidance on the format for replies;
- Flyer for the Environment Agency R&D Technical Report 'Toxicity-Based Consents Pilot Study';
- Flyer for the 'Direct Toxicity Assessment (DTA) Seminar and Workshop' in Torquay.

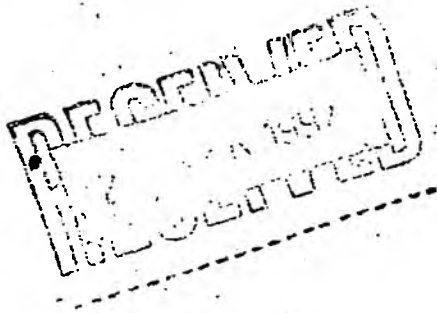
A breakdown of the recipients of the document is shown in Figure 1.



**Figure 1.** Sectors receiving the consultation document (percentages). "Other" includes environmental groups, consultancies and press; REPAC is the Regional Environment Protection Advisory Committee.

The period for written responses ran from 16th July 1996 to 30th September 1996. In total 111 replies were received largely from industry and their associations. Both DoE and OFWAT were also involved in the consultation process. A breakdown of the sectors that replied to the document is shown in Figure 2.

Date: 79/3/97



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Dear Sir/Madam,

**Response compendium for the consultation exercise 'The application of toxicity-based criteria for the regulatory control of wastewater discharges'.**

As you are aware the Agency conducted a consultation exercise, during July-October 1996, on proposals for 'the application of toxicity-based criteria for the regulatory control of wastewater discharges'. The proposals were outlined in a consultation document. The document provided industry and other interested parties with an opportunity to comment on the proposals. An opportunity to debate the major issues was provided at a meeting held at Torquay (29-31st October 1996). The exercise was considered worthwhile and generally very constructive.

The Agency has considered all of the comments received and replied to all those who responded. In addition we have produced a response compendium, which represents a summary of the comments on the proposals and the Agency's position on particular issues, which we have enclosed with this memo. This document will be sent to the consultees who responded and anybody else that requests it. The programme is under continued development and it should be noted that the statements in the document represent the Agency's current position in respect to Direct Toxicity Assessment (DTA).

As discussed at the Torquay meeting the DTA initiative will be progressed by means of a demonstration programme. A steering group has been set up to scope and manage this programme with representatives from the Environment Agency, The Scottish Environment Protection Agency, the Water Services Association, the Confederation of British Industry and the Chemical Industries Association. Information sheets will be produced to keep you informed of progress, the first of which will be available soon.

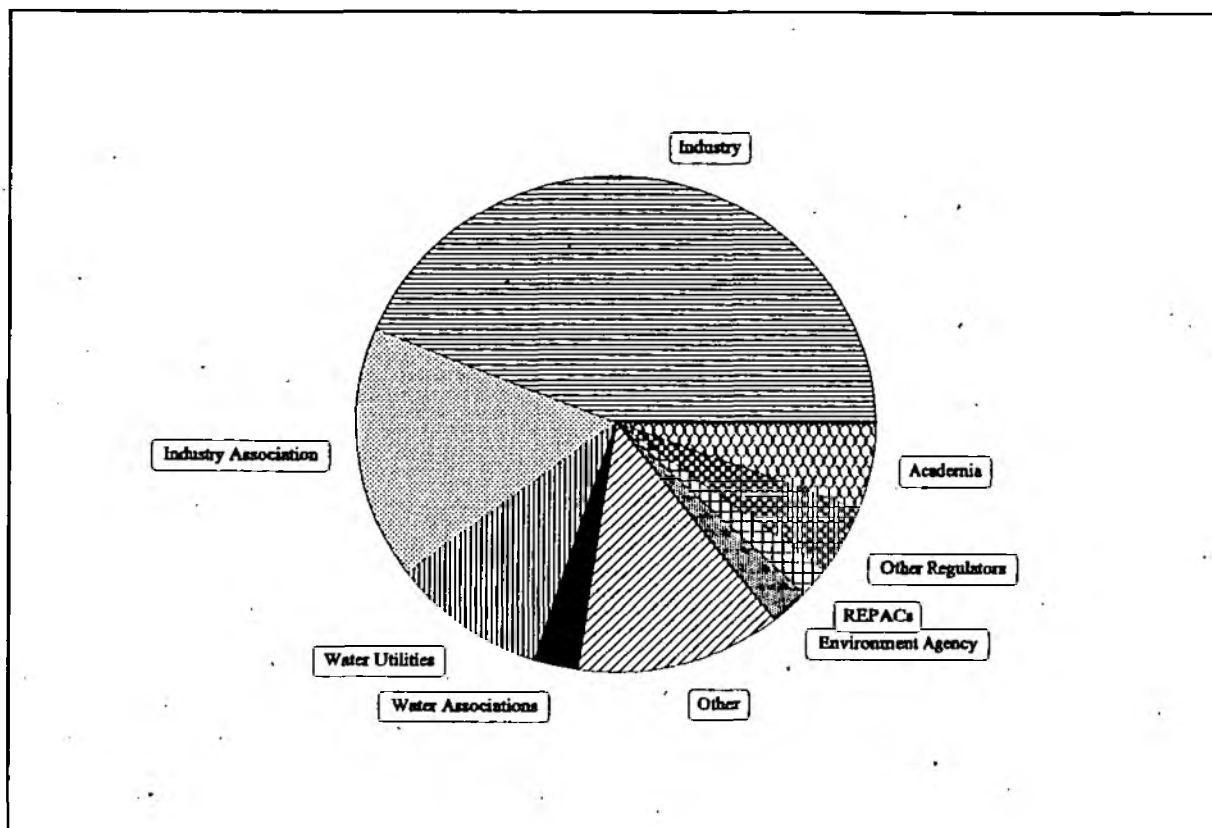
If you require further copies of the response compendium, please contact us at the address at the bottom of the page. Further discussions on the implementation of DTA will continue at various fora.

Yours faithfully,

Dr Dave Forrow  
DTA National Centre  
Environment Agency







**Figure 2.** Sectors replying to the consultation document (percentages). "Other" includes environmental groups, consultancies and press.

Following the closing date for written replies a major symposium and workshop, hosted by Zeneca (Brixham Environmental Laboratory), was held in Torquay on the 29-31st October 1996. This gave industry and other interested parties an opportunity to debate the major issues and suggest credible alternatives to the proposals which would achieve the Agency objectives in the most efficient manner. The workshop was attended by over 170 people representing more than 95 organisations. Four workshop sessions were held, each to discuss four major issues identified from the written replies. These are listed Table 1.

**Table 1:** The major consultation issues discussed at the Torquay workshop and symposium 29-31st October 1996.

ISSUE	% of written replies that raised issue
How do we take account of variability?	50.0
How should cost and benefit be dealt with?	46.5
Which ecotoxicity statistic(s) should be used to determine the point of protection and the achievement of desired ecotoxicity targets?	40.4
How should the point of protection be determined and who should be involved?	40.4
What information should be considered in the prioritisation of discharges and how will the decision be made to use DTA?	36.8
How should the DTA approach be integrated with the IPC need to assess the BPEO?	34.2
Should the introduction of DTA be based on action levels or compliance limits?	34.2
Should environmental protection be based on risk assessment or environmental impact assessment (or both)?	28.1
How should self-monitoring be undertaken and is there a need for separate Agency monitoring (audit)?	24.6
Are tests undertaken on indigenous species essential or is it more important to have methods that are consistent and based on high quality information?	21.9
How should DTA procedures be progressed (by implementation on a single discharge or catchment basis, by further pilot studies etc.)?	20.2
How will discharges to sewer be dealt with under DTA procedures?	18.4
Which measures of environmental quality should be used to demonstrate sustainable environmental benefit?	9.7
Which source of diluent water should be used for ecotoxicity testing?	7.0
Which data need to be made available from the pilot study and for what purpose?	5.3
Toxicity is perceived to be an emotive word-is there a suitable alternative?	4.4

Following the meeting Zeneca (Brixham Environmental Laboratory) produced proceedings which have been distributed to all delegates. In addition to the consultation document and the Torquay symposium, industry had the opportunity to feedback their comments at other fora as follows:-

Chartered Inst. of Water and Environmental Management	South-East	15 Nov 1995
Chartered Inst. of Water and Environmental Management	West Midlands	16 Jan 1996
Royal Commission on the Environment	London	1 March 1996

Toxic Impact of Waste on the Aquatic Environment	Loughborough	14-17 Apr 1996
Waste Water Network	Manchester	11 Sept 1996
Paper Ind. Research Assn. Meeting	Leatherhead	17 Sept 1996
Effluent Management Forum	Bristol	25 Sept 1996
Industrial Ecotoxicology Conference	London	4/5 Nov 1996
Chartered Inst. of Water and Environmental Management	Manchester	7 Nov 1996
Society of Chemical Industry Open Forum	London	8 Nov 1996

It is envisaged that the Environment Agency and industry will hold a number of further workshops to discuss some of the technical issues (e.g. methods, laboratory approval scheme etc).

#### **4. Consultees replies and Agency positions**

All points raised by consultees have been considered. The programme is under continued development and it should be noted that these statements represent the Agency's current position. The first thirty issues are common key issues that were raised by a number of consultees; the remaining issues are more specific issues raised by fewer consultees. The issues raised (bold text) and the corresponding Environment Agency position (normal text) follow:-

**1 Is there a need for Direct Toxicity Assessment? What information should be considered in the selection and prioritisation of discharges and how will a decision be made to use DTA? What type of discharges are expected to be controlled by DTA?**

As stated in the consultation document, current chemical-specific controls on wastewater effluents are always not adequate because only 0.1% of listed chemicals are controlled by statutory environmental quality standards and these standards do not take into account interactive ecotoxicity between chemicals. Even though some effluents may be subjected to treatment the discharges may still be toxic as these plants have not usually been designed to remove 'toxicity'.

As presented at the DTA Torquay workshop, there is an appreciable proportion of inland waterways where the biological quality is significantly poorer than expected, based on assessments of chemical quality. Where such situations can be shown to be attributable to toxic discharges, the Agency takes the view that additional regulatory controls may be warranted. The Environment Agency proposes to introduce Direct Toxicity Assessment (DTA) as a tool which will be applied selectively and only where appropriate to help provide better protection of the environment. This does not mean that current chemical conditions will be replaced.

The major factor in prioritising discharges for control will be evidence of impact i.e. application of DTA will, initially, be driven by environmental need although other factors will also be taken into account, as shown below. The original protocol presented in the consultation document is being modified in the light of comments received.

Evidence of impact: This can be assessed by biological surveys (macroinvertebrate, fish, macrophyte etc) or by DTA of the receiving waters. A discharge causing impact would be a high priority for control, irrespective of whether or not existing consent conditions are being met.

Use related objectives/water quality objectives: Failure to meet current WQOs or plans to upgrade receiving waters to meet more stringent WQOs in future would be important environmental drivers. Although there are no ecotoxicity targets within WQOs at present it may be considered appropriate to incorporate them at a later date. A significantly toxic discharge entering a receiving water intended for agricultural irrigation, fisheries, drinking water etc would assume a higher priority for control by DTA than one discharging into waters which do not have such high quality requirements.

Chemical class > biological class: Locations of concern may be identified by comparing the Environment Agency national chemical class with the biological class for freshwater rivers. Where the chemical class (which is based on a limited number of sanitary determinands) indicates good quality but the biology is poor then this warrants further investigation to assess whether, or not, this is due to toxicants not accounted for in the chemical classification scheme. Where both chemistry and biology are poor then further investigation is required to assess what is responsible for the poor biology. This may result in particular catchments, or individual discharges being targeted for control using DTA.

Risk of impact: Of lesser immediate priority are sites where there is a calculated high risk of impact yet no demonstrable impact as determined using current techniques. Application of DTA in these instances will only be considered once the effectiveness of applying DTA techniques to sites where measured impact has occurred is demonstrated. However risk assessment will be used to identify those discharges most likely to be causing a measured impact in the receiving water. Risk assessment will consider any allowable zone of deterioration and initial dilution/dispersion. This will require an assessment of ecotoxicity of the discharge (possibly based on ecotoxicity screening information) and of the available dilution.

Sensitivity of receiving water: If the receiving water body is deemed particularly sensitive then any discharge which is considered to be potentially toxic in the receiving water will have a higher priority. A sensitive water may include Sites of Special Scientific Interest, nature reserves or sites with protected species.

Type and nature of the discharge: The type and nature of the discharge will be considered before applying DTA control measures. If the Agency consider that the discharge is adequately controlled by current chemical criteria then there will be no need to apply DTA measures. Any existing data on the discharge will help in making this decision.

Involvement of LEAPs: The need for environmental improvement and for toxicity reduction will be considered on a catchment by catchment basis as part of a Local Environment Agency Plan(formerly Catchment Management Plans). LEAPs may require that ecotoxicity is reduced to meet use-related needs.

Costs and benefits: The Agency will take into account costs and environmental benefit in its goal to maintain and improve water quality in the UK. The Agency is not under an obligation to do full cost-benefit analyses and cost will not be the main driver in prioritisation.

In prioritising discharges for control by DTA the Environment Agency will make every effort to ensure decisions are fair and transparent. Industry will be able to provide additional evidence (of adequate quality) which may be used in discussions with the regulator in the prioritisation process. Any discharges which are controlled by a Water Resources Act (1991) consent or an Environmental Protection Act (1990) authorisation may be reviewed and DTA used to provide a more effective form of control. This would include landfill leachates and agricultural effluents discharging to controlled waters.

**2 Should the introduction of DTA be based on action levels or compliance limits?**

This was a major issue of concern for industry in the consultation process. There was overwhelming support for action levels which trigger toxicity reduction measures within improvement plans rather than compliance limits within licences. The Environment Agency's DTA objectives may be achieved through action levels and improvement plans providing there is co-operation from industry. The Agency supports this refinement to the proposal but reserves the option to implement compliance limits within licences if the level of co-operation is insufficient to meet objectives. Improvement plans can be written into discharge licences and are therefore enforceable. Default on the agreed plan could lead to prosecution. The improvement plans and ecotoxicity action levels should be clear and achieved over reasonable timescales. The Agency recognises that most effective progress towards environmental protection, with the minimum of bureaucracy, will be achieved through co-operation and agreement between dischargers and the regulator.

There will be an opportunity to explore the success of action levels and improvement plans during the demonstration project. A final decision on action levels or compliance limits will be made by the Agency following this project. Existing toxicity-based consents will remain in place but will be reviewed following the demonstration project.

**3 How will Sewage Treatment Work (STW) discharges and discharges to sewer be dealt with under DTA procedures?**

The Environment Agency accepts that ecotoxicity of effluents arising from STWs merits special attention due to technical complexities involved in detecting sources of ecotoxicity, and the legal issue of apportioning liability and controlling the toxicity. Although protocols exist for toxicity reduction evaluation in the US for STW (e.g. USEPA, 1994a) the situation in the UK is somewhat different. Many UK STWs receive a significant amount of trade effluent, unlike their US counterparts, making the task of ecotoxicity sourcing more technically and legally onerous. It was evident during consultation that the assignment of responsibilities between the sewerage

undertakers and the Environment Agency with respect to how DTA could be applied was complex. In particular, the powers of the sewerage undertakers to place controls on trade wastes discharged to sewer and to trace ecotoxicity within the sewer catchment were questioned.

Sewerage undertakers charge to receive trade wastes and the Agency believes they should take some responsibility for the ecotoxicity of the final effluent. Based on existing legislation, it will be the responsibility of the sewerage undertaker to identify the sources of ecotoxicity and formulate improvement plans. Although the Agency believes mechanisms do exist for trade effluent control and toxicity reduction within STWs it is recognised that these may involve more complicated improvement programmes and require longer timescales than for 'direct' discharges to receiving waters.

It is expected that STWs will be involved in the demonstration programme. This will give all parties an opportunity to clearly identify the responsibilities of the water companies and the Environment Agency in relation to the Water Industry Act (1991) and Water Resources Act (1991) and how best to approach the process of ecotoxicity source tracing and toxicity reduction.

There was concern that the potentially variable nature of inputs to STWs may mean that toxicity reduction procedures would have to be conducted repeatedly. This possibility will be addressed in the demonstration programme by a regulator and industry technical working group. The TBC pilot study suggested that STW effluents were not as toxicologically variable as may have been thought. However this is based on a small number of samples.

Some sewerage undertakers already have plans to control toxic influents in order to protect the operation of their works. However the proposed DTA test battery differs in some respects from the test battery currently being developed by sewerage undertakers to protect their plants, rather than to ensure the protection of the receiving environment.



#### **4      How should cost and benefit be dealt with?**

This was one of the major issues of concern to consultees. Written replies commented on the issue but few suggested credible ways forward. However there was constructive debate at Torquay on options to progress cost and benefit issues.

The Agency will take into account costs and benefits when following the protocol for the use of DTA for effluent control. The protocol is being modified to reflect this at each major stage of the process and the modifications will be evaluated during the demonstration study.

The Agency supports the concept of 'the polluter pays' in relation to DTA and feels the polluter has a responsibility to make every reasonable effort to control the release of toxic effluents to receiving waters. As the costs of introducing improvement measures will be site-specific they cannot be fully quantified prior to initial testing.

It should be noted that although the Agency has a duty to 'take into account the likely cost and benefits of the exercise' (Environment Act 1995, Section 39) it does not always have to carry out a fully quantitative cost-benefit analysis (New tools are currently being developed by the Agency which may help to fulfil this duty). The Agency's cost benefit duty is considered a defence for the Agency not to take socially and economically irresponsible measures to achieve environmental benefit. However, if dischargers consider the cost of any proposed action cannot be justified given the environmental benefit then they may make representation either to the Agency, to the Secretary of State (industry) or to OFWAT (water Plc's).

The Agency will describe the environmental benefit and consider presentation from industry on costs in making decisions to progress with further action, on a case-by-case basis. All cost or benefit determinations by industry and the Agency should be fully transparent. As it is difficult to put monetary values against some environmental benefits these assessments may not necessarily be totally equitable units (e.g. monetary value) and therefore 'balance sheets' do not necessarily have to be positive in financial terms before action can be taken. The Agency will make every

effort to be reasonable in these assessments. 'Costs' could include social responsibilities such as job losses.

Toxicity reduction assessments will consider BATNEEC and will suggest reasonable timescales for improvement allowing expenditure planning. The Agency are looking into the possibility of licence charge reduction if the numbers of chemical determinands measured are reduced as a result of toxicity reduction measures (The current charging scheme is being reviewed in 1999).

There was concern amongst some consultees that site-specific DTA assessments may put companies in different geographical situations at a competitive advantage or disadvantage depending on the size and type of receiving water to which they discharge. Environmental protection based on site-specific characteristics (e.g. EQSs) is widely supported by UK industry and the Department of the Environment. The Agency supports this approach in relation to DTA and other control measures. This is consistent with expenditure appropriate to the specific needs of the receiving environment. There is an advantage in introducing site-specific DTA procedures in the UK early to mitigate fixed ecotoxicity emission standards being promoted by several countries within Europe.

## **5 How should DTA procedures be progressed?**

Consultees felt that there were many questions which needed to be addressed prior to full implementation of toxicity-based controls. It was suggested at Torquay that a demonstration programme should be set up as a next step. It is our intention that this programme will be a totally transparent application of a revised procedure using real discharges at locations/sites in the UK, which are still to be decided. The aim of the programme would be to evaluate a revised protocol in which the need for DTA is driven by environmental need, takes account costs and benefit, and which includes the use of action levels and improvement plans rather than ecotoxicity licence compliance limits. Toxicity reduction would be progressed through improvement plans in a stepwise fashion, taking into account costs and benefits at each stage.

The programme would be co-funded by the agency and industry and would be directed by a steering group consisting of representation from UK regulatory bodies (e.g. Environment Agency, SEPA) and industry (CIA, CBI, WSA). The demonstration programme will give industry and the Agency an opportunity to become better informed and to gain experience of using DTA. The results from the programme would be freely available and widely disseminated.

The Agency will ensure further consultation with interested parties in the UK and are also making international contacts to explore cooperation on protocols and bioassay methods.

**6 How do we take account of variability in the method, the discharge and the environment?**

There was concern from consultees that there were several sources of variability in ecotoxicological determinations of environmental samples and in predictions of the effects of the ecotoxicity of the effluents in the receiving water. The Agency recognises these concerns and the need to assess and take into account any sources of variability. Accordingly, these issues have featured prominently in the Agency's R&D programme and a number of safeguards to minimise the risk of false positive conclusions have been built into the proposals.

Method variability - There was concern that variability in the results from ecotoxicological testing was too high for these methods to be used for effluent control. The Agency's proposals represent state-of-the-art with respect to dealing with method variability for regulatory decision-making. Sound ecotoxicity test data depends on two things, the availability of robust methods and proficiency in their application. The Agency is promulgating the use of a small number of well-established and scientifically robust methods and, in addition, is setting minimum performance standards for those tests. The tests incorporate controls and standard reference toxicant testing to ensure good experimental procedure and that the initial health of the test organisms is satisfactory. Procedures to correct for possible effects due to salinity and pH are also available. Tests which are performed and fall outside the range of acceptable reference toxicant response limits or control response will be rejected.

The Agency has assessed the performance and variability of the recommended tests in intra- and inter-laboratory testing programmes using standard reference toxicants. The use of single substances for reference toxicants is defensible because a number of studies have shown that single substances reveal either similar or greater variability than mixtures (e.g. Parkhurst *et al.*, 1992). It is important to select the substance used as a reference toxicant such that the end result is affected by, for instance, variations in the health of test organisms or water quality. Some substances are rather insensitive to such factors and can give a false sense of precision as a result. Thus inadequate control of the required test conditions may go undetected. The Agency is aware of these technical issues and in 1995 commissioned an extensive research programme to address this subject. It became clear that, for most purposes, zinc sulphate was a suitable reference toxicant.

As with any form of measurement, some variability in the measured response is inevitable. Although the Agency is committed to controlling this variability, it will take residual variability into account when assessing the ecotoxicity of a discharge against an action level. When measured ecotoxicity is close to the action level, the benefit of the doubt will be accorded to the discharger using standard statistical procedures (see Whitehouse *et al.*, 1996).

It is important to remember that regulatory decisions are already made on the basis of ecotoxicity testing, notably to derive Environmental Quality Standards and to undertake classification, packaging and labelling of new products. Measures to ensure quality data for the introduction of DTA as a regulatory tool go beyond those used at present for chemical-based control.

Discharge variability - There is concern that DTA would be used with effluents which may be highly variable. This is not an issue which is peculiar to DTA. The Agency approach to sampling for DTA is the more variable the discharge is, the more samples that will be required to characterise the effluent. Therefore assessments will be on a case-by-case basis. It is in the interest of the discharger to generate a data set which is comprehensive enough to describe the highest level of ecotoxicity in order that toxicity reduction programmes reduce ecotoxicity to levels that will prevent action levels being exceeded in the future. There is a balance to be struck between

the costs of characterisation and generating a dataset of sufficiently high quality. The Agency are also looking into the possibility of using modelling techniques to predict worst-case ecotoxicity from a limited dataset (e.g. extreme value models as used in the US).

The Agency is interested in the development of rapid methods which may offer more cost-effective characterisation of effluents and possible development to on-line monitoring and has commissioned research in this field. However the use of such methods depends, mainly, on their commercial development and availability.

Environment variability - Changes in the physicochemical conditions and flows (or dispersion) in the receiving water will have an effect on the final ecotoxicity of the effluent. It is important to consider this when ecotoxicity action levels based on dilution of the discharge in the receiving water are set. Environmental variability is again an issue that applies to all forms of discharge control, not just DTA. The available dilution in the receiving water will be based on probability models in much the same way that chemical parameters are consented at the moment, using worst case low flows for risk assessment, though there may be modifications according to local physicochemical and climatic conditions. The Agency will take into account the 'background' ecotoxicity of intake water when conducting toxicological assessments.

**7 Should environmental protection be based on risk assessment or environmental impact assessment (or both)?**

This issue is not new or specific to DTA. The Agency believes that it should be proactive and should therefore base environmental protection on risk assessment. It is not appropriate for an environmental protection agency to be reactive and only respond when damage has occurred. At present the use of EQSs for chemical specific control are set based on the risk of ecological damage occurring. Therefore, the Agency proposes to use DTA for risk assessment in the future. However, prioritisation for DTA in the first instance will be based on evidence of impact. It should be noted that this will be based on a number of impact criteria including biological survey (e.g. macroinvertebrate, algal, macrophyte, fish) and DTA and chemistry of the receiving water

(water column and sediment).

The Environment Agency believes there is the possibility that the onus to demonstrate 'proof of no harm' could be placed on the discharger. It is expected that the Agency would do the majority of receiving water monitoring though the discharger may wish to provide its own evidence of no-harm in any dispute. As with BOD and other determinands the discharger would be responsible for paying for this additional evidence. The aim should be for industry and the Agency to co-operate to concentrate resources on those areas where it is most required. The risk of environmental damage from new processes can be tested at bench-scale or pilot plant level.

Data from receiving water monitoring will give an insight into the mechanisms which reduce effluent ecotoxicity in the receiving water but which may not be apparent in laboratory tests, e.g. losses of toxicants by biodegradation, sediment accumulation and volatilisation, and effects on bioavailability due to sorption onto suspended solids. Evidence of such processes may be used to modify ecotoxicity action levels on a case-by-case basis.

Concern has been expressed about the suggestion that an ecotoxicity condition might be introduced for discharges even if a favourable risk assessment was indicated after the characterisation phase. The primary factor determining the need for control by DTA will be evidence of impact. If the Agency moves toward risk assessment to identify discharges for DTA control in the future, those discharges where a risk of damage is indicated may be subject to this type of control.

## **8 Which measures of environmental quality should be used to demonstrate sustainable environmental benefit?**

There were several statements in the written replies from consultees indicating that DTA measurements were not suitable for regulating effluent discharges. However there was general agreement at the Torquay workshop that DTA is suitable as a measure of receiving water quality and as a tool to trace source ecotoxicity in wastewater discharges. The Agency believes that

biological effects measures, in association with chemical measures, are appropriate for both discharge control and as an assessment of receiving water quality. The measures of environmental quality which the Agency intends to use include chemical class or chemical survey, biological class or biological survey (microbiological, macroinvertebrate, macrophyte, fish etc), DTA of the receiving water and compliance with use-related objectives (e.g. SWQO, EC Directives). It is expected that the Environment Agency would do the majority of the monitoring of receiving waters though the discharger may wish to provide evidence of no-harm.

Clearly defined and agreed targets for environmental improvement will be important in gauging the success of toxicity reduction programmes. Industry, water companies, NGOs, and the public are involved, and contribute to the quality targets in LEAPs.

**9 How should the DTA approach be integrated with IPC, with existing chemical criteria and with waste minimisation?**

Integration with IPC: There was concern from some consultees that the introduction of DTA to control wastewater discharges was inconsistent with BPEO and IPC. However the final opinion of the delegates at the Torquay seminar was that DTA could fit into the BPEO framework. Some consultees suggested that IPC legislation (EPA, 1990) is only concerned with prescribed substances, but the Environment Agency does have powers to include any other conditions it considers appropriate into an IPC authorisation. A plan for toxicity reduction can be incorporated into an IPC improvement programme. The conclusion of ecotoxicity source tracing and toxicity reduction programmes is likely to involve the control of specific chemicals, improved housekeeping or an abatement option which, again, are consistent with actions in IPC. In some cases an abatement option may produce waste to another compartment (land or air). In these cases the BPEO will be considered. In addition DTA will follow the principles of BATNEEC which the discharger is responsible for demonstrating. Although there is some possibility of extending DTA to land and air, their success in controlling releases to water will be assessed before their application to other media is considered. There will be a chance to further explore the BPEO and BATNEEC issues in the demonstration programme.

Integration with waste minimisation: Measures to reduce effluent volume may indeed result in concentration of toxic components and therefore a lower PNEC. However, this will not have an adverse effect in risk assessment because the lower PNEC is counterbalanced by greater dilution in the receiving water (i.e. a more favourable PEC), assuming this is the only change to the discharge. DTA and waste minimization are, therefore, not inconsistent.

Integration with chemical-specific controls: There is a requirement to keep current chemical conditions in place because many are statutory. DTA, through toxicity reduction programmes, will direct effort to reduce the concentration of any chemicals which are demonstrated as being responsible for excessive ecotoxicity. This may result in revised limits for these chemicals in discharge licences on a site-by-site chemical-by-chemical basis. In addition, potentially bioaccumulative and persistent substances are currently better controlled by individual chemical limits. Other properties of the whole discharge such as hydrophobicity, lipophilicity, volatility are not considered directly in the protocol within the consultation document (some of these properties of individual substances are assessed in formulating EQSs). There will be an opportunity to consider such factors in the revised protocol during the demonstration programme.

**10 Is a laboratory approval or accreditation system necessary? Can it achieve high quality information and is there sufficient laboratory capacity for the introduction of DTA?**

Experience from the US has demonstrated that consistency of method application and the quality of data is vital to the success of any DTA programme. Laboratory approval/ accreditation schemes for ecotoxicity testing have been adopted in certain US states and in Canada. The Agency also believes a laboratory approval scheme is vital to the success of the DTA initiative in the UK and that industry would expect testing to be equitable, consistent and of high quality. Consultees generally supported these concepts.

The laboratory registration scheme will be an extension of existing systems (GLP, NAMAS) with which many laboratories are already familiar. The proposed scheme consists of two aspects: proficiency in the use of standard methods and a quality system to ensure integrity of data.



Ecotoxicology laboratories will be expected to apply for approval under the scheme to perform regulatory ecotoxicological testing. Intra and inter-laboratory variability has been assessed for a number of test methods and steps have been taken to reduce variability and to take account of residual variability in regulatory decision making. The Ecotoxicology Methods Guidelines will allow existing approved methods to be used providing certain essential steps specified in the guidelines are achieved. This will mean laboratories may not have to adopt new SOPs and accredit these new SOPs in order to attain approval unless there are unacceptable procedural weaknesses in their SOPs.

Checks on compliance with the SOP, integrity of test data and auditability of test data are part of the normal QA procedure of a laboratory which complies with GLP or NAMAS. Additionally, laboratories will be required to participate in a Quality Control (QC) scheme which is designed to promote the accuracy and precision of test data. Although such schemes are routinely used in chemical analysis (and are a requirement of accreditation under NAMAS) this is the first time that a QC scheme has been formally proposed in conjunction with ecotoxicity testing in the UK. This additional measure reflects the Agency's commitment to ensuring data, used for regulatory decision making and which will guide investment, are of the highest quality. For a laboratory which is already monitored under the UK's GLP scheme or is accredited under NAMAS, the extra requirements to register as an approved laboratory will be modest. Non-regulatory testing e.g. for TIE studies, internal monitoring or effluent management purposes may be performed in non-registered laboratories but test data intended for regulatory submission i.e. effluent characterisation and formal monitoring data, would need to be generated by a registered laboratory.

The next phase of implementation of DTA will be a limited demonstration programme and the Agency believes there is currently an adequate testing capability in the UK for this programme. With a phased prioritisation plan there would also be adequate capacity for initial implementation. During the period of the demonstration programme laboratories may wish to become proficient in the methods or obtain any necessary accreditation. A dischargers own laboratory can seek registration.

A proposal for a laboratory registration scheme will be ready for piloting as a part of the demonstration programme.

**11 How do we ensure methods are consistent and of a high standard? How will rapid methods be used in the DTA programme?**

The Agency recognises the importance of generating high quality information from ecotoxicity methods for DTA application and expects that the quality of data should never be an issue. Only established, performance-tested methods will be used in DTA programmes directly affecting regulatory decisions and steps to minimise the incidence of false positive results will be implemented. The Agency is promoting the use of a small number of tests for any particular application to ensure that quality control can be maintained. The Agency will wish to ensure that the best available procedures are employed for DTA purposes and so it retains an interest in new methods. A procedure for evaluating the performance of new methods against certain performance criteria has been developed. Some concern was expressed about the way in which the evaluations were carried out. This procedure will be revisited, paying particular attention to the requirement for minimum scores against certain, critical, criteria.

The Environment Agency and SNIFFER R&D performance testing programme identified the intra- and inter-laboratory variability associated with proposed tests. Procedures for promoting the precision and accuracy of testing have been embraced within the laboratory registration scheme and, in addition, procedures for taking variability into account in assessing compliance with an action level have been developed. The approach taken by the Agency is to accord the benefit of the doubt caused by variability to the discharger. The performance testing programme included the use of commercial testing facilities who are likely to be performing this sort of work when DTA is implemented, so the assessed levels of variability are considered realistic.

The laboratory approval/accreditation system will ensure testing is consistent and performed to the highest standards. Laboratories will operate to SOPs within the guidelines specified in the Environment Agency and SNIFFER Ecotoxicology Method Guidelines. Controls and reference

toxicants will be used in testing to ensure high performance of the operator and adequate initial health of test organisms. The Environment Agency and SNIFFER ecotoxicology guidelines also have guidance for treatment of difficult samples.

As with any new or existing procedure or product it is expected that techniques will be replaced or improved. New or improved methods will be therefore be developed or commercial products adopted for both effluent control and receiving water monitoring. The fact that methods may be subject to improvement should not be used to delay implementation. After suitable trialing, new methods or improvements to protocols will be implemented. This will take place within reasonable timescales to allow budgeting for changes, taking into account cost and benefit and familiarity of industry and testing laboratories to the changes.

The Agency is investing in the development of rapid methods which may be used for continuous monitoring and more effective effluent management. These methods must be related to significant ecological endpoints and provide adequate protection of the receiving water environment. The demonstration programme will provide an opportunity for further evaluating rapid screening tests but it should be recognised that availability of suitable methods depends on their commercial development.

Finally, biological survey methods for national classification schemes are currently in place with appropriate quality control procedures to ensure national consistency and quality of data. Site-specific surveys will be performed under the same QC conditions.

## **12 How should the point of protection be determined and who should be involved in its determination?**

There was overall support for the concept of allowing for dilution and dispersion in an area of the receiving water body (i.e. consistent with the chemical-specific EQS approach). As mixing zones are transient, a fixed point in the receiving body (point of protection) is proposed at which no acute ecotoxicity should occur. A worst case dilution at this point is used for the calculation of

the PEC. The area within this zone is the zone of deterioration where ecological damage may be tolerated. The size of this zone will be site- specific and depend on the use and sensitivity of the receiving water. For example, it would usually be unacceptable for the zone of deterioration to occupy the whole width of a river used by migratory fish. In some cases there may be no zone of deterioration in which case the no acute ecotoxicity action level would apply at end of pipe.

- As determinations of dilution/dispersion are crucial in setting the ecotoxicity action level then it is important that they are based on sound data. The Agency recognise that there is a need for improved assessments of the mixing and dispersion of effluents. Dispersion models are being determined at present both by the Agency and industry (often in collaboration).

The toxicity trigger level will be set in order that a no-observed effect level of ecotoxicity is achieved at the point of protection in the receiving water. Individual assessments will not therefore consider receiving water ecotoxicity. Where it is believed that several discharges are contributing to receiving water toxicity these would all be targeted for control.

All interested party are involved in the consultation process for developing Local Environment Agency Plans (formally Catchment Management Plans) but only the discharger and the Environment Agency (or any specialists working on their behalf) will be involved in direct discussions to set ecotoxicity action levels for a discharge.

### **13 How should the cost of testing be taken into account in the design of sampling programmes: in screening; characterisation; toxicity identification and reduction; monitoring?**

The cost of testing will be taken into account in cost and benefit determinations. It is likely that some initial testing may be required before full characterisation and toxicity reduction allowing potential costs to be provisionally determined.

The use of probability models for predicting worst case ecoecotoxicity from limited data sets and

discontinuation of the use of less sensitive methods at an early stage of the characterisation phase to concentrate effort on the most sensitive species can be explored further during the demonstration programme. Initial indications of the interest of commercial testing laboratories and consultancies suggest that there will be competition for testing work which should also help keep the cost of testing down.

There were a number of concerns expressed about the need to rely on relatively expensive higher organism tests rather than rapid screening tests. This was seen by some consultees as an impediment to effective monitoring and management of effluent discharges. The Agency is sympathetic to these concerns and this is reflected in the substantial R&D effort applied to the development of rapid methods which should adequately predict hazards to aquatic organisms. We are aware that industry is also making some investments in this field. The demonstration programme will provide a forum for the further evaluation of rapid screening tests but much of the progress in this area depends on the commercial development of suitable procedures.

**14 What are the mechanisms involved in improvement action once a ecotoxicity problem is identified?**

Once a need for toxicity reduction has been identified, the aim should be to reduce effluent ecotoxicity to an acceptable level through a toxicity reduction plan. A toxicity reduction plan will form part of an improvement plan triggered by exceedance of a ecotoxicity action level. Targets, actions, timescales etc within the plan will be agreed between the discharger and the Agency. The plan will most probably use the methods described in Section 4 of the consultation document but the most appropriate methods and protocols should be agreed with the Agency. The Agency will endeavour to ensure that toxicity reduction plans and ecotoxicity target levels can be achieved at reasonable cost and within the timescales agreed.

The Agency will work within current controls, notably IPC. Studies may indicate the need to control or replace single substances used in industrial processes or consider abatement options. It should be noted that costs and benefits will be taken into account at each stage of the

programme. The Agency will need to be involved in toxicity reduction planning as it will have information on local environmental conditions. This collaborative approach to toxicity reduction has been used successfully in a number of case studies in Scotland (e.g. Haig *et al.*, 1989) although clarification of the process and the responsibilities of the Agency and the discharger will be explored further during the demonstration programme.

**15 Which toxicity statistics should be used to determine the point of protection and the achievement of the desired ecotoxicity targets?**

Although NOECs are currently used for regulatory decision making e.g. for setting annual average limits as part of EQSs, the limitations of the experimentally derived NOEC are well understood. The Agency has, therefore, commissioned research to explore the most appropriate ecotoxicity statistic to use for action limit setting and experimental design for exceedance monitoring. This work will report on an OECD workshop describing the consensus opinion on the use of NOEC, EC<sub>x</sub> or NEC values and techniques for extrapolating to NEC and chronic values. The Agency is committed to using best available practice in its final recommendations. The limit test approach, advocated in the consultation document, proposed for monitoring effluent ecotoxicity (after the characterisation phase) estimates the responses of test organisms at an effluent concentration corresponding to that at the edge of the zone of deterioration. It is not designed to estimate the NOEC and so is not subject to the legitimate concerns about the use of the NOEC in decision making.

At present the Agency does not intend to incorporate arbitrary safety or uncertainty factors to calculations of ecotoxicity limits. The Agency believes that safety will be built in by the use of the most sensitive species from a battery of test methods to define the PNEC, and the worst case dilution calculations in the risk assessment step. It is proposed to control ecotoxicity problems using measures of chronic ecotoxicity or predictions of long-term effects from short-term tests if this can be shown to produce significant cost-effective environmental protection. This will follow further research and technical debate.

There is now good evidence that ecotoxicological measures on effluents predict the effects in the receiving water, at least for lotic freshwater systems. The USEPA believe there is no further need to validate this relationship to justify whole effluent controls in these types of situations (Groethe *et al.*, 1995). However there needs to be more research in this area for marine, estuarine and wetland systems. This is complicated by the difficulty of biological survey in marine/estuarine systems and the lack of any national marine survey classification scheme (the Environment Agency is researching this area at present). The Agency is also currently conducting research using receiving water (water column and sediment) ecotoxicological tests to assess general quality in comparison with biological community data at a limited number of sites, both freshwater and saline.

**16 How should self-monitoring be undertaken and is there a need for separate Agency monitoring?**

Consultees generally accepted the concept of self-monitoring although the auditing role for the Environment Agency was questioned. In order for self-monitoring to be effective the responsibilities of the discharger and the regulator must be clear. These will be discussed by the regulator/industry steering group in the demonstration programme and developed during that study.

**17 Are tests undertaken on indigenous species essential or is it more important to have methods that are consistent and produce high quality information?**

With any scheme which involves the use of ecotoxicity testing (e.g. ecotoxicity testing for effluent control, product registration, setting EQSs, tests to demonstrate safety to humans), there is a balance to be struck between conducting tests on relevant organisms and the costs in generating quality information used for assessing potential hazards. In environmental safety testing it could be argued that tests on hundreds of species would be necessary. Clearly this is impractical and so it is necessary to use a limited range of species which are intended as surrogates for other species. Nowhere is this better exemplified than the use of surrogate species (e.g. rats) in testing the safety

of products to humans.

The test species and experimental procedures used should provide high quality data that can be used for regulatory purposes. Many indigenous species are not currently suitable for laboratory testing and their use would be problematic and could compromise the quality of data. To use all resident species would require the development of laboratory culturing methods and the assessment of intra and inter-laboratory variability for each species in order to set performance limits. Such testing would be more costly, more difficult and potentially more variable and therefore less reliable. Furthermore, field collection of organisms can cause local population extinction and the health of the organisms can be uncertain.

Experience in the US has shown that the most cost effective approach is to use a small number of robust methods. The Agency have decided to place emphasis on a restricted set of methods which use laboratory cultured, sensitive species representative of organisms which should be able to survive in good quality receiving waters. In addition, the generation of high quality data is seen to be more important than the use of indigenous species which may not be present at all locations and which will often not permit adequate control over repeatability and reproducibility. This approach was overwhelmingly supported by the participants of the Torquay seminar.

Tests are being developed for *in-situ* monitoring of receiving waters. New methods will be introduced for both effluent and receiving environment testing, in reasonable timescales, if they can provide better protection of the receiving environment and good quality data in laboratory testing. However, the Agency is aware of the balance to be struck between improvements to methods and the need for stability in test requirements.

#### **18 Information from the pilot study should be peer reviewed.**

The Environment Agency Toxicity-Based Consent Pilot Study was performed in collaboration with the Scotland and Northern Ireland Forum for Environmental Research (representing the Scottish Environmental Protection Agency and the Department of Environment-Northern Ireland)



and industry. A draft toxicity-based licensing protocol was presented in the consultation document and was tested using UK discharges. Over 60 discharges were considered for the study and 12 discharges were studied in detail over a period of three years.

The Environment Agency (then NRA) signed confidentiality agreements at the request of a number of the companies involved in the pilot study and to date these agreements have been maintained. The project proposals and findings were reported to the companies in at least two meetings per company. The Agency considers every effort has been made to promote the issue of toxicity-based consents to trade associations, private industry, NGOs and academia over the last 7 years. Non-attributable information from the pilot study has been presented in numerous leaflets, presentations, posters and papers. Requests for written information or presentations by the Agency on the details of the scheme have never been refused.

In addition to the toxicity-based consent pilot study research effort was also directed at establishing a core set of tests and good quality control procedures including performance testing of methods and a system for test laboratory approval.

Publications from the study include:-

Toxicity-based consent pilot study. Project Record. This document is currently being finalised. It will not be released into the public domain due to confidentiality agreements with the companies involved in the pilot study. The possibility of releasing a non-attributable version of the document will be explored with the companies involved in the pilot study.

The application of toxicity-based criteria for the regulatory control of wastewater discharges- Consultation document. This document was released in July 1996 to over 3000 consultees.

Support paper for the Environment Agency consultation document. Released in July 1996 with the consultation document.

**Toxicity-Based Consents- Pilot Study.** Released in September 1996 and supplied free on request, during the consultation period. The document summarises the pilot study and is currently available as an Agency R&D document (P23) through the Foundation for Water Research (approx. £7).

**Toxicity Reduction Evaluation Case Summary for the pulp and paper industry.** Released in December 1996. Review commissioned as an example of how US case study experience could be summarised. Available as an Agency R&D document (P28) through the Foundation for Water Research (approx. £7).

**Toxicity Reduction Evaluation Case Summary for the chlor-alkali industry.** Released in December 1996. As above. Available as an Agency R&D document (P29) through the Foundation for Water Research (approx. £7).

**Registration of laboratories involved in the derivation and monitoring of licences containing toxicity-based limits- Discussion Document.** This document was released in July 1996 to over 50 experts, principally in commercial contract laboratories, for review. A workshop with the experts was held in Luton on the 17th July 1996.

**Direct Toxicity Assessment (DTA) Methods Guidelines.** The draft document was released for peer review primarily by experts with testing experience in December 1996.

It is expected that further documents will be produced from the study presenting non- attributable information. Industry associations are aware of the companies involved in the pilot study and can approach them directly to gain access to raw data. Industry and other interested parties will be able to see revised protocols in advance of any wider application following the demonstration programme.

As stated in the consultation document DTA procedures have been used for many years in the US where there are an extensive number of publications on the subject. Some of these are listed in the references section at the end of this document.

**19 Toxicity is perceived to be an emotive word. Is there a suitable alternative?**

This issue was debated at the Torquay seminar and other meetings. There was no consensus from consultees on this issue. The Agency therefore proposes to use the words 'Ecotoxicity' and 'Direct Toxicity Assessment (DTA)' wherever possible. The Agency will take every opportunity to promote the public understanding of issues related to ecotoxicology.

**20 Which sources of diluent water should be used for ecotoxicity testing?**

The dilution water for laboratory ecotoxicological assessments will be a standard water (either dechlorinated tap water, water from a 'natural clean' water source or a formulated water) and not one specific to the receiving water. The composition of receiving water will vary over time and reliance on these as sources of diluent would increase test result variability. Local knowledge and DTA assessments of the receiving water will help identify sites in which the biological community is impacted by natural, diffuse or other sources of contamination (e.g. mine runoff) and where site-specific factors are shown to influence the environmental risk posed by a discharge.

**21 Should both acute and chronic methods be used in DTA?**

The programme will initially use acute, largely lethal, exposures to determine ecotoxicity because these methods are fully validated. In the US they go a stage further and use chronic, sub-lethal ecotoxicity as determined in a *Ceriodaphnia* reproduction test. The introduction of chronic, sublethal controls in the UK will be considered following the implementation of acute measures. Chronic sublethal methods will be selected and developed, alternatively current research in progress may indicate that chronic endpoints can be extrapolated from acute ecotoxicity test data. This will be within reasonable timescales to fit in with the plans by industry for plant modification and improvement.

Some concern has been expressed with regard to the sensitivity of the Pacific oyster embryo test. It has been suggested by some consultees that this test should be regarded as a chronic test

method. As a 24h exposure test, it is considered an acute test. Furthermore, although the test endpoint is described as embryo development, it is widely accepted that the end point is a measure of lethal toxicity.

**22 The 48 hour reporting and 24 hour retest periods suggested in the consultation document are considered to be too restrictive. What are sensible timescales? Will the reported information go onto public register?**

There was much criticism about the expected reporting times for ecotoxicological data from monitoring of ecotoxicity action levels. The Agency accept that it may not be possible to report fully quality assured test data from testing laboratories within 24 hours of test completion. The Agency will therefore review turn-around times for reporting quality assured and provisional test data. This will be done during the progress of the demonstration programme. Reporting times of 1-2 weeks have been suggested.

It was also stated that laboratories may not be able to perform repeat testing within 24h of the result from the first test. One possibility may be for laboratories to prepare for repeat testing (even if it does not occur) as part of the contract between the lab and the discharger. This will be explored further in consultation with dischargers and test laboratories.

The Agency will require all information within the sampling programme- non- exceedences, as well as failures of action levels to be reported. Failure must be reported more rapidly than passes although, as noted above, the timescales are to be reviewed. Any information collected will go onto the public register.

Existing legislation (WRA, 91; EPA, 90 and Environment Act 1995) already has provision for ensuring dischargers keep records, provide relevant data to the Agency (and for the Agency to provide data to external bodies) and to prevent falsification of information. It is proposed at present that the Agency will archive the ecotoxicity data, ecotoxicity targets and timescales for toxicity reduction. The laboratory approval scheme and accreditation systems will ensure testing

and test data is of high quality. The Agency will audit reported data to ensure true and accurate reporting of data.

**23 How should we deal with the ethical issues of ecotoxicity testing?**

The use of vertebrate testing for environmental protection is not a new issue. Such tests are currently used for the derivation of EQSs for single substances and for new substance registration. The Agency is advocating the use of a small number of cultured organisms to assess the risk of harm to, and therefore protection of, resident populations, communities and ecosystems. However it is important to ensure that the ecotoxicity testing programmes performed for DTA assessments are scientifically sound and provide maximum information using the least number of organisms possible. If particular tests are obviously producing no useful data about the ecotoxicity of the discharge they will be discontinued and the programme will continue with the remaining tests.

The use of vertebrate testing (e.g. fish) will be kept to an absolute minimum. Fish proved to be relatively insensitive in the pilot study so their use is likely to be minimal unless there is a strong environmental justification. Research is continuing to develop microbial and in-vitro tests to predict effects on invertebrates and vertebrates.

**24 Is there a need to notify all changes in plant operation which may affect effluent ecotoxicity?**

Only those changes in plant operation that may result in a level of ecotoxicity of the discharge that would exceed an agreed action limit need be reported. These changes may result in the need for re-characterisation of effluent ecotoxicity.

**25 Should limit test or concentration-response test designs be used for testing against action levels?**

Valid points were made with regard to the use of limit tests to monitor exceedences against limits

or action levels during the consultation exercise. Limit tests give no indication of the magnitude of an ecotoxicity problem and will not therefore allow for prioritisation of effort. Furthermore, limit tests assume a standard concentration-response curve so that changes to the slope of the dose-response could mask changes in the EC50 even though the response around the NOEC is unaltered, and vice-versa. The Environment Agency will therefore review the use of limit and concentration-response tests for regulatory control purposes during the demonstration programme.

**26 Due to the possible problems involved in sampling effluents for ecotoxicity testing sampling protocols are required.**

Consultees were concerned that sampling, sample storage and sample treatment can introduce a possible source of variation in the results obtained from ecotoxicological testing. The Environment Agency will employ the standard procedures for sampling and sample storage that are already in place for samples used for chemical analysis, as DTA assessments have similar requirements. Sampling, storage and transport details are described in the 'Ecotoxicology Methods Guidelines' sent out for peer review.

**27 How should the PEC: PNEC comparison be made?**

In calculating an action level for ecotoxicity the Agency proposes to perform a risk assessment using information on effluent ecotoxicity and the available dilution. Currently determination of the PEC (effluent dilution) is based on the highest discharge volume or maximum licensed discharge volume of the effluent and on a low flow probability statistic in the receiving water (or worst case dispersion/dilution model). In addition we propose to use the highest recorded ecotoxicity to the most sensitive test in calculating the PNEC. Although this may seem over-precautionary, the assessment of risk is currently based on acute ecotoxicity data and there are no proposals to apply safety factors to extrapolate to possible chronic effects. The Environment Agency is aware of the possibility of using probabilistic models to assess environmental risk, based on the expected frequency distributions for the PEC and PNEC. This option will be reviewed during the course

of the demonstration programme.

It was pointed out during consultation that some discharges are subject to unpredictable and large changes can occur due to storm run-off etc. In these cases the maximum discharge volume may be used (alternatively, these changes may have to be controlled e.g improved on-site control or holding tanks). Dischargers will be discouraged from increasing the volume of their effluent to reduce ecotoxicity (i.e. diluting) as this is contrary to current efforts directed at waste minimisation and will not decrease the load of chemicals released to the receiving environment.

**28 What are the major lessons learnt for the US experience of applying whole effluent testing (WET)?**

The US has had toxicity-based controls in place for many years. There are many lessons to be learnt from their experience. Representatives of the Environment Agency went on a fact-finding trip to the US in October 1994 to talk to key staff from American industry, the US Environmental Protection Agency, commercial toxicity testing laboratories and environmental consultancies. Since then Agency staff have been in continued discussion with colleagues in the US on the development of Whole Effluent Testing (WET), Direct Toxicity Assessment (DTA) and Toxicity-based licencing programmes.

In 1995 the Pellston workshop was held in the US to discuss various WET implementation issues between the USEPA and members of the regulated community, particularly the Association of Metropolitan Sewage Agencies (AMSA). This workshop was designed to discuss the policy, to debate scientific issues and identify areas where more research was or was not required. This workshop was followed by an open public forum at the end of 1995. The outcome of the workshop and open forum are presented in the proceedings (Groethe *et al.*, 1996)

The general messages from the fact finding trip, and from the Pellston workshop are presented below.

Prior to the 1995 Pellston Workshop:

1. Whole effluent testing methods are scientifically justifiable
2. Application should be nationally consistent and tightly controlled
3. Quality of ecotoxicological data and consistency of testing is crucial. A limited number of well tested methods should be adopted for ecotoxicological assessments.
4. The variability in ecotoxicological tests should be assessed and incorporated in compliance assessments.

Following the 1995 Pellston workshop:-

1. Whole effluent testing methods are technically sound
2. Problems have occurred due to different interpretation of USEPA guidelines. This will require increased training and broadly based and standardised QA/QC programmes to increase consistency of testing and application
3. Assessments should be site-specific
4. There is no need to further validate laboratory to field extrapolation for flowing freshwater systems. However these sorts of relationships for wetland, estuarine and marine systems are lacking.
5. Field assessments are needed to compensate for the limitations of WET tests to predict sediment ecotoxicity, bioaccumulation, genotoxicity, indirect biotic effects and chemical persistence. In addition these tests can be used to modify under or overprotective limits.

**29      "The nature of the ecotoxicity may change and therefore the most sensitive species may also change over time".**

Results from the toxicity-based consent pilot study generally suggested that the most sensitive species remained so throughout the testing period. There will be an opportunity to explore these issues during the demonstration programme. It may be feasible to have testing of the action level against a battery of tests at a lower frequency, as was suggested.



**30 "Given that the NOEC has to be a test concentration, will the Agency recommend concentration factors for the full range toxicity test and hence specify the LOEC/NOEC ratio?"**

The draft methods guidelines suggest that 10-11 concentrations with  $\leq 2.2x$  difference between the concentrations should be used on the first one or two tests on the effluent. The concentration should span the range from 0.1 to 98-100% v/v effluent (e.g. 0, 0.1, 0.22, 0.46, 1.0, 2.2, 4.6, 10.0, 22.0 and 98-100%). If the effluent demonstrates consistent toxicity then subsequent tests may use a modified design with 5-6 concentrations with narrower concentration intervals. The Agency has commissioned research to explore the most appropriate toxicity statistic for action limit setting and experimental design for exceedance monitoring (see issue 15).

**31 "It is important to ensure standardisation and agreement between the Agency in the different regions of the country"**

Although action levels and toxicity reduction requirements will be site-specific, every attempt will be made to ensure consistency in approach across Agency regions. The Agency recognise this will involve internal training programmes, the production of detailed guidance notes and national auditing of the application of the protocol.

**32 "It should be the regulators that characterise the PNEC as a full knowledge of the receiving water is necessary for its calculation"**

The predicted no-effect concentration is the concentration of (diluted) effluent which has no measurable effect on the test organism in the particular test employed for the assessment. This represents the 'required minimal dilution' in the receiving water and is determined in the laboratory by diluting the effluent with control water. Therefore ecotoxicity characterisation requires no knowledge of the receiving water. It is the PEC that uses information on the volume of the discharge and receiving water to calculate available dilution in the receiving water. There may be a need for collaboration between the Agency and the discharger to generate or gather this

information.

**33 "The proposals implicitly assume that additivity is the dominant mode of chemical interaction, an assumption for which there is little scientific justification and little empirical evidence".**

Recent literature reviews commissioned by the Environment Agency (or its NRA predecessor) have concluded that although synergism and antagonism may occur in complex mixtures neither is common (Wroath and Johnson, 1995; Wroath and Hedgecott, 1996). Additivity, however, is a much more common phenomenon (Wroath, 1996) with mixtures approaching additivity as the number of components increase (Warne and Hawker, 1995). DTA assessment is therefore considered the most appropriate means for assessing the interactive toxicity of complex mixtures.

**34 "It will be cheaper for an operator to divide his waste stream thus transferring synergistic toxic effects from the combined effluent to the receiving environment".**

The Agency would encourage environmentally responsible solutions to toxicity problems. It will discourage dischargers (using its legal powers) from dividing their waste streams, transferring additive toxicity to the receiving environment in attempts to avoid the cost of toxicity reduction programmes.

**35 "Toxicity is a function of concentration and exposure. At the end-of-pipe there is no exposure and therefore no toxicity. The 'ultimate goal' of no ecotoxicity at the end-of-pipe is therefore flawed".**

The ultimate objective would be no measurable ecotoxicity in the receiving water in the immediate vicinity of the pipe (i.e. infinitely small zone of deterioration) taking into account initial dilution at worst case conditions, costs and environmental benefits.

**36 "Of all the parameters which may be important at the point of discharge the issue of temperature must be significant. There seems to be no recognition of temperature effects in the testwork proposed".**

Death of organisms in the receiving water directly as a result of high temperatures is outside the scope of the discussion on toxicity-based controls (though it is still of concern to the Environment Agency and controlled by other means such as physical parameters in licences). However the effect of extreme temperatures on the toxicity of effluents will be addressed later in the programme if considered significant.

**37 "Why cannot single rapid ecotoxicity tests be used for effluent characterisation?".**

The Environment Agency is keen to explore the most cost-effective means of generating data to adequately characterise an effluent discharge. As no individual ecotoxicology test is sensitive to all categories of toxicants a battery of tests must be used to characterise the ecotoxicity of an effluent which may contain many toxicants. At this stage, the Agency believes it must retain the requirement for a battery of tests, but would be prepared to consider the possibility of restricting the range of test methods if there is clear evidence of method 'redundancy'. Although the Agency believes there is a necessary and useful role for rapid tests in DTA more well trialed, rapid tests are needed to provide a rapid test battery to replace conventional tests. These methods must be related to significant ecological endpoints in order to provide adequate protection for the receiving environment. The Agency and other organisations are investing in the development of rapid methods which may be used for continuous monitoring and more effective effluent management.

**38 "Introduction of Whole Effluent Testing in the US has resulted in companies either shutting down or else moving their activities outside the US".**

We have had no indication that industry has shut down or moved outside the US as a result of toxicity-based consents. US industry generally recognise whole effluent testing as a sensible and

scientifically justified approach to toxics control. The demonstration programme is intended to assess the success of toxicity reduction in bringing about environmental improvements.

### **39 Consultation document corrections and clarification**

The format of the consultation document was generally well received.

#### Corrections:

'regraded' to 'regarded' (pp vii, para 10, line 3)

'Battery of tests: a set of toxicity tests which is intended to address the major, common, modes of toxic action' (pp v, para 4, line 1)

'Water Quality Objective or Environmental Quality Objective: A formal statement of the desired use of a particular water, such as potable abstraction or fishing'. (pp x, para 1)

'Environmental Quality Standard: a standard, normally a concentration, which, prescribes the level of a substance in the environment, which may not be exceeded'. (pp vi, para 7)

'same' to 'similar' (pp v, para 5, line 3)

'No-effect' to 'No-observed effect' (pp vii, para 10, line 1)

'PROBIT' to 'Probit' (pp vii, para 11, line 1, and page 15, para 4, line 9)

'Quality Control: specific actions, usually within a programme of quality assurance, including routine checks and calibrations of normal operations, within a laboratory' (pp viii, para 1, line 1)

'maxima' to 'maximum' (pp ix, para 7, line 2)

'accreditation inspection accreditation' to 'accreditation inspection' (pp 38, para 2, line 1)

'desired of toxicity' to 'desired toxicity' (pp 47, para 1, line 2)

It is accepted that:

Not all toxicity data sets need to be statistically transformed prior to calculation of the summary statistic- only those that are non-normally distributed, have heterogeneous variances or are percentage/proportional numbers. Also probit transformation is only one of many possible models to achieve this. It should be noted that the information presented on page 15 was for illustrative purposes only and that toxicity responses do not always follow the pattern illustrated in figure 3.

The NOEC and control response in figure 3 are generally associated with some level of effect rather than the zero response illustrated. The NOEC is the highest concentration used in the experiment at which there is no significant difference in response from the control.

The executive summary should have included the consultation issue 'Is the introduction of toxicity-based conditions as a licence condition the most satisfactory way of ensuring the control of toxics'

To clarify:

The key point on page 3 refers to toxicity-based licencing as described in the document. Direct toxicity assessment of the receiving water is currently being explored through R&D and will be used to demonstrate environmental benefit of toxicity controls in the future.

The definition of 'harm' in the document is consistent with that in the Environmental Protection Act 1990 and the Environment Act 1995.

Costs of ecotoxicity testing quoted in the consultation document were based on rates quoted by a commercial testing laboratory.

## 5. Conclusion

The use of direct toxicity measures for effluent control and for environmental monitoring were generally seen as a positive move towards better environmental protection. Debate centred on a number of the specific proposals. These were mainly concerned with the following issues:-

- Prioritisation driven by environmental or adverse risk assessment;
- Legal issues and complexity of toxicity reduction plans within Sewage Treatment Works;
- Action levels which trigger toxicity reduction measures in improvement plans versus compliance limits within licences;
- Cost and benefit;
- Implementation.

Generally, consultees believed that implementation should be based on environmental need (i.e. where impact is occurring) rather than on an adverse risk assessment determined by the ecotoxicity of the effluent and its dilution in the receiving water. There was general support for the introduction of action levels and improvement plans rather than licence compliance limits.

The Agency agreed there were additional legal and technical complexities involved in applying toxicity-based controls to sewage treatment works. However, these will not exclude the use of DTA for controlling these types of discharges. The Agency recognises that further collaborative work is required to assess how this should best be done.

Consultees also thought the DTA initiative should proceed via a demonstration programme. This would allow experience to be gained from 'real world application'. The programme will be scoped and managed by a joint industry (CIA, CBI, WSA) and regulator (Environment Agency, SEPA) steering group. The programme will consist of a number of projects in which a revised protocol will be tested. This protocol uses information on environmental impact to prioritise sites, takes into account costs and benefits and includes use of action limits and improvement plans to achieve toxicity reduction. Information sheets will be produced during the course of the programme.

## 6. Appendices

### Appendix 6.1 Glossary of terms

Acute	a short exposure period in the life span of the organism; this would be in the order of minutes for bacteria and usually up to 4 days for fish.
Additivity	where the toxicity ( <i>q.v.</i> ) of a mixture is the sum of the toxicity of the individual components.
BATNEEC ( <i>q.v.</i> ) and BPEO ( <i>q.v.</i> )	the principle statutory objectives set out in the Environmental Protection Act 1990 and against which the Environment Agency regulates processes under IPC ( <i>q.v.</i> ). They dictate pollution prevention strategies and demand an holistic approach to environmental protection.
Battery of tests	a set of toxicity tests ( <i>q.v.</i> ) which is intended to address the major, more common, toxic modes of action ( <i>q.v.</i> ).
Bioassay	a test used to evaluate the potency of a substance or mixture of substances by comparing its effect on an organism or biological process, relative to the similar organism or biological process exposed to a control in which the substance(s) are absent.
Biological Assessment	an evaluation of the biological condition of a medium ( <i>q.v.</i> ) using biological surveys and other direct measurements of the resident biota.
Biomarker	a physiological, biochemical or histological change as an indication of exposure and/or effects of toxicants ( <i>q.v.</i> ) at the suborganism or organism level.
Chemical-Specific Control	the control and assessment of effluents ( <i>q.v.</i> ) and environmental samples using methods based on the chemical analysis of individual substances or groups of substances.
Chronic	a relatively long exposure period, usually a significant proportion of the life span of the organism such as 10% or more.
Complex Effluent	a toxic wastewater discharge of variable and mixed composition (i.e., where the observed toxicity ( <i>q.v.</i> ) cannot be accounted for fully, nor numerically limited and controlled, by chemical-specific limits).
Compliance Monitoring	the determination, through measurement or deduction, of substances (and/or surrogates including process conditions) subject to a limit or condition in a licence. Note: compliance monitoring may be carried out by the discharger ( <i>q.v.</i> ) (when it is often referred to as self monitoring)

and/or the regulator.

Direct Toxicity Assessment	an Environment Agency term to describe the use of toxicity tests ( <i>q.v.</i> ) to give a measure of effluent ( <i>q.v.</i> ) and environmental quality expressed in toxicological parameters.
Discharger	the person, operator or corporate body making a discharge.
Ecotoxicity	the toxicity ( <i>q.v.</i> ) of a sample measured using ecologically relevant end points ( <i>q.v.</i> ).
Effluent	a liquid output (e.g. industrial, municipal) from a process. Effluent may be directly discharged to the environment or may be subsequently input to a treatment process before discharge.
End point	the variables (e.g. time, reaction of the organisms) that indicate the termination of a test and/or the measurements or values derived that characterise the results of the test (e.g. EC <sub>x</sub> or NOEC).
Environmental Quality Objective	A formal statement of the desired use of a particular water, such as potable abstraction or fishing.
Environmental Quality Standard	a standard, normally a concentration, which, prescribes the level of a substance in the environment, which may not be exceeded.
Established Toxicity Test	a toxicity test ( <i>q.v.</i> ) defined for the purpose of this document as a non-rapid ( <i>q.v.</i> ), well-tested bioassay ( <i>q.v.</i> ) usually with an alga, macrophyte ( <i>q.v.</i> ), macroinvertebrate or fish as the test organism and carried out under rigorously controlled conditions in accordance with a recognised standard operating procedure ( <i>q.v.</i> ).
Harm	harm is defined in the Environmental Protection Act (1990) as "harm to the health of living organisms or other interference with the ecological systems of which they form part".
Independent Monitoring	monitoring including sampling and testing of discharges made by, or on behalf of, the Environment Agency to provide checks on compliance and assurance that self-monitoring is working honestly and effectively.
Improvement Plan	a timetable of actions intended to enhance the environmental performance of a process regulated under IPC ( <i>q.v.</i> ). It may include initiatives declared by the operator of the process or imposed by the Environment Agency; actions of either origin are enforceable obligations.



Integrated Pollution Control	the pollution control and regulation regime introduced by the Environmental Protection Act 1990. The Act's provisions apply to processes which offer the potential for most environmental harm and include obligations concerning BATNEEC ( <i>q.v.</i> ) and BPEO ( <i>q.v.</i> ).
Lethal	causing the death of organisms.
Licence	generic term referring to WRA'91 consents and EPA'90 authorisations.
Local Environment Agency Plan	integrated management documents designed to address problems and opportunities resulting from activities impacting on the three media: air, land and water. The boundaries of plans are primarily defined by surface water catchments.
Macrophyte	vascular plant.
Medium or Media	term used to express a compartment of the ecosystem e.g. sediment, water column, soil or air.
Performance Testing	procedures to determine and control the sources of variability of toxicity test ( <i>q.v.</i> ) results.
Permissive Chemical Analysis	an Environment Agency term for a chemical sampling/analysis programme performed as part of a non-statutory requirement e.g. not as a necessary requirement in a consent or EC directive.
Predicted Environmental Concentration	the predicted concentration of an effluent at a point in the environment, following release, taking into account the initial volume of the discharge and the available dilution/dispersion in the receiving water.
Predicted No-Observed Effect Concentration	the environmental concentration which is regarded as a level below which the balance of probability is that an unacceptable effect will not occur. For the purpose of this document this is regarded as the lowest measured no-observed effect concentration for the most sensitive species in the test battery.
Quality Assurance	a system of management and operational activities designed to ensure adequate control of quality in the work produced by a laboratory.
Quality Control	specific actions, usually within the programme of quality assurance ( <i>q.v.</i> ), including routine checks and calibrations of normal operations, within a laboratory.
Rapid Tests	toxicity tests ( <i>q.v.</i> ) which can produce the desired toxicity end point ( <i>q.v.</i> ) in a short time (usually <6 hrs).

Receiving Water	inland and coastal waters to which pollution control legislation applies generally or by individual or local designation (referred to as controlled waters by the Environment Agency).
Risk	the probability or likelihood that an event will occur.
Risk Assessment	the process of identifying and quantifying risks ( <i>q.v.</i> ) and determining the acceptability of those risks.
Screening	a procedure to obtain an estimate of toxicity ( <i>q.v.</i> ) prior to comprehensive toxicity testing ( <i>q.v.</i> ).
Self-monitoring	compliance monitoring of discharges carried out by (according to a pre-defined programme in a licence) and paid for by the discharger ( <i>q.v.</i> ). It should be noted that monitoring by the regulator is also paid for by the discharger ( <i>q.v.</i> ), through charging schemes.
Self-monitoring Audit	the physical inspection and assessment of a discharger's ( <i>q.v.</i> ) arrangements for compliance monitoring including sampling procedures and records.
Standard Operating Procedure	a clearly defined method or protocol adhered to by all operational staff and described precisely in a written document.
Sub-chronic	a period of exposure that falls between acute ( <i>q.v.</i> ) and chronic ( <i>q.v.</i> ) exposure periods.
Sub-lethal	a biological response to a toxicant ( <i>q.v.</i> ) below the level that causes death.
Substance-Specific Control	the control and assessment of effluents ( <i>q.v.</i> ) and environmental samples using methods based on the chemical analysis of individual substances or groups of substances.
Synergism	where the toxicity ( <i>q.v.</i> ) of a mixture exhibits greater-than-additive ( <i>q.v.</i> ) total toxic effect.
Toxicant	a substance which has the inherent potential or capacity to cause adverse effects on living organisms.
Toxicity Action limit	a level of toxicity which, if exceeded, would trigger further investigative work to identify the source of toxicity and options for reducing the toxicity.
Toxicity	the inherent potential or capacity of a substance to cause adverse

effects on living organisms.

<b>Toxicity Condition</b>	toxicological stipulation in a discharge licence (q.v.) consisting of a toxicity limit (q.v.) and associated circumstances under which the limit is to be monitored.
<b>Toxicity Criteria</b>	a toxicity measure to assess environmental or discharge quality.
<b>Toxicity Limit</b>	requirement in a discharge licence (q.v.) expressed as a toxicological maximum not to be exceeded.
<b>Toxicity Reduction Plan</b>	a plan of work submitted by the discharger to the Environment Agency to identify the source of toxicity (q.v.) in an effluent (q.v.), and subsequent remedial action to reduce this toxicity. The plan, plus agreed timescales, forms the Toxicity Reduction Programme (q.v.).
<b>Toxicity Reduction Programme</b>	a programme of work designed to identify the source of toxicity (q.v.) in an effluent (q.v.) and reduce this toxicity in order that whole effluent toxicity is reduced within agreed timescales.
<b>Toxicity Screening</b>	a procedure to obtain an estimate of toxicity (q.v.) prior to comprehensive toxicity testing (q.v.).
<b>Toxicity Test</b>	a procedure conducted in order to measure the degree of effect on test organisms of a specific chemical, mixture of chemicals, effluent (q.v.) or environmental sample.
<b>Toxic Mode of Action</b>	mechanism by which a toxicant (q.v.) causes an adverse effect on living organisms.
<b>Trophic Level</b>	a general term for each step of a food chain or food pyramid.
<b>Trophic Level Testing</b>	a battery of toxicity tests (q.v.) with organisms from several trophic levels (q.v.) such that they simulate a micro-ecosystem.
<b>Water Quality Objective</b>	a set of requirements to be met to achieve specified water quality standards.
<b>Whole Effluent Toxicity</b>	a United States Environmental Protection Agency (USEPA) term to describe the total toxic effect of an effluent (q.v.) measured directly with a toxicity test (q.v.).

**Appendix 6.2 Abbreviations**

BATNEEC ( <i>q.v.</i> )	Best Available Techniques Not Entailing Excessive Cost
BPEO ( <i>q.v.</i> )	Best Practicable Environmental Option
DTA	Direct Toxicity Assessment ( <i>q.v.</i> )
EC	European Community
EC <sub>50</sub>	Median Effective Concentration
EC <sub>x</sub>	Effective concentration producing an x% response
EPA'90	Environmental Protection Act (1990)
EQO	Environmental Quality Objective
EQS	Environmental Quality Standard
GLP	Good Laboratory Practice
IPC	Integrated Pollution Control ( <i>q.v.</i> )
LC <sub>50</sub>	Median Lethal ( <i>q.v.</i> ) Concentration
LC <sub>x</sub>	Lethal ( <i>q.v.</i> ) concentration killing x% of organisms
LOEC	Lowest-Observed Effect Concentration
NOEC	No-Observed Effect Concentration
NRA	National Rivers Authority
PEC	Predicted Environmental Concentration ( <i>q.v.</i> )
PNEC	Predicted No-Effect Concentration ( <i>q.v.</i> )
QA/QC	Quality Assurance ( <i>q.v.</i> )/Quality Control ( <i>q.v.</i> )
SNIFFER	Scotland and Northern Ireland Forum For Environmental Research
SOP	Standard Operating Procedure ( <i>q.v.</i> )

UKAS	UK Accreditation Service (formerly NAMAS)
WET	Whole Effluent Toxicity ( <i>q.v.</i> )
WRA'91	Water Resources Act (1991)

### Appendix 6.3 Respondees

Amoco (UK) Exploration Company  
 Anglian Water  
 Association of British Pharmaceutical Industries  
 BP Chemicals Ltd  
 BP International Limited  
 BPB Paper and Packaging Ltd  
 Britannia Zinc Ltd  
 British Agrochemicals Association Ltd  
 British Association for Chemical Specialties  
 British Coatings Federation Ltd  
 British Gas Plc  
 British Iron & Steel Producers Association  
 British Non-Ferrous Metals Federation  
 British Steel  
 British Sugar Plc  
 British Waterways  
 Carless Refining & Marketing Ltd  
 Chemical Industries Association  
 CIBA Grimsby  
 CIBA-GEIGY Plc  
 Cleanaway Ltd  
 Conestoga-Rovers and Associates (UK) Ltd  
 Confederation of British Wool Textiles Ltd  
 Confederation of British Industries  
 Courtaulds Plc  
 Courtaulds Chemicals  
 Department of Trade & Industry  
 DG (Farmer and REPAC member)  
 Eastern Merchant Generation Ltd  
 English Nature  
 Environment and Resource Technology Ltd  
 Environment Agency SouthWest (Consenting)  
 Environment Agency SouthWest (IPC)  
 Environment Agency (Anglian Region)  
 Environment Agency NorthEast (IPC/RAS Team)  
 Environment Agency NorthEast (Water Quality)  
 Environmental Services Association  
 Fertiliser Manufacturers Association Ltd  
 Friends of the Earth (Ltd)  
 General Utility Projects Ltd  
 Glaxo Wellcome Operations (SD)  
 Glaxo Wellcome Operations (CM)  
 Greenpeace (UK)  
 Greenways Waste Management  
 Hamilton Garrod Ltd  
 Houseman Ltd  
 ICI Chemicals and Polymers Ltd  
 Institute of Wastes Management  
 Institute of Terrestrial Ecology  
 International Wool Secretariat  
 Jamont UK Ltd  
 John Heathcoat and Co Ltd-Heathcoat Fabrics

Joseph Mason Plc (Mason Paints)  
 Kimberley-Clark Ltd  
 Leigh Interests Plc  
 MAFF Environmental Protection Division  
 MAFF Fisheries Laboratory  
 Merck Sharp and Dohme Ltd  
 Merck Ltd  
 Metal Finishing Association  
 Microbics (UK) Ltd  
 Monsanto Plc  
 Montgomery Watson  
 National Power Plc  
 National Farmers Union of England and Wales  
 Nestle (UK) Ltd  
 Northumbrian Water Ltd  
 Nuclear Electric Ltd  
 Octavius Hunt Ltd  
 OFWAT- Yorkshire Customer Services Committee  
 OFWAT- Office of Water Services, Birmingham  
 Paper Federation of Great Britain  
 Peter Fisk Associates  
 Plymouth Marine Laboratory  
 Portals Ltd  
 Powergen  
 REPAC (NorthEast)  
 REPAC (Anglian)  
 Robert Stuart Plc  
 Robert Fletcher (Greenfield) Ltd  
 RPS Clouston Environmental Consultancy  
 SEAL  
 Severn Trent Water Ltd  
 Shanks & McEwan (Southern waste services) Ltd  
 Shell UK Ltd (Stanlow)  
 Shell UK Ltd (Shell-Mex House)  
 SmithKline Beecham Pharmaceuticals  
 Sonoco Ltd - Board Mills  
 South West Water Services Ltd  
 Southern Water Services Ltd  
 Thames Water Utilities Ltd  
 The Water Services Association of England and Wales  
 The Shellfish Association of Great Britain  
 Thomas Bolton Ltd  
 UK Petroleum Industry Association Ltd  
 University of Liverpool (ME)  
 University of Glasgow (PS-D)  
 University of Sheffield (LM)  
 University of London - Royal Holloway (MC)  
 Wansdyke Constituency Green Party  
 Waste Water Network  
 Water Services Association  
 Water Companies Association  
 Wessex Water Services Ltd

Worldwide Fund for Nature UK  
WRc Plc  
Wye College University of London (JG)  
Yorkshire Water Services Ltd  
Zeneca Ltd- Brixham Environmental Laboratory (DT)  
Zeneca Ltd- Brixham Environmental Laboratory (RP)

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