ENVIRONMENT AGENCY

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

A consultation document issued by the Environment Agency on the proposed introduction of toxicity-based conditions to discharge licences.

July 1996

ENVIRONMENT AGENCY
DIRECT TOXICITY ASSESSMENT NATIONAL CENTRE

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

A consultation document prepared by the Direct Toxicity Assessment National Centre and issued by the Environment Agency on the proposed introduction of toxicity-based conditions to discharge licences.

This document is issued with the accompanying paper 'Support paper for the Environment Agency consultation document'.

Written comments should be addressed to:

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Date of issue: 16th July 1996
The deadline for written comment is **30th September 1996**

CONSULTATION EXERCISE ON THE INTRODUCTION OF TOXICITY BASED CRITERIA FOR REGULATORY CONTROL

Direct toxicity assessment (DTA) provides a meaningful and easily understood measure of poisonous matter in whole samples, and the likely risk of environmental damage which could be caused by the release of complex mixtures of toxic substances. The Environment Agency will introduce new measures for general quality assessment, together with regulatory controls, to provide better protection of the environment. The environment we live in is an issue for us all. It is important that we have simple, meaningful measures of assessment, and achievable targets, which can be costed and used to demonstrate sustainable environmental benefit.

Collaborative research programmes, on the application of toxicity based criteria for the control of toxic waste discharges to receiving waters, have been sponsored by the Environment Agency and by the Scotland and Northern Ireland Forum for Environmental Research. The procedures will compliment the traditional approach whereby complex mixtures of chemicals are controlled by substance specific limits.

The development of DTA, based on the acquirement of high quality information and a consistent approach to enforcement, has benefitted from close collaboration with our regulatory counterparts in the United States where similar procedures are well established and where they have been shown to have had environmental benefit. During the research programme every effort has been made to release information on the progress of the work and to liaise closely with the business community and their associations.

A consultation exercise on the proposals to introduce toxicity based licence conditions to control complex waste discharges is planned. A summary report of the research work is also available to provide further information on some of the issues raised in the consultation document. Written comment on the document is invited and should be received by 30 September 1996. The consultation exercise will be managed by the DTA National Centre of the Environment Agency to ensure all views are acknowledged and considered. A further opportunity for constructive debate, on the key issues raised during the consultation period, will be provided at a meeting to be held in Torquay, 29/31 October 1996.

At the end of the consultation exercise, guidance notes will be written to accompany the protocols for the determination and enforcement of toxicity limits as part of a licence to discharge. Emphasis will be placed on the collaborative efforts of dischargers and the regulatory agency to demonstrate environmental awareness and the need for a sensible and sustainable approach to protect the environment from releases of toxic substances in toxic amounts.

For the Environment Agency of England and Wales

Dr David Slater (Director of Pollution Prevention and Control)

ENVIRONMENT AND HERITAGE SERVICE

Use of Toxicity Based Consents for the Regulatory Control of Effluent Discharges

The Environment and Heritage Service (EHS), an Agency within the Department of Environment for Northern Ireland considers that Direct Toxicity Assessment (DTA) provides a meaningful measure of toxic matter present in complex effluent samples. It will therefore be possible, where appropriate, to include conditions in discharge consents which rely on accepted and standardised toxicity test methods as a means of providing additional protection to the aquatic environment. This would normally be in addition to the current numerical based chemical parameter approach.

In order to ensure that we have a robust protocol for applying toxicity based consents, EHS, through the Scotland and Northern Ireland Forum for Environmental Research (SNIFFER) has participated with the Environment Agency in collaborative research on the application of toxicity based criteria for the control of potentially toxic discharges to the aquatic environment.

EHS welcomes and supports this consultation exercise of the Environment Agency in giving dischargers an opportunity to comment on their proposal to introduce toxicity based consents and the means of monitoring compliance. EHS will have access to the consultation responses and will consider these in drawing up it's own policy on toxicity based consents, compliance assessment and enforcement.

The legislation in Northern Ireland for the control of effluent discharges is different from the rest of the UK. Prescribed processes will be regulated from October 1996 by the Industrial Pollution Control (Northern Ireland) Order 1996. Non prescribed processes are currently regulated by the Water Act (Northern Ireland) 1972. Where consultees consider their comments have particular relevance to Northern Ireland they should mark them accordingly so that the DTA National Centre can relay them to EHS.

For Environment and Heritage Service
An Agency within the Department of the Environment for Northern Ireland

Jim Lamont.

J R Lamont
(Director of Environmental Protection)

SCOTTISH ENVIRONMENT PROTECTION AGENCY

Application of Toxicity Based Criteria for the Regulatory Control of Waste Discharges SEPA View

The River Purification Board predecessor bodies of the Scottish Environment Protection Agency have for some years used toxicity based conditions in consenting discharges of complex effluents to the aqueous environment. It is considered that Direct Toxicity Assessment (DTA)can enable a meaningful measure of toxic matter present in an effluent sample to be determined. Inclusion of appropriately framed conditions using standardised and accredited toxicity tests can then provide an additional means of safeguarding the aqueous environment where monitoring by solely chemical based parameters may not allow the necessary control.

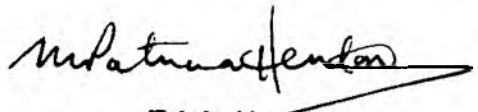
In order to ensure that a robust protocol is used for applying toxicity based consents in a fair and uniform manner, SEPA, through the Scotland and Northern Ireland Forum for Environmental Research (SNIFFER) has participated with the Environment Agency in collaborative research into the application of toxicity based criteria for the control of potentially toxic discharges to the aquatic environment.

SEPA welcomes and supports the initiative of the Environment Agency in giving dischargers an opportunity to comment on their proposed protocol for drawing up toxicity based consents and subsequent monitoring of compliance. Through the collaborative research projects SEPA will have access to the responses to the consultation and will give these due consideration in drawing up its own policy with regard to toxicity based consenting and the procedure for compliance assessment and enforcement.

Legislation within Scotland is slightly different from the rest of the UK. Prescribed processes are regulated similarly to England and Wales, via the provisions of the Environmental Protection Act 1990, but non prescribed processes are regulated by the Control of Pollution Act 1974 as modified by the Environment Act 1995. The DTA National Centre of the Environment Agency will provide a centre for the receipt of responses but where dischargers consider their responses have particular relevance to Scotland they should mark them accordingly so that the DTA National Centre can relay them directly to SEPA.

SEPA aims to draw up policies which protect the environment whilst taking into account the draft guidance issued by the Secretary of State on Sustainable Development.

For the Scottish Environment Protection Agency



Tricia Henton
(Director of Environmental Strategy)

CONTENTS

EXECUTIVE SUMMARY

This document has been prepared by the DTA.National Centre of the Environment Agency in collaboration with Regional and Head Office staff. Proposals for the introduction of toxicity-based conditions into licences for the regulatory control of wastewater discharges to the aquatic environment are presented. All interested parties are invited to comment on the proposals.

It is an offence under Section 85 of the Water Resources Act (1991) "to cause or knowingly permit any poisonous, noxious or polluting matter or any solid waste matter to enter controlled waters". Under section 7 of The Environmental Protection Act (1990) a person must use the best available techniques not entailing excessive cost (BATNEEC) for rendering harmless both prescribed and other substances which are released into any environmental medium. There are a number of exceptions to these overall rules. In particular no offence is committed if a discharge is made in accordance with a WRA'91 consent or an EPA'90 authorisation. The introduction of toxicity-based conditions into licences will provide a more relevant and meaningful measure of 'poisonous matter' and 'rendering harmless'.

The document discusses the proposed application of direct toxicity assessment for the regulatory control of wastewater discharges and introduces the wider application of these procedures for the purpose of assessing environmental quality.

The Environment Agency and the Scotland and Northern Ireland Forum For Environmental Research (SNIFFER) have sponsored collaborative programmes to test protocols for deriving and monitoring compliance with licences containing toxicity-based conditions. The approach is based on international experience and emphasises the need to promulgate a small number of toxicity test methods, to deliver high quality information and to ensure consistency of approach in method application.

Research has been directed to select and develop suitable methods and the production of quality data. Proposals for discharge selection, derivation of licences containing toxicity-based conditions, toxicity reduction, compliance monitoring, cost liabilities and the reporting of information, and the expected responsibilities of the regulator and regulated are presented. The major consultation issues presented in the document include:-

- Selection of toxicity test methods and end points.
- Procedures for ensuring good quality data for regulatory monitoring.
- The derivation of toxicity conditions for use in licences.
- Proposals for self-monitoring.
- Toxicity condition breach procedures.
- Toxicity reduction programmes.

Written comments on the proposals are invited by no later than 30th September 1996. A final meeting hosted by Zeneca (Brixham Environmental Laboratory) is planned on the 29-31st October 1996 to debate the proposals.

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 (*q.v.*) of a mixture is the sum of the toxicity of the individual components.
BATNEEC (*q.v.*) and BPEO (*q.v.*)	the principle statutory objectives set out in the Environmental Protection Act 1990 and against which the Environment Agency regulates processes under IPC (*q.v.*). They dictate pollution prevention strategies and demand an holistic approach to environmental protection.
Battery of tests	a set of toxicity tests (*q.v.*) which is intended to address all toxic modes of action (*q.v.*).
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 same 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 (*q.v.*) 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 (*q.v.*) at the suborganism or organism level.
Chemical-Specific Control	the control and assessment of effluents (*q.v.*) 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 (*q.v.*) 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 (*q.v.*) (when it is often referred to as-self monitoring) and/or the regulator.

Control Charts	a statistical procedure and graphical display commonly used in process control to monitor whether a system is operating within defined limits.
Direct Toxicity Assessment	an Environment Agency term to describe the use of toxicity tests (*q.v.*) to give a measure of effluent (*q.v.*) and environmental quality expressed in toxicological parameters.
Discharger	the person, operator or corporate body making a discharge.
Ecotoxicity	the toxicity (*q.v.*) of a sample measured using ecologically relevant end points (*q.v.*).
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_x or NOEC).
Environmental Quality Standard	a limit, normally a concentration, which sets an objective for an environmental compartment, e.g. freshwater, marine water or air.
Established Toxicity Test	a toxicity test (*q.v.*) defined for the purpose of this document as a non-rapid (*q.v.*), well-tested bioassay (*q.v.*) usually with an alga, macrophyte (*q.v.*), macroinvertebrate or fish as the test organism and carried out under rigorously controlled conditions in accordance with a recognised standard operating procedure (*q.v.*).
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 (*q.v.*). 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 (*q.v.*) and BPEO (*q.v.*).
Lethal	causing the death of organisms.
Licence	generic term referring to WRA'91 consents and EPA'90 authorisations.
Local Environment Action 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 (*q.v.*) 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-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 regraded as the lowest measured no-observed effect concentration for the most sensitive species in the test battery.
PROBIT Analysis	a statistical method that calculates the divergence from the mean of a normal distribution, expressed in terms of the standard deviation of the distribution. Its practical use in estimating an LC_{50} or EC_{50} is in straightening the sigmoid curve of the normal distribution for percentage effect as a function of logarithm of concentration.
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 within the programme of quality assurance (*q.v.*), including routine checks and calibrations of normal operations, within a laboratory..
Rapid Tests	toxicity tests (*q.v.*) which can produce the desired toxicity end point (*q.v.*) 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 (*q.v.*) and determining the acceptability of those risks.
RTDL Methods	a statistical procedure, the Reliable Toxicity Detection Level method, which considers both intra-test and inter-test variability in order that false indications are avoided in compliance monitoring due to natural test variability.
Screening	a procedure to obtain an estimate of toxicity (*q.v.*) prior to comprehensive toxicity testing (*q.v.*).
Self-monitoring	compliance monitoring of discharges carried out by (according to a pre-defined programme in a licence) and paid for by the discharger (*q.v.*). It should be noted that monitoring by the regulator is also paid for by the discharger (*q.v.*), through charging schemes.
Self-monitoring Audit	the physical inspection and assessment of a discharger's (*q.v.*) arrangements for compliance monitoring including sampling procedures and records.
Spot-sampling	a procedure to sample at a single period in time.
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 (*q.v.*) and chronic (*q.v.*) exposure periods.
Sub-lethal	a biological response to a toxicant (*q.v.*) below the level that causes death.

Substance-Specific Control	the control and assessment of effluents (*q.v.*) and environmental samples using methods based on the chemical analysis of individual substances or groups of substances.
Synergism	where the toxicity (*q.v.*) of a mixture exhibits greater-than-additive (*q.v.*) total toxic effect.
Toxicant	a substance which has the inherent potential or capacity to cause adverse effects on living organisms.
Toxicity	the inherent potential or capacity of a substance to cause adverse effects on living organisms.
Toxicity Condition	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.
Toxicity Criteria	a toxicity measure to assess environmental or discharge quality.
Toxicity Limit	requirement in a discharge licence (*q.v.*) expressed as a toxicological maxima not to be exceeded.
Toxicity Reduction Plan	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.*).
Toxicity Reduction Programme	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.
Toxicity Screening	a procedure to obtain an estimate of toxicity (*q.v.*) prior to comprehensive toxicity testing (*q.v.*).
Toxicity Test	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.
Toxic Mode of Action	mechanism by which a toxicant (*q.v.*) causes an adverse effect on living organisms.
Trophic Level	a general term for each step of a food chain or food pyramid.
Trophic Level Testing	a battery of toxicity tests (*q.v.*) with organisms from several trophic levels (*q.v.*) such that they simulate a micro-ecosystem.

Water Quality Objective	a set of requirements to be met to achieve specified water quality standards.
Whole Effluent Toxicity	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.*).

ABBREVIATIONS

AQC	Analytical Quality Control (*q.v.*)
BATNEEC (*q.v.*)	Best Available Techniques Not Entailing Excessive Cost
BPEO (*q.v.*)	Best Practicable Environmental Option
DTA	Direct Toxicity Assessment (*q.v.*)
EC	European Community
EC_{50}	Median Effective Concentration
EC_x	Effective concentration producing an x% response
EPA'90	Environmental Protection Act (1990)
EQS	Environmental Quality Standard
GLP	Good Laboratory Practice
IPC	Integrated Pollution Control (*q.v.*)
LC_{50}	Median Lethal (*q.v.*) Concentration
LC_x	Lethal (*q.v.*) concentration killing x% of organisms
LOEC	Lowest-Observed Effect Concentration
NOEC	No-Observed Effect Concentration
NRA	National Rivers Authority
PEC	Predicted Environmental Concentration (*q.v.*)

PNEC	Predicted No-Effect Concentration (*q.v.*)
QA/QC	Quality Assurance (*q.v.*)/Quality Control (*q.v.*)
RTDL	Reliable Toxicity Detection Level (*q.v.*)
SNIFFER	Scotland and Northern Ireland Forum For Environmental Research
SOP	Standard Operating Procedure (*q.v.*)
UKAS	UK Accreditation Service (formerly NAMAS)
WET	Whole Effluent Toxicity (*q.v.*)
WRA'91	Water Resources Act (1991)

NOTICES

Environmental Protection Act 1990 (authorisations)

Enforcement	Notice issued specifying the nature of a contravention of an authorisation, the action required to remedy that contravention and a timescale in which to achieve it.
Prohibition	Notice issued when there is an imminent risk of serious pollution to the environment regardless of a breach of an authorisation. The notice may require the discharger to suspend the operation responsible for the risk.

Water Resources Act 1991 (consents)

Prohibition	Notice issued imposing conditions on the discharger, prohibiting or placing conditions on certain types of discharges e.g. discharges onto or into land.

Environment Act 1995

Enforcement	Notice issued if a discharger is contravening or likely to contravene the conditions of a consent or authorisation. The notice specifies the contravention, the steps necessary to remedy the situation and the period within which the steps must be taken before any prosecution is considered.
Works	Notice served on a person who has contravened the Water Resources Act 1991 requiring preventative works to avoid potential pollution, remove or dispose of polluting water, remedy or mitigate the cause of pollution and restore, so far as is reasonably practicable, of waters, flora and fauna to their state prior to the pollution event.

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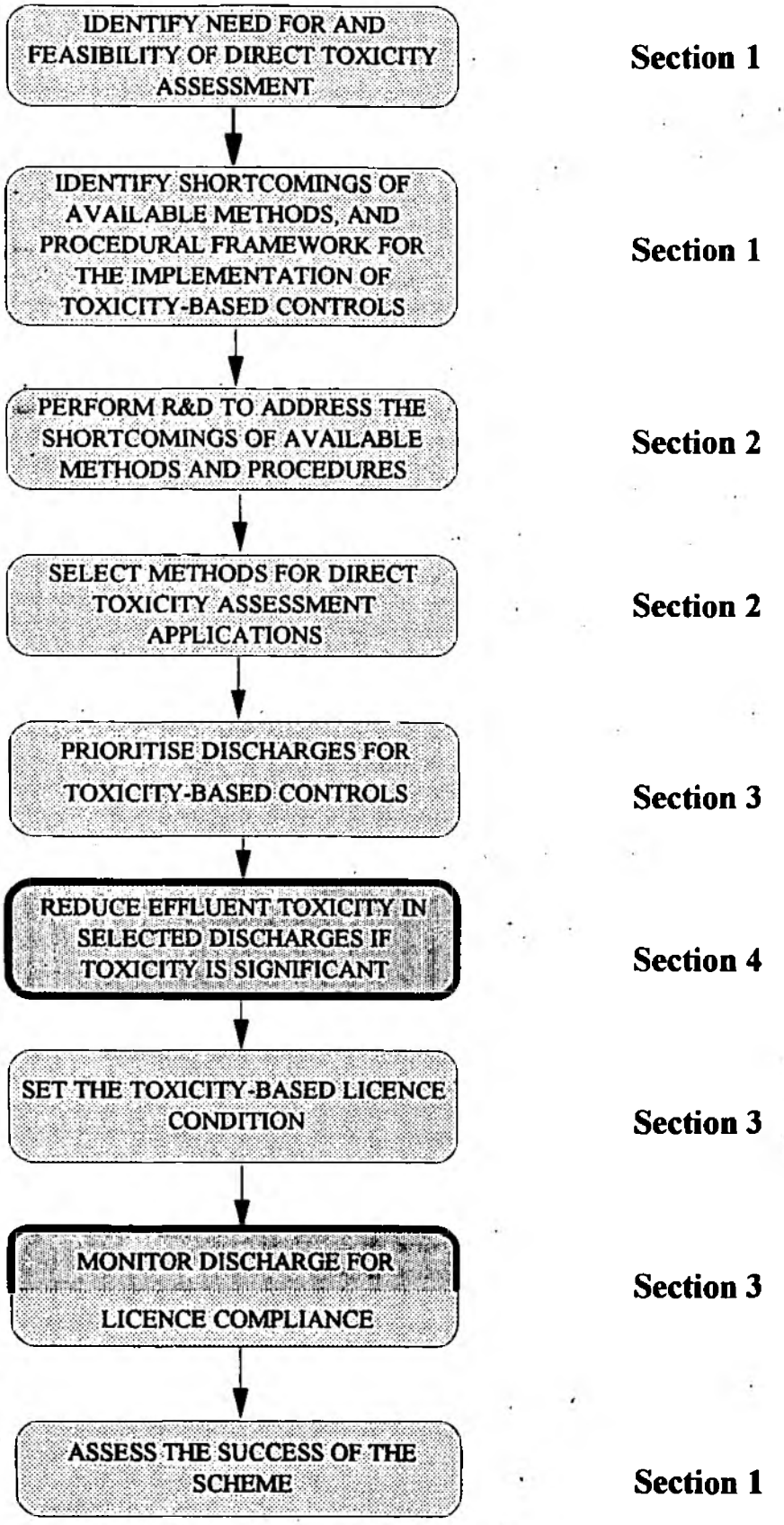


Figure 1. Structure of the document.

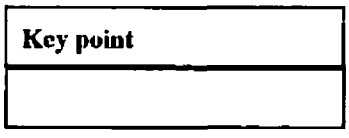
1 INTRODUCTION

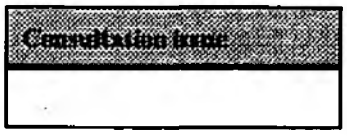
1.1 Purpose of this document

Written comment is invited from interested parties on proposals by the Environment Agency to introduce toxicity-based criteria for the regulatory control of wastewater discharges. The structure of the document is shown in **Figure 1**.

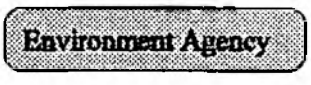
In the document both 'Discharge Consents' (issued under The Water Resources Act, 1991; ***WRA'91***) and 'Authorisations' (issued under The Environmental Protection Act, 1990; ***EPA'90***) will be referred to as 'licences'. When referring specifically to WRA'91 consents these will be described as consents and when referring specifically to EPA'90 authorisations these will be described as authorisations.

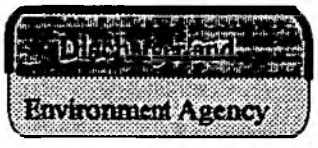
Although the entire document should be considered for comment, key points and consultation issues are highlighted as follows:



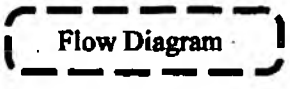


Terms explained in the glossary, and abbreviations, are ***italicised*** and in ***bold*** the first time they are encountered in the text. The shading in the flow-diagrams indicates expected responsibilities as follows:





Where a flow diagram directs to another this is indicated by:



The document:

- identifies the limitations of current practice for the regulatory control of ***complex effluents*** and advocates a combined approach including ***Direct Toxicity Assessment*** (***DTA***);
- presents proposals for the introduction of toxicity-based criteria for the regulatory control of complex wastewater discharges.

Consultation issues include:

- Selection of ***toxicity test*** methods and ***end points*** (EC_x or *NOEC*). **(Section 2.4)**
- Quality assurance. **(Section 2.5)**
- ***Compliance monitoring*** & assessment. **(Section 3.4)**
- Breach procedures. **(Section 3.4.4)**
- ***Toxicity reduction programme***. **(Section 4)**

Guidance notes will be prepared to support protocols for deriving and monitoring compliance with licences containing toxicity conditions following the consultation exercise. It is proposed that these will form part of the Environment Agency's discharge licencing procedures.

Key Point
The document is concerned, primarily, with toxicity-based criteria within discharge licences for controlling effluents and not with environmental monitoring. It should be noted that all monitoring is performed on the discharge and not within the *receiving water* body.

1.2 Current situation

Under Section 85 of WRA'91 it is an offence to cause or knowingly permit the introduction of poisonous, noxious or polluting matter or any solid waste matter to controlled waters. Under

EPA'90 authorisations must include conditions to ensure that the Best Available Techniques Not Entailing Excessive Costs (***BATNEEC***) are used for preventing the release of substances prescribed for any environmental medium into that medium or, where that is not practicable by such means, for reducing the release of such substances to a minimum and for rendering harmless any such substances which are so released; and for rendering harmless any such substances which might cause ***harm*** if released into any environmental medium.

There are a number of exceptions to these overall rules. In particular no offence is committed if a discharge is made in accordance with a WRA'91 consent or an EPA'90 authorisation. It should be noted that, in ***IPC***, prevention and minimisation take priority over rendering harmless, a concept which the Environment Agency is applying on several river catchments (***NRA***, 1995).

Water quality monitoring and the regulatory control of toxic discharges is currently based on the achievement of ***Environmental Quality Standards (EQSs)*** in receiving waters. These standards are derived from physical, chemical and toxicological properties of the individual chemicals and are set to relate to the river quality needs based on local circumstances (***Water Quality Objectives***). Although preferable to fixed emission standards, this approach, in isolation, is inadequate for the control of complex discharges for the following reasons:

- It is not possible to derive and monitor an EQS for all chemicals (less than 0.1% of listed chemicals have an EQS).
- Some existing EQSs are based on limited data and therefore incorporate standard, and often large, safety factors.
- By-products and contaminants produced during industrial processes are not considered in EQSs.
- Interactive toxicity between chemicals (e.g. ***additivity***, ***synergism***) cannot be controlled by setting EQSs for individual substances.
- In some cases EQSs are set below or close to the current limit of detection.

As a result, some ***dischargers*** may comply with their chemical-specific licences and yet the discharge may still be causing environmental damage (indicating under-protection), conversely others may breach their licence without causing environmental damage (indicating over-protection).

Biological surveys can provide information to help assess the harmful effects of discharges. However, they only show damage after pollution has occurred, and provide little or no information about the cause or source of toxicity.

Key point
Chemical specific standards in discharge licences and biological surveys of receiving waters provide only limited control of toxic discharges.

A limited number of consents containing toxicity conditions are currently in use by the Environment Agency, in the Anglian Region, where the regulator and industry have co-operated in their introduction. However, there is no national strategy and no standardised procedures, the absence of which produces a risk of real or perceived inconsistency. This risk, and the absence of the technical authority of a national strategy, leads to a reluctance to enforce.

1.3 Recent developments

In July 1989 the then NRA established a group to review discharge consenting policy. As a result, the National Rivers Authority Water Quality Series Report No. 1- Discharge Consents and Compliance Policy: a blueprint for the future ('Kinnersley Report'; NRA, 1990), made recommendations to change aspects of consenting procedure.

Paragraph 84 of the report states:

> " Some discharges.....can contain a complex and variable cocktail of toxic chemicals which it is impractical or even impossible to identify and control by means of individual limits. For significant discharges of this sort, toxicity testing provides an effective control of their overall impact on the receiving water. In such cases the consent should specify the maximum acceptable level of toxicological response, and also stipulate the frequency with which this limit should be tested using one of the routinely available tests".

This observation leads to Recommendation 16 of the report which states:

> "For environmentally significant discharges of complex composition where not all important constituents can be individually identified and numerically limited, consents should specify a clearly-defined toxicity limit, the appropriate form of toxicity test to be used, and the minimum frequency with which it should be applied".

Key point
The Environment Agency proposes to implement Recommendation 16 of the 'Kinnersley Report'.

1.4 Combined approach for the control of toxic discharges to receiving waters

The proposed combined approach consists of:

- ***Substance Specific Control*** - To regulate particularly hazardous chemicals.
- Direct Toxicity Assessment (DTA) - To reduce toxicity at source via toxicity-based conditions within discharge licences.
- ***Biological Assessment*** - To establish environmental status via biological survey.

The combined approach aims to control toxic discharges and to demonstrate environmental improvement. Each element has capabilities and limitations. Used together they complement each other, offering a more complete approach to the protection of controlled waters.

Substance-specific control and biological assessment are well established. DTA, as a national initiative of the Environment Agency is a new, and key component of the approach. It is proposed that toxicity conditions in discharge licences will be used as one of the techniques for controlling discharges available to Environment Agency staff and introduced where appropriate. The introduction of ***toxicity testing*** by the Environment Agency will be based on sound science. A number of research and development initiatives have been undertaken to ensure that cost-effective procedures based on high quality data are developed.

Consultation issue
The Environment Agency proposes to introduce DTA as part of a combined approach to control toxic wastewater discharges, employing chemical controls, toxicity-based conditions within discharge licences and biological surveys where each is appropriate.

DTA procedures have been used successfully in the United States, Canada and some European countries for a number of years (Wall and Hanmer, 1987; Bonsor *et al*, 1988; USEPA, 1991; 1994; Hunt *et al*, 1992; MISA, 1992). Government, industrial and international agencies have increasingly adopted single-species toxicity tests to predict potential effects in the environment. The Organisation for Economic Cooperation and Development (OECD, 1987) concluded that toxicity testing is a scientifically sound tool that should be used in member countries, in conjunction with chemical and ecological measurements, to identify, quantify and control the discharge of toxic pollutants. In addition to toxicity-based conditions in discharge licences the Environment Agency DTA National Centre is developing DTA for assessing environmental water quality and promoting an internationally consistent approach to the application of DTA.

A great deal of information has been gained from a fact-finding trip to the United States and from close liaison with regulatory agencies, consultants, industry and academia both nationally and internationally. Toxicity-based conditions in discharge licences have proved an effective method for controlling complex effluents in the United States for almost 15 years. This is particularly evident when the necessary *QA/QC* procedures are in place. A review of the procedures in the US have recently endorsed the approach (SETAC, in press). When properly applied and enforced, licences containing toxicity conditions provide a real-effect, risk assessment measure of 'what is poisonous' (WRA'91) or can be used as a demonstration of 'rendering harmless' (EPA '90).

Key point
Experience from the United States has demonstrated that DTA can be used successfully as a discharge control measure, when adequate quality controls are in place, resulting in improved environmental quality. This was endorsed by the recent 'Pelston workshop' in the US (SETAC, in press).

In some cases, controlling toxic discharges will not necessarily show immediate environmental benefits; residual problems from historical pollution may exist. However, by reducing toxicity, further contamination will be restricted allowing the receiving environment to recover.

Environmental benefit as a result of toxicity-based controls will be assessed by biological survey and the Direct Toxicity Assessment of the receiving waters.

1.5 Key benefits of Direct Toxicity Assessment

Consideration is under way to introduce a 'harm' condition into WRA'91 consents, similar to that used for authorisations in the EPA'90. The introduction of licences containing toxicity conditions will help to provide a more relevant measure of 'poisonous matter' and 'harm' as described in the WRA'91 and EPA'90. In finalising the proposals emphasis will be placed on the collaborative efforts of the business community and the regulatory agency to demonstrate

environmental awareness and the need for a sensible and sustainable approach to protect the environment from releases of toxic substances in toxic amounts. The Environment Agency will use its powers in a fair and even handed manner to improve environmental quality, which may include the need for penalties as clearly stated in WRA'91, EPA'90 and the Environment Act 1995. However, the emphasis will be on toxicity reduction through negotiated agreement rather than through prosecution.

Key Point
The discharger shall properly undertake its responsibilities or be subject to penalties as outlined in the EPA'90 and WRA'91 [and amended by the Environment Act (1995)]. However, emphasis will be placed on the collaborative efforts of the business community and the Environment Agency to demonstrate environmental awareness and the need for a sensible and sustainable approach to protect the environment from releases of toxic substances in toxic amounts.

For the protection of aquatic life a combined approach is required with each component providing valuable, if incomplete information. In the immediate future, it is proposed that, DTA will be additional to, rather than a replacement for, chemical limits and associated monitoring. Chemical licence conditions will still be required to limit specific substances and to comply with statutory requirements e.g. the EC Dangerous Substances Directive. Where a single toxicity condition can characterise the cumulative environmental effect of a suite of chemicals in an effluent it is possible that a toxicity-based condition may, in time, reduce the monitoring frequency or replace the need for individual numeric concentration limits for such substances. However, the combined approach offers advantages to both the regulatory and regulated communities. In summary the benefits of DTA are as follows. DTA can:

- provide clear, unequivocal target levels of toxicity that relate directly to the protection of aquatic life;
- provide a measure of aggregate toxicity that cannot be identified and licenced on a substance specific basis;

- be a measure of 'harm' and what is 'poisonous' as required by law;
- prioritise discharges for regulatory control;
- target monitoring resource by rationalising ***permissive chemical analysis***;
- prioritise expenditure for effluent treatment processes;
- provide advance warning of the risk of environmental damage (this is of particular value in any risk assessment strategy);
- improve the public image of industries shown to be releasing discharges of insignificant toxicity;
- provide information for general water quality assessments;
- aid in directing water quality improvement programmes.

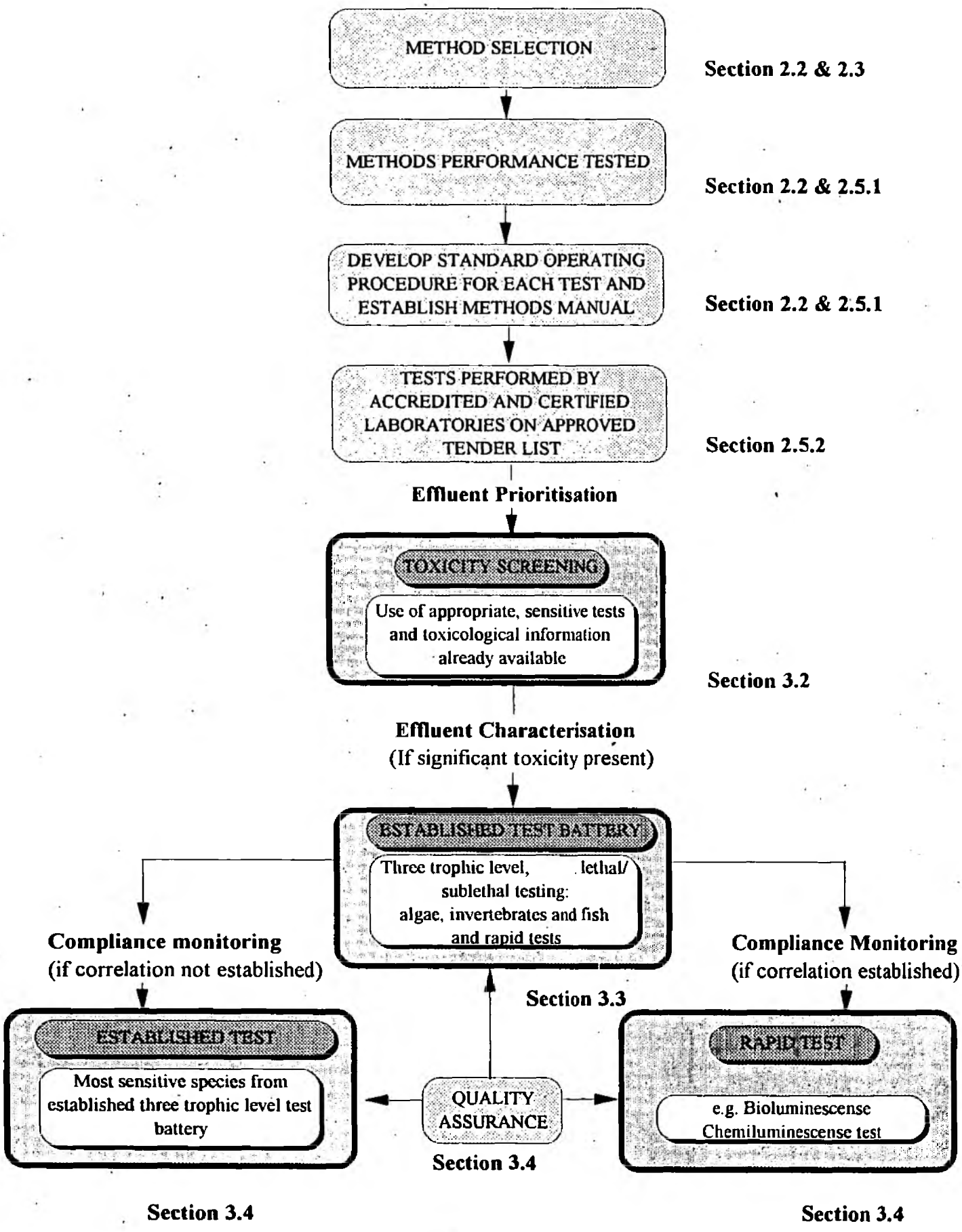


Figure 2. Method development and application protocol

2 ECOTOXICOLOGICAL METHODS AND QUALITY ASSURANCE

2.1 Overview

The success of any Direct Toxicity Assessment application is dependent on the ability of the toxicity test methods to deliver robust and relevant data at reasonable cost to both the Agency and the discharger. Since August 1993 the Environment Agency and Scotland and Northern Ireland Forum For Environmental Research ***(SNIFFER)*** have been sponsoring collaborative research and development to develop a strategy for the introduction of toxicity criteria into licences to regulate complex discharges. DTA is also being developed for the wider application of assessing environmental water quality.

The number of available toxicity test methods is large and increasing. However, there are few which are ***established*** and that have been ***performance tested***. The larger the number of methods employed, the more difficult it is to achieve consistent quality control. The selection of a small number of methods is preferred. The development and application of test methods are outlined in **Figure 2**.

Key Point
Many toxicity test methods are available but it is important to select those that are suitable for discharge control and environmental quality monitoring. The Environment Agency proposes to promulgate the use of a small number of *performance tested* toxicity assessment methods.

2.2 Method selection

A major task for the Environment Agency is to identify those tests which would suit the different applications, particularly those relating to regulatory control and which have been fully validated through performance testing. It is important, for any specific application, to use appropriate methods which generate good quality data.

The Environment Agency is sponsoring an R&D project to develop suitable methods for regulatory control. This project is assessing new and existing ecotoxicological methods against a checklist of criteria including:

- **Ease of use**; in particular, the time involved in training staff to achieve consistent results.
- **Cost**; of implementing and conducting a method (setting up a test, purchasing the equipment, staff costs for carrying out a test, plus costs of materials and maintenance of organisms).
- **Rapidity**; the test method duration from initiation to the collation of the final data set.
- **Sensitivity**; the exposure concentration of a test substance required to elicit a standardised response.
- **Spectrum of response**; the range of chemical classes (and ***toxic modes of action***) to which the method is sensitive.
- ***Standard Operating Procedure (SOP)***; the availability of a SOP which can be used to ensure the method is conducted consistently by the different laboratories.
- **Precision**; the repeatability and reproducibility of the test method (i.e. the level of variability found within and between-laboratories).

For a given operational role some criteria may be considered more important than others and are assigned different weightings.

Key point
Tests will be selected according to a number of criteria and will be application specific.

2.3 Method evaluation for the toxicity-based control of complex effluents

A pilot study has been undertaken to evaluate the protocol for the derivation of licences containing toxicity criteria for the regulatory control of complex discharges.

Tests used in the pilot study are shown in **Table 1**. As no particular group is most sensitive to all categories of ***toxicants*** a ***battery of tests*** will be used for ***screening*** and setting the toxicity condition in the discharge licence (USEPA, 1994a). The most sensitive test in the battery (or a surrogate rapid test) will be used for subsequent compliance monitoring.

Key point
The list in Table 1 is not definitive and does not necessarily imply that these tests will be selected for licence conditions.

Table 1. Toxicity tests used in the toxicity-based consent pilot study

	FRESHWATER	**MARINE/ ESTUARINE**
	***Rapid* Tests**	
	Chemiluminescence (Enzyme; R)	Chemiluminescence (Enzyme; R)
	Bioluminescence (Bacterium; R)	Bioluminescence (Bacterium; R)
	***Established* Tests**	
Trophic level 1	*Selenastrum* (Alga; AL & ASL)	*Skeletonema* (Alga; AL & ASL)
Trophic level 2	*Daphnia magna* (Crustacean; AL & ASL)	Oyster embryo larvae (Bivalve; AL & ASL)
		Acartia tonsa (Crustacean; AL & ASL)
Trophic level 3	Trout (Fish; AL & ASL)	Turbot/ Plaice (Fish; AL & ASL)
	Key: R: Rapid; AL: ***Acute-Lethal***, ASL: ***Acute-Sub-lethal***.	

Many of the discharges used in the pilot study were found to be acutely toxic using the toxicity tests in **Table 1**. There are requirements for the following, or other tests, to be developed in both the marine and freshwater environment:

- ***chronic***
- ***sub-chronic***
- sub-lethal
- rapid
- ***biomarker***
- screening

Consultation issue

It is suggested that suitable toxicological tests are available for immediate application although a definitive test set for discharge licencing, as proposed, is still to be finalised.

2.4 Toxicity test end points and experimental design

2.4.1 Test end-points (EC_x or NOEC)

An end-point should be meaningful but simple to derive and unambiguous in legal terms. As there is a choice of toxicity test, so there is also a choice of end-point.

Two test end-points are considered below:- the EC_x (or LC_x) and the NOEC.

EC_x and LC_x values (e.g. EC_{50} and LC_{50}) and associated confidence limits, and NOEC values are derived from full concentration range toxicity tests. Typically, a minimum of six concentrations are used in a logarithmic scale with replicates at each concentration. A control of dechlorinated tap water, a formulated standard water or 'clean' reference water is also used. Percentage response data obtained following exposure of test organisms to the test concentrations and control is transformed prior to the calculation of toxicity values. A typical concentration response curve, prior to transformation of the response data, is shown in **Figure 3**. When testing effluents the concentration term would be replaced by percent effluent. In order to establish the EC_x or LC_x values the toxicity data is generally ***PROBIT*** transformed to generate a straight line. The EC_x or LC_x values are derived from the regression of response against the logarithm of the concentration. This value is therefore not necessarily one of the test concentrations.

To calculate the NOEC (No Observed Effect Concentration) analysis of variance (generally on arcsine transformed data) is used to establish the lowest concentration at which a significant

response is observed when compared with the control (this is the ***Lowest Observed Effect***

Concentration; *LOEC*). The NOEC is one concentration below the LOEC. Both values are actual exposure concentrations used in the experiment (*cf.* EC_x or LC_x which are derived values).

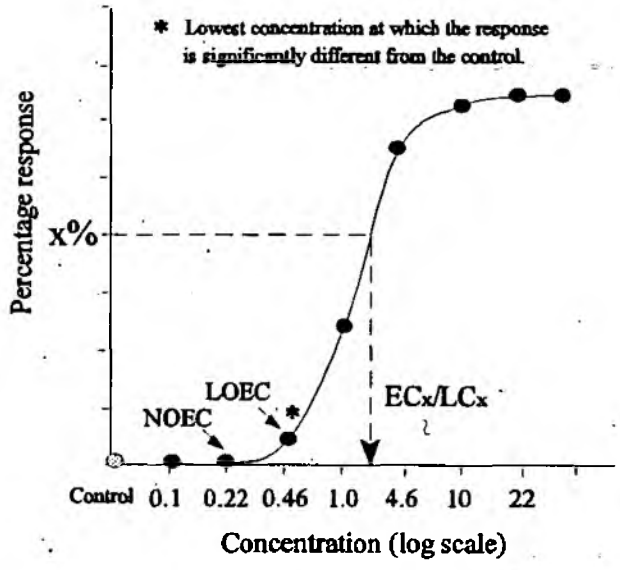


Figure 3. Typical concentration-response curve. (In this example the NOEC is 0.22 and the LOEC is 0.46).

2.4.2 Test experimental design

There are several types of experimental design used in determining the toxicity of an effluent. Two designs considered for regulatory purposes are the full range toxicity test (or multi-concentration test) and the limit test (or single concentration test). The full range test is conducted over a logarithmic range of, usually, 6 or more concentrations plus a control. From this test the concentration producing a specific result, such as the EC_x (LC_x), NOEC and LOEC, can be determined. The results give an estimate of the degree of toxicity of the test material. In contrast, a limit test compares the response in a single concentration against a control. This gives either a significant or non-significant result i.e. toxic or non-toxic. In regulatory monitoring the sample concentration in a limit test is often set such that no-significant toxicity would be expected compared to the control and a pass or fail decision can

be made. Although the limit test cannot be used to calculate EC_x (LC_x), LOEC or NOEC values it is simple, cheap and uses a pass/fail toxicity limit which is unambiguous in legal terms and therefore easy to judge compliance against.

2.4.3 Preferred option for end points and experimental design for regulatory purposes

From a public viewpoint, setting the toxicity limit in terms of a 50 % (or any other percentage) response, as has been used in current toxicity-based control, has limitations. It may lead people to believe that the discharge will be causing a toxic response in the receiving water even when the discharge licence condition is achieved. Therefore, it may be preferable to set the licence toxicity condition such that achievement of the toxicity condition involves a demonstration of no-observed toxic effect of the discharge to the test species at a certain effluent concentration relative to a control.

It is proposed that a combination of full range and limit toxicity tests will be used to set licences and monitor for compliance. Toxicity tests employing a wide range of concentrations would be conducted to provide the data to set the concentration for the limit test against which compliance would be monitored. Subsequent compliance monitoring would be undertaken using limit tests employing single concentrations (i.e. no-effect at a given concentration or effluent dilution). Full range testing would then assess the seriousness of any breach of a toxicity licence condition for further action. This is considered the most scientifically and financially acceptable method for successful implementation of toxicity controls. Appropriate methods and assumptions for statistical analysis of the data obtained from testing will be written into the standard methods.

It is initially intended to set licences containing toxicity criteria using short-term (acute) lethal and sub-lethal toxicity tests, based on a no-observed effect end point. However, long-term (chronic) lethal and sub-lethal tests may be considered at a later stage.

Consultation issue
Initially the Environment Agency proposes to use a measure of no-observed toxicity to set toxicity limits. Tests involving a range of test concentrations would be used in the initial effluent characterisation stage. Limit tests would be used to monitor compliance with the toxicity condition in the discharge licence.

2.5 Variability of the data

The need for a quality system to ensure high quality data has been identified. This will focus on the performance of aquatic toxicity test methods, improvements in the operation of the tests, review of their applicability to different operational roles and the adoption of quality auditing. It is proposed that laboratories undertaking toxicity testing for regulatory purposes will have to satisfy specific QC and QA requirements before approval and registration.

Key point
Test methods and test facilities must be quality controlled and audited.

2.5.1 Quality control

Like biological and chemical measurements, determinations of toxicity exhibit variability. It is important to understand the levels and sources of variability in toxicity tests if they are to be used to make equitable and enforceable regulatory decisions.

It has been shown that when performance testing is undertaken, results from toxicity tests are generally consistent between laboratories and over time. Variability in results obtained from certain toxicity tests is no greater than for commonly accepted chemical analytical methods (Rue *et al.*, 1988; Grothe *et al.*, 1990). An R&D programme is proceeding to identify and reduce sources of variability, incorporating:

- use of standard test methods with Standard Operating Procedures (SOPs);
- ring-testing with standard reference chemicals (inter-laboratory);

- batch-testing (intra-laboratory);
- use of ***control charts***.

It should be noted that toxicity testing requires replication and statistically sound experimental design. Statistical protocols and experimental procedures are being developed to ensure that false positive or negative results are avoided based on the ***RTDL*** methods of Dhaliwal *et al.* (1995). This will ensure confidence in the reported results.

Key point
Toxicity test variability can be reduced to a level similar to, or better than, that obtained by chemical analyses when strict quality control procedures are followed.

The culmination of method selection and performance testing will be the production of the Environment Agency/SNIFFER 'Ecotoxicology Methods Manual', incorporating SOPs for the selected tests, sample collection, transportation and storage procedures, cleaning and storage of apparatus, culture set-up and maintenance and ***quality control*** (***QC***) procedures. This manual will be available, and updated, at each toxicity testing service laboratory, and will be adhered to by all operational staff.

Key point
It is proposed that toxicity tests used for discharge licence compliance monitoring will be undertaken to the standards in the Environment Agency/SNIFFER 'Ecotoxicology Methods Manual'.

2.5.2 Laboratory approval scheme

The reliability of test data (whether chemical or toxicological) is synonymous with their quality, which is indicated by the QA practices of the testing laboratory. It is proposed that a scheme will be introduced by the Environment Agency which will ensure SOPs, QC and operational performance criteria are met by laboratories undertaking toxicity testing for regulatory purposes. To implement this, a project is under way to establish a scheme which will provide:

- documented guidance for laboratories on quality control requirements (the Environment Agency/SNIFFER 'Ecotoxicology Methods Manual');
- a demonstration that the laboratory is competent to carry out toxicity testing for regulatory purposes;
- assurance of the integrity of the test data and a suitable audit trail.

A laboratory will need to be ***GLP*** compliant or ***UKAS*** accredited for methods in the Environment Agency/ SNIFFER 'Ecotoxicology Methods Manual'. In addition the laboratory will submit QC data to the Environment Agency DTA National Centre. The National Centre will maintain a register of approved laboratories whom have attained accreditation and satisfy the necessary QC requirements for regulatory ecotoxicological testing.

The process by which a laboratory will gain approval will include the following:

- the initial application;
- laboratory inspection;
- performance evaluation;
- registration;
- periodic review of approval.

Consultation issue
It is proposed that test laboratories that satisfy the approval requirements be registered before being allowed to undertake toxicity testing for regulatory purposes. Facilities will be audited by the appropriate accreditation scheme. Test data will be audited by the Environment Agency or its agent.

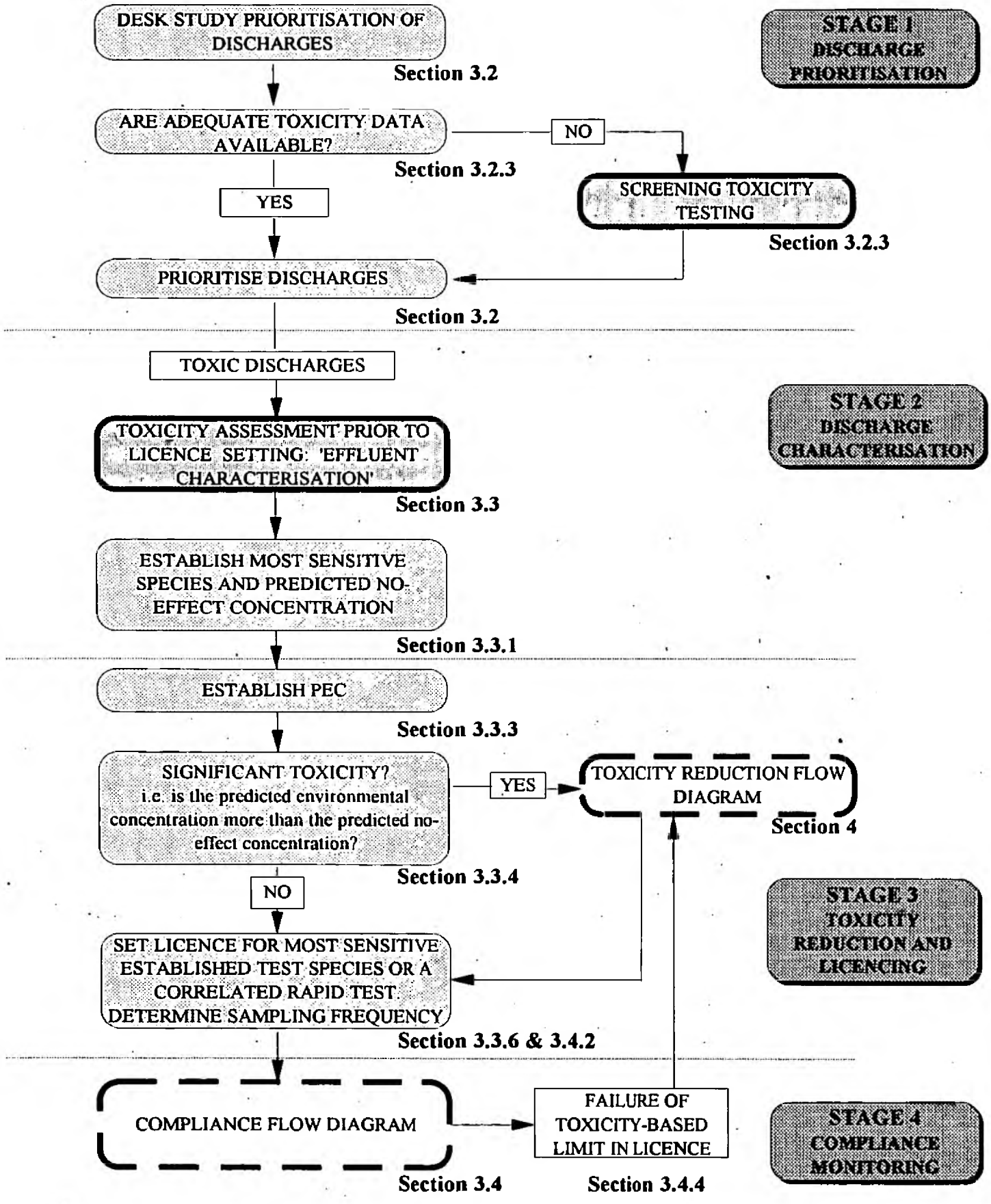


Figure 4. Toxicity-based licencing protocol.

3 DISCHARGE LICENCING PROCEDURE AND COMPLIANCE MONITORING

3.1 Introduction

It is proposed that toxicity conditions will form part of a discharge licence and, initially at least, will complement existing forms of control. It is therefore important that all other discharge licencing policies and requirements are taken into account when using a toxicity condition. It is possible that toxicity conditions may, in time, replace numeric concentration limits for some substances.

The use of a toxicity condition is acceptable in both WRA'91 consents and EPA'90 authorisations. The WRA'91 and the EPA'90 may introduce "such other conditions (if any) (into an authorisation) as appear to the enforcing authority to be appropriate" (EPA'90, Part I Section 7) and 'such conditions as the Authority may think fit (into a consent)... for minimising the polluting effects of the discharges on any controlled waters" (WRA'91, Sch 10 Section 5).

Where it is reasonable to conclude that the discharge is causing, or has the potential to cause, harm to the receiving water, this harm may be reduced and controlled by the use of a toxicity condition. This licence condition can be applied with a knowledge of the dilution capacity of the receiving water and any acceptable zone of deterioration. Prioritisation and application of toxicity conditions will follow the procedures set out in **Figure 4**. The four yearly licence review will provide an opportunity to incorporate the toxicity conditions into existing licences.

It is proposed that modification of licences will be undertaken on a priority basis. The procedure for existing licences outlined in **Figure 4** consists of the following stages:

- Licence Review (pre-modification of the licence)

- monitoring of the existing discharge to characterise toxicity;
- calculation of Predicted No-Effect Concentration ***(PNEC)***;
- calculation of Predicted Environmental Concentration ***(PEC)***;
- determination of toxicity condition if PNEC>PEC or toxicity reduction if PEC>PNEC **(Section 4)**;

- Licence Modification

- complete the licence review imposing the toxicity condition, with an associated schedule describing methods and compliance assessment criteria and any time limits for completion of a toxicity reduction programme .

Existing licences will either be reviewed/varied at the request of the discharger or by the Environment Agency. Inclusion of a toxicity condition could be by the review of an existing licence or the issue of a replacement licence.

STAGE 1- Discharge Prioritisation

3.2 Selection and prioritisation of discharges for toxicity-based licence conditions

Initial selection of existing discharges will be a desk-based appraisal combined with, if necessary, ***toxicity screening*** using a battery of tests. Discharges will be selected and prioritised by Environment Agency staff according to the criteria detailed in **Sections 3.2.1-3.2.7**.

3.2.1 Effluent complexity

Priority will be given to the inclusion of toxicity conditions in licences for discharges which are known to contain a mixture of substances and which are considered by the Agency not to be adequately controlled by the chemical EQS approach. The chemical EQS approach may be unsuitable because of synergies or interactions between individual components, or where there is inadequate data to derive an EQS.

3.2.2 Environmental impact

Where biological and/or fishery surveys have demonstrated a receiving water quality which is lower than that which could be reasonably expected, and where it is reasonable to conclude that reduced quality results from one or more toxic inputs, toxicity conditions should be

introduced into licences as a priority. Compliance with existing chemical or descriptive licence conditions, or chemical EQS values, should not lessen the priority.

3.2.3 Existing toxicity data and toxicity screening

It is proposed that existing toxicological discharge data and published toxicological data available for chemicals which are known to be in the discharge will be used to assess the potential toxicity of the effluent in the receiving waters. If no data are available, the discharger will be required to provide them. Suitable candidate discharges will be those where toxicity is demonstrated from existing data or from toxicity screening using a complementary battery of tests. The battery will consist of rapid and/or established tests.

3.2.4 Available dilution and receiving water usage

The initial impact of an effluent discharge on a receiving water body will depend on the volume of effluent discharged, the available dilution in the receiving water, the quality of the receiving water and the initial toxicity of the effluent. Information on the volume of the effluent discharged at high flow, and a measure of low flow in the receiving watercourse or tidal dispersion will be required to determine the dilution of the effluent following discharge. Toxic complex effluents which receive little dilution in the receiving water would be a priority in the initial stages of implementation. The discharger would supply data on discharge flows. The sensitivity of the receiving water and current (or future) water usage will also be taken into account when selecting discharges for control. Toxic effluents that discharge into more sensitive waters or waters requiring high water quality will be considered a high priority.

3.2.5 Other considerations

It is envisaged that discharges shown to be toxic by DTA measures will be controlled, most usually, on a catchment basis as decided by regional/area Environment Agency staff as part of the ***Local Environment Action Plan*** process. The Environment Agency will assess the costs and benefits of the toxicity-based conditions in each case. However this does not exclude the possibility of individual major toxic discharges being targeted for control where a need exists .

Key point
It is proposed that licenced effluent discharges be prioritised for control, using toxicity conditions by Environment Agency regional/area staff.

3.2.6 Toxicity licence conditions requested by the discharger

Some dischargers may wish to include a toxicity conditions in their licence to demonstrate pro-active environmental awareness to the public. This will be particularly advantageous to companies that release discharges of insignificant toxicity.

3.2.7 Licencing of new and proposed discharges

Ideally, the suitability of a discharge for control using toxicity conditions should be decided following discussion with the Environment Agency before application is made for a licence. However, it may not be until the initial assessment of any discharge licence application that concerns about the toxicity of a discharge are raised. In such cases, in addition to the normal information supplied by the applicant, the Environment Agency may serve a notice requiring the following information:

a) details of the toxicity of similar discharges where possible;
b) environmental assessment exploring the risk of toxicity to aquatic life (i.e. is PEC>PNEC).

It may be appropriate to set a time limited condition which requires the discharger to carry out a toxicity assessment of the discharge and provide information to the Environment Agency for consideration with a view to determining a toxicity condition.

STAGE 2- Discharge Characterisation

3.3 Effluent characterisation

3.3.1 Effluent characterisation prior to the determination of the toxicity limit (characterisation programme)

In the derivation of a licence containing a toxicity condition the first step will be for the discharger to characterise the toxicity and variability of the discharge. It is proposed that this initial characterisation will be conducted on samples using a battery of established tests at three trophic levels (algae, macroinvertebrates and fish). It is important to take sufficient samples as are necessary to characterise the variability of the discharge. The sampling strategy may also be directed to assess the toxicity of different batch processes. Results from the characterisation stage will be used to determine the sampling frequency for routine monitoring of the toxicity condition. In addition, the discharger may wish to run rapid tests to demonstrate a correlation with established tests. The Environment Agency may subsequently consider the use of these rapid tests for routine monitoring. Toxicity testing will be used to determine the effluent dilution required to achieve no observed toxic effect (determined as the No-Observed Effect Concentration; NOEC) using the most sensitive test in the battery (algae, invertebrate or fish). This is the predicted no-effect concentration (***PNEC***) which is equivalent to the lowest no-observed effect concentration (NOEC) determined from the testing.

Consultation issue

It is proposed that the discharger will be required to undertake testing to characterise the toxicity of the discharge and the PNEC.

It is suggested that characterisation of the discharge, including provision of data (e.g. toxicity information), would be achieved by informal agreement between the discharger and the Environment Agency. In cases where agreement cannot be reached, other methods of acquiring the information may be considered. These measures include licence review/variation, an ***enforcement notice*** or an ***improvement plan*** depending on the current discharge control, i.e. WRA'91 or EPA'90 and state of implementation of the Environment Act 1995.

STAGE 3- Toxicity Reduction and Licencing

3.3.2 Point of protection in the receiving water

It is not always practicable for the effluent to meet receiving water quality criteria at the point of discharge (licence compliance sampling point). Traditionally, the size (volume, area) of the impact zone has been defined by the Environment Agency and the dilution and dispersion provided within this zone used in determining discharge licence conditions. The majority of current discharge conditions are set in this way to ensure (as a minimum) compliance with the EQS in the receiving water. It is proposed that the toxicity condition will be set in a similar manner with a PNEC at a point of protection in the environment being achieved by taking into account the available dilution and dispersion of the effluent. It should be noted that samples will be taken at the usual Environment Agency sampling point (i.e. the effluent prior to discharge). The point in the environment where the no-effect condition will apply will depend on receiving water usage and sensitivity. This may be end-of-pipe for sensitive systems where high water quality is required, or at a defined point in the receiving water for systems that are less sensitive and where water of a lower quality is required. The point of protection and zone of deterioration will be determined by the Environment Agency in discussion with the discharger and other interested parties, on a site by site basis.

It is proposed that acute criteria will be applied initially, with an aim to setting chronic criteria in the future. It is hoped that the discharger and the Environment Agency will work together to gradually reduce any area of impact over achievable timescales.

Consultation issue

The point of protection will depend on the sensitivity and/or use of the receiving water. It is proposed that this point is to be determined by the Environment Agency in discussion with the discharger and other interested parties, on a site by site basis.

3.3.3 Determining the Predicted Environmental Concentration

The ***PEC*** at the point where protection (no-observed effect) is to be achieved will be determined by considering the volume of the effluent and the dilution and dispersion in receiving waters. This point may be at end-of-pipe or at a defined point in the receiving waters.

Consultation issue
It is proposed that the PEC be determined by considering the volume of the effluent and the dilution and dispersion in the receiving waters.

3.3.4 Ecotoxicological significance (risk assessment)

It is proposed that the PNEC (derived from toxicity measured at the usual Environment Agency licence sampling point) will be compared with the PEC at the point of protection (**Figure 5**). If the PNEC exceeds the PEC then a licence containing toxicity-based conditions can be set and compliance monitoring initiated (**Section 3.3.6 and 3.4**). Conversely, if the PEC exceeds the PNEC then a reduction in effluent toxicity is required (**Section 4**). This may be achieved in a planned manner using a time limited stepped consent in WRA'91 or an improvement plan in EPA'90 until the toxicity condition is achieved (**Figure 6**).

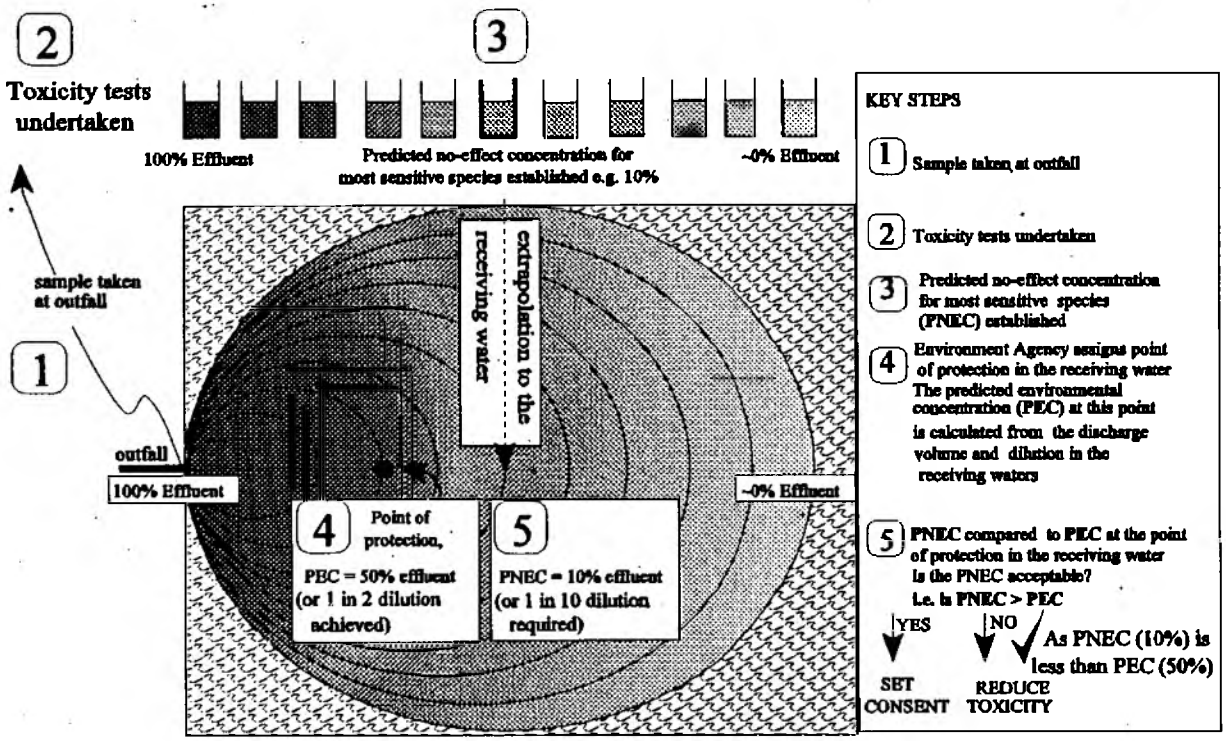


Figure 5. Ecotoxicological Significance. Key steps undertaken prior to setting a toxicity based licence or reducing toxicity. In this example the PEC = 50% effluent and the PNEC = 10% effluent. As PEC exceeds PNEC (i.e. the available dilution is less than the required dilution) toxicity reduction is required.

Time limited stepped consents and improvement notices can also be used to improve environmental protection in a phased manner. For instance the zone of impact may be reduced (and therefore the toxicity licence condition changed) as toxicity in the effluent is reduced over achievable timescales. It may be expected that chronic and/or sub-lethal toxicity conditions are to be achieved later in the life-span of the licence. **Figure 6** illustrates these principles, with progressively more stringent conditions being set for more sensitive receiving waters and over time. The degree to which we progress with this scheme will depend on technological and socio-economic considerations (e.g. BATNEEC and cost-benefit).

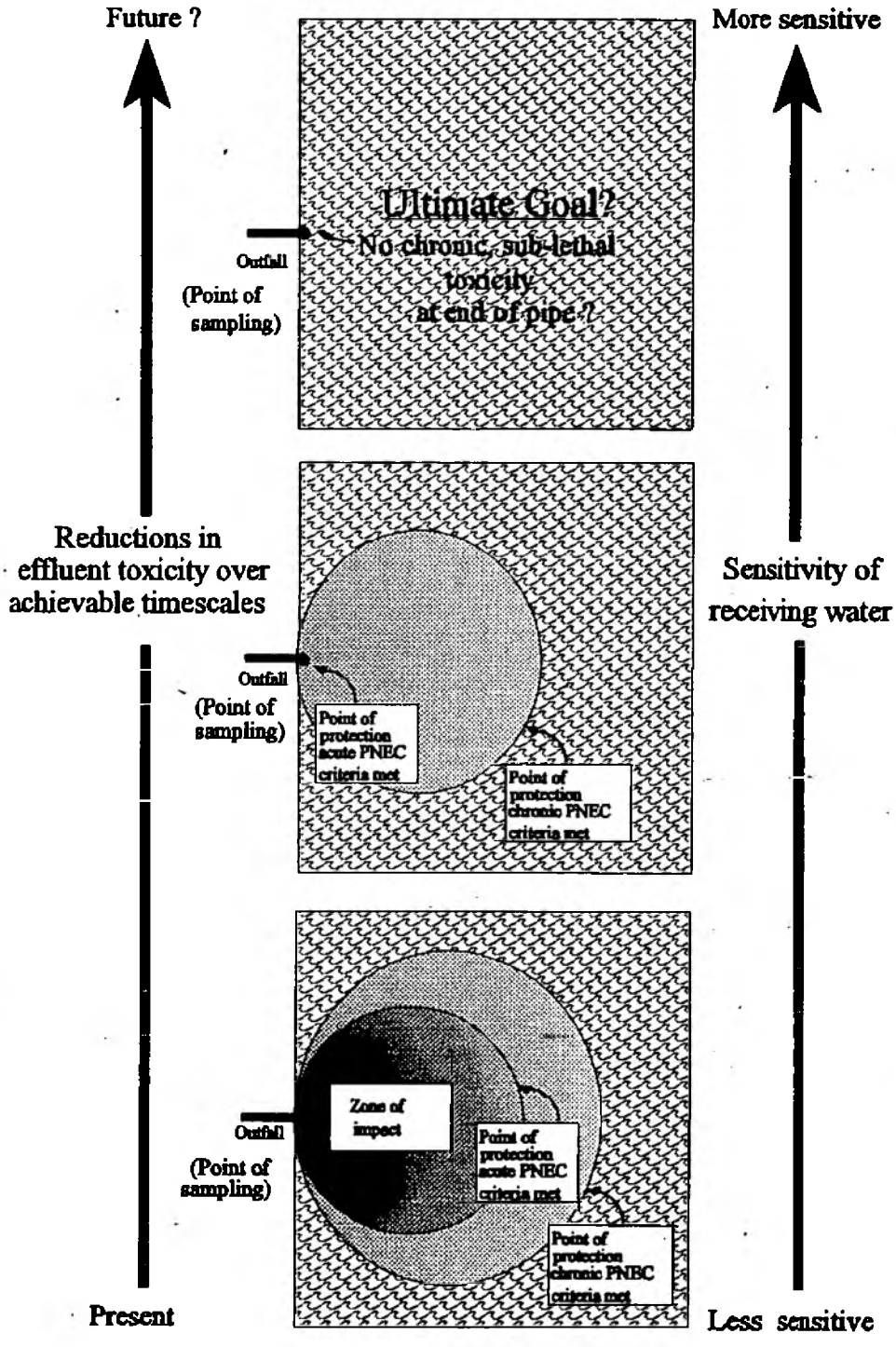


Figure 6. Targets for reductions in effluent toxicity. Figure indicates sampling point, zones of impact and point of protection in the receiving water.

3.3.5 Failure to meet the toxicity condition

It is proposed that if the data provided by the characterisation programme suggest that the effluent will be toxic at the point of protection in the environment (i.e. PEC>PNEC) then the discharger will be required to proceed with a toxicity reduction programme to a timescale agreed with the Environment Agency (**Section 4**).

Consultation issue

It is proposed that if the PEC > PNEC then the discharger be required to enter into a toxicity reduction programme agreed with the Environment Agency which will set toxicity reduction targets and timescales for achievement.

3.3.6 Setting the toxicity licence condition

If the PNEC exceeds the PEC before or following a toxicity reduction programme then a licence containing toxicity conditions can be set. The licence condition and associated schedules will specify:

- a clearly defined toxicity limit for the discharge;
- the appropriate form of toxicity test to be used (including reference to a standard test procedure);
- reference to the schedule to follow which will stipulate the minimum sampling frequency, type of sampling, data reporting requirements etc.;
- existing conditions of the licence (or necessary physico-chemical conditions for new licences).

The toxicity tests written into the licence will be:

the most sensitive of the established tests where there is not an acceptable correlation between the established and the most appropriate rapid test

or

a rapid test where an acceptable positive correlation exists with the most sensitive of the established tests. The most sensitive established test will be used intermittently (at a predetermined frequency) to confirm the correlation (further research may be required before this can be implemented).

Consultation issue
It is proposed that a toxicity condition in a licence will specify a toxicity limit, and an associated schedule with the sampling requirements, data reporting, appropriate form of toxicity test to be used and the existing conditions on that discharge.

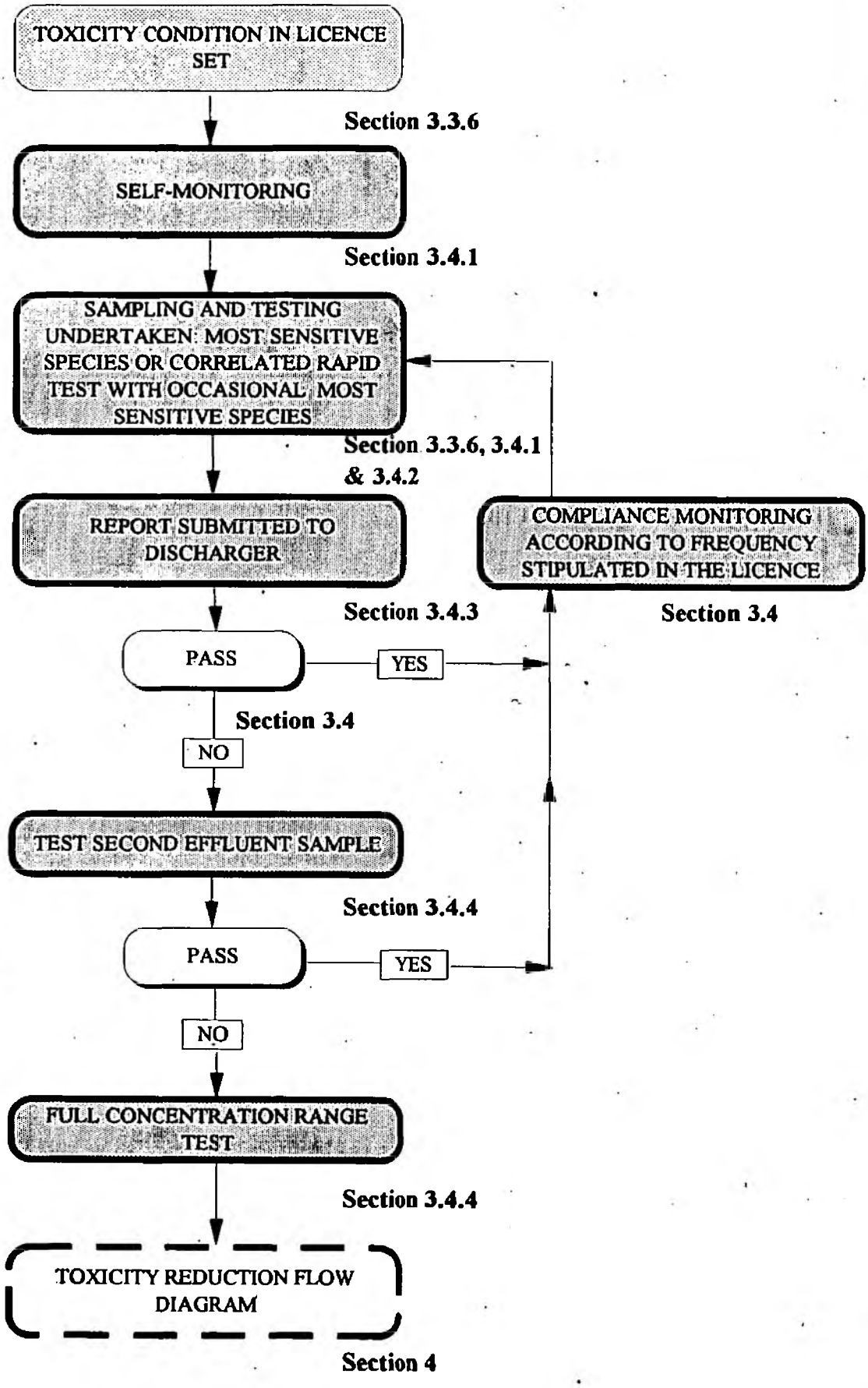


Figure 7. Compliance monitoring and toxicity exceedence protocol .

STAGE 4- Compliance Monitoring

3.4 Compliance monitoring

This section considers compliance monitoring and exceedence procedures (Figure 7).

3.4.1 Self monitoring - feasibility and cost liabilities

The WRA'91 currently provides provision for discharge charging schemes, and for recovery of Environment Agency costs incurred in the issuing and monitoring of consents and maintenance of the public register. Implementation of the European Community Urban Wastewater Treatment Directive (1994) and the introduction of IPC places much of the responsibility for monitoring on the discharger. The Environment Agency maintains both a central and regional specification and audit function, both for continuously monitored data and for sample analysis. It is suggested that ***compliance monitoring*** of the toxicity-based condition will be undertaken and funded by the discharger. Toxicity testing will be performed by an Environment Agency approved facility. A register of approved laboratories will be maintained and provided by the Environment Agency. All samples should be tested in accordance with time scales specified in the Environment Agency/SNIFFER Ecotoxicology Methods Manual (**Section 2.5.1**). Results will be reported by the discharger to the Environment Agency within 48 hrs of test completion. Failure to achieve all requirements may be considered a breach of the licence and could lead to enforcement action. Compliance sampling procedures by self-monitoring will be audited (see ***self-monitoring audit*** in the glossary). In addition to the discharger conducting ***self-monitoring*** of the effluent for licence compliance, the Environment Agency will conduct a programme of ***independent monitoring***.

Consultation issue

It is proposed that toxicity-based conditions in licences be self-monitored. Results will be reported by the discharger to the Environment Agency within 48 hrs of test completion. The Environment Agency will conduct a programme of self-monitoring audit and independent monitoring.

3.4.2 Sampling and sampling frequency

The sampling frequency and method of sampling will depend on the toxicological variability of the discharge. This will be determined at the effluent characterisation stage and may be refined during the lifetime of the licence (**Section 3.3.1**).

Sampling location.

Sampling will normally be at the usual Environment Agency licence sampling location (e.g. end-of-pipe or end of discharge channel) unless specified differently in the licence.

Sampling method.

Sample collection for toxicity testing will normally be by ***spot-sampling*** or, where appropriate, on-line or high frequency rapid test sampling (when these methods are available) for more variable discharges.

Sampling Frequency.

Sampling frequency will be specified in the licence schedule and will depend on the variability of the discharge. Once established, discharges which consistently pass and are generally of a uniform nature may be allowed a reduction in the frequency of compliance monitoring.

Consultation issue

It is proposed that the type and frequency of monitoring be discharge specific, will be determined by the Environment Agency, and be written into the licence schedule.

3.4.3 Compliance monitoring reporting

It is proposed that data will be reported to the Environment Agency and kept on the Public Register. Dischargers will be required to keep copies of all self-monitoring data for inspection for a period of not less than 5 years. In specific circumstances information may not be held on the public register if its disclosure would prejudice an applicant's commercial

interests to an unreasonable degree.

Additionally, dischargers would be required to inform the Environment Agency of any likely changes which may affect the toxicity of the effluent. The discharger must also inform the Environment Agency of any major shut down or maintenance of the plant. The Environment Agency may require spot-sampling, by the discharger, in these instances.

Consultation issue

It is proposed that the discharger be required to report to the Environment Agency any changes to the discharge that may affect effluent toxicity.

3.4.4 Compliance failure

It is proposed that the toxicity limit be imposed as a pass/fail limit. If a sample fails to comply with the toxicity condition the discharger must ensure that:-

i) a repeat sample is taken and subjected to the toxicity test within 24 hours of notification of the original test result;

ii) the agency is notified of the failure within 24 hours, and subsequently of the result of the repeat sample within 24 hours of test completion.

A second failure will require further investigation by full concentration range toxicity testing, with the toxicity test specified for compliance monitoring, to establish the degree of toxicity. The results may require the discharger to implement a toxicity reduction programme approved by the Environment Agency (**Section 4**). In the event of a catastrophic failure remedial action will be required immediately. The Environment Agency proposes to set toxicity reduction targets which are achievable over realistic timescales rather than automatically prosecute.

Effluents failing on the first occasion and passing the retest may require more frequent monitoring. Replication within toxicity tests, RTDL methods (Dhaliwal *et al.*,1995),

subsequent testing of a second sample, and full range testing of a third sample will ensure true and accurate results. This will avoid unnecessary remedial measures being taken by dischargers due to false positive results.

Non-compliance with any condition in a consent or authorisation is subject to enforcement by means of notices or by prosecution in accordance with Environment Agency policy.

Consultation issue

It is proposed that toxicity conditions be set as pass/fail limits. Non compliance may necessitate a toxicity reduction programme to be approved by the Environment Agency. Enforcement action may be taken to ensure that the discharger brings the discharge to compliance.

3.4.5 Review and appeal process

Both the WRA'91 and the EPA'90 provide for review of consents or authorisations and for appeals against Environment Agency decisions. Reviews are undertaken by the Agency. Appeals are to be determined by the Secretary of State or his nominee.

3.4.6 Licence review

The toxicity based licence conditions will be reviewed as appropriate. This may occur, for example, if the discharge is having a damaging effect on the quality of the receiving environment or if the composition of the discharge changes. In cases where the toxicity condition of the licence is failing to protect the receiving environment sub-lethal and/or chronic tests may be used to review the licence.

3.5 Approximate costs of effluent screening, characterisation, monitoring and laboratory registration

This section presents an approximate costing scenario for in-house toxicity test facility accreditation, discharge toxicity characterisation and one year of compliance monitoring of the

toxicity-based condition. Approximate costs for toxicity identification and toxicity reduction evaluations and remedial measures are considered in **Section 4**.

i) Laboratory accreditation.

If this facility is already an accredited laboratory (GLP or UKAS), then the cost of accreditation for the ecotoxicity tests listed in the Environment Agency/SNIFFER ecotoxicology methods manual would vary from zero under GLP to approximately £2,000 under UKAS. The test laboratory would need to purchase the methods manual from the Environment Agency (cost to be agreed) and to allocate time for its staff to become proficient in the use of the methods as judged by QC results submitted to the EA.

If this facility is not already accredited, then the charges for an accreditation inspection accreditation would increase by approximately £2000 under GLP and by approximately £1,500 under UKAS. The fee for a UKAS annual inspection is approximately up to £2000. A GLP annual inspection is free of charge.

ii) Discharge toxicity characterisation

The cost of each test will depend on the number of replicates used. The calculations are based on the following approximate costs: Rapid test, £100. Full concentration range tests: 72hr Algal test, £700; 24hr OEL/*Daphnia* test, £800; 96hr fish test, £900. Limit tests: 24hr OEL/Daphnia test, £500.

The scenario considers:

1. Initial screening of the discharge with 2 x OEL and 2 x Rapid test;
2. Discharge characterisation with three trophic level testing on six occasions with full concentration range algal test, invertebrate test (OEL or *Daphnia*) and fish test, followed by further characterisation with the most sensitive species on six occasions (e.g. OEL or *Daphnia*);
3. Compliance monitoring using limit tests for the most sensitive species (e.g. OEL or *Daphnia*) on twelve occasions over the period of one year.

The total initial testing costs would be approximately £27,000 for this scenario (including one years compliance monitoring). Subsequent compliance monitoring would be approximately £6,000 a year. Characterisation costs would be increased if a greater number of samples were required to establish effluent variability or if rapid toxicity tests were run alongside the established toxicity tests. However if the rapid tests were found to be a good surrogate for the most sensitive established test than the use of the rapid test in subsequent compliance monitoring would substantially reduce the overall costs. With a compliant discharge ongoing costs would be those associated with compliance monitoring only. It is also envisaged that regular testing programmes and multiple discharge testing by the toxicity testing facilities would reduce unit testing costs in the medium-term.

Rationalisation of current monitoring programmes that include a high level of permissive chemical analysis to minimum mandatory requirements may eventually reduce the overall costs of compliance monitoring.

3.6 Liability, discharger responsibility and environment agency responsibility

The Environment Agency wishes to liaise closely with industry to achieve reductions in the toxicity of complex effluents. The aim will be to maintain, and where possible, seek sustainable improvement in the quality of controlled waters.

The Environment Agency will be responsible for:

- prioritising the discharges for toxicity-based control implementation (**Section 3.2**);
- implementing the toxicity-based regulatory controls;
- setting the toxicity licence conditions and administering the licence (**Section 3.3.6**);
- enforcing the licences and breach procedures (**Section 3.4**);
- agreeing, where necessary, a toxicity reduction programme (if unacceptable toxicity is demonstrated; **Section 4**);
- conducting a self-monitoring audit and independent monitoring programme, where appropriate;
- auditing test facilities and test data (**Section 2.5.2**);
- maintaining the quality assurance system and the approved register of toxicity testing

facilities (Section 2.5.2);

- producing and updating the Environment Agency/SNIFFER 'ecotoxicology methods manual';
- performing R&D to develop test methods and the wider application of DTA.

The discharger will be responsible for:

- applying for a licence when considering a new discharge (**Section 3.2.7**) or changes in an existing discharge;
- providing adequate toxicity data from toxicity screening requested by the Environment Agency for discharge prioritisation (**Section 3.2**);
- undertaking and reporting the results of toxicity tests conducted during the effluent characterisation stage (**Section 3.2**);
- any actions to comply with the licence;
- self-monitoring as described in the licence conditions (**Section 3.4.1**);
- undertaking and reporting monitoring data within a specified time period (**Section 3.4.3**);
- reporting true and accurate data and other relevant information (**Section 3.4.3**);
- where necessary, agreeing and acting on a toxicity reduction programme (if unacceptable toxicity is demonstrated; **Section 4**).

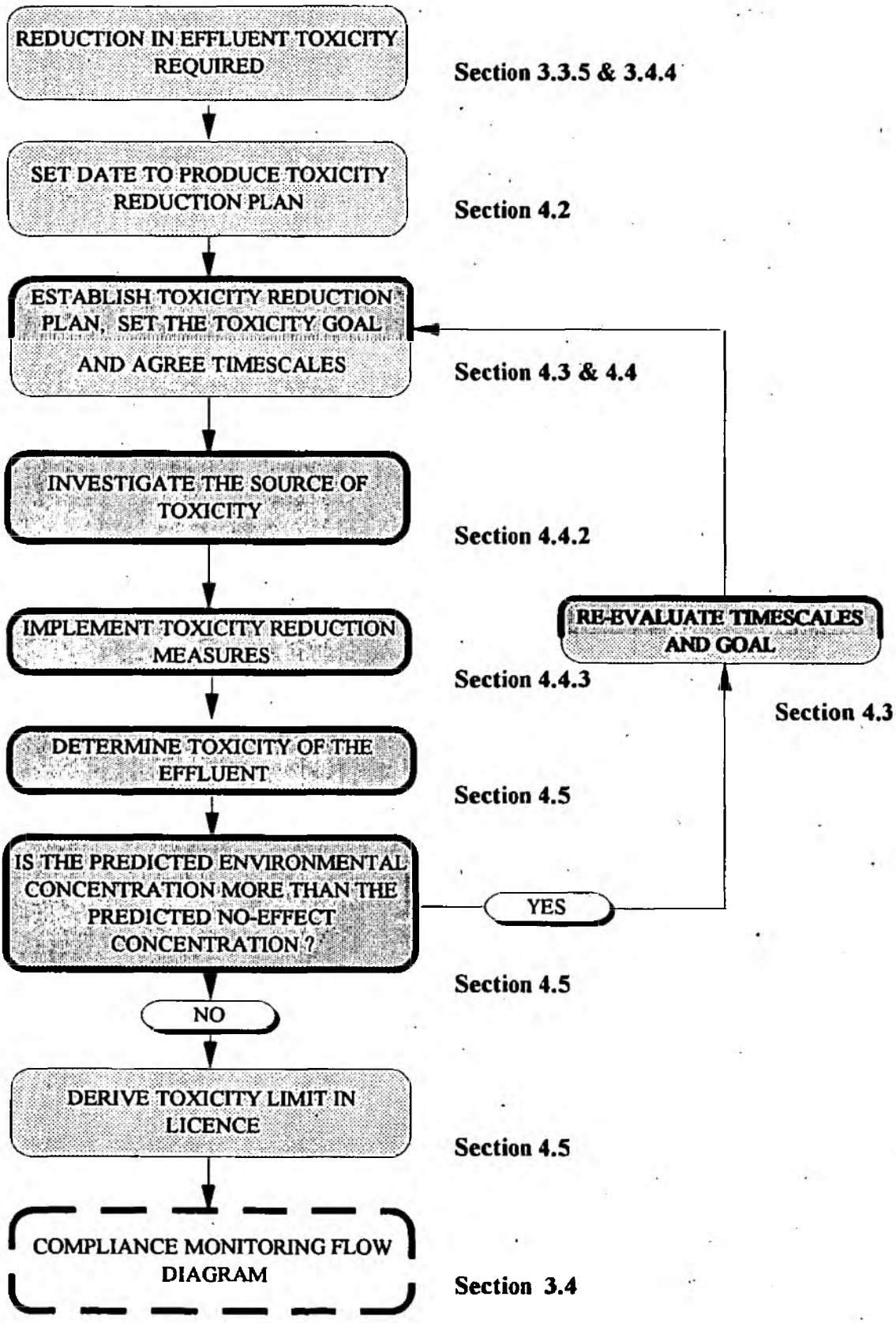


Figure 8. Toxicity reduction protocol.

4 TOXICITY REDUCTION

4.1 Toxicity reduction overview

This section describes the action expected of the discharger following:

the requirement for toxicity reduction in an effluent prior to the issue of a licence containing toxicity conditions,

or

a failure to comply with the licence containing the toxicity-based conditions.

Toxicity reduction should be undertaken in close liaison with the Environment Agency and will consider site-specific environmental options, the available technology and costs for achieving improvements. It is acknowledged that some toxicity problems will be more difficult to resolve than others and timescales for toxicity reduction will differ on a case by case basis. The Environment Agency will act reasonably in setting timescales. This can only be achieved where the Agency is kept informed of the progress of toxicity reduction programmes. The toxicity reduction measures may be introduced as part of the dischargers existing plant improvement plans if the timescales are considered acceptable.

The protocol for the procedure is shown in **Figure 8**.

4.2 Toxicity reduction enforcement

The requirement and action necessary for toxicity reduction can be by written agreement, stepped consents, consent modification, works notices, improvement plans or as part of an enforcement notice depending on the current discharge control, i.e. WRA'91 or EPA'90 and state of implementation of the Environment Act 1995. It is proposed that the discharger will be required to implement a programme to reduce the toxicity of the effluent to the acceptable level (or below) which will be set by the Environment Agency. The toxicity reduction programme will specify targets for toxicity reduction and timescales for achievement, and will be agreed with the discharger. The discharger will be required to submit a ***toxicity reduction plan*** to achieve the agreed targets specified in the programme.

Consultation issue

It is proposed that the toxicity reduction programme be enforced by stepped consents, consent modification, works notices, improvement plans or as part of an enforcement notice depending on the current discharge control, i.e. WRA'91 or EPA'90 and state of implementation of the Environment Act 1995.

4.3 Toxicity reduction programme

This programme will include the toxicity reduction plan and the agreements between the Environment Agency and the discharger regarding toxicity targets and timescales. These timescales may be changed, with agreement and after discussion with the Agency, as the work progresses and the nature of the problem is evaluated. The programme will therefore be facility specific and will be contained in a document which may be modified during the course of the programme.

Consultation issue

It is proposed that a toxicity reduction programme will consist of toxicity reduction plan submitted by the discharger and targets and timescales agreed between the Environment Agency and the discharger.

4.4 Toxicity reduction plan

A toxicity reduction plan will be submitted by the discharger to the Agency. This will include plans for toxicity tracking and remedial action.

4.4.1 Information and data acquisition for toxicity reduction

The first step in a toxicity reduction plan is for the discharger to gather all available chemical, toxicological, plant process (design, operation and efficiency) and effluent treatment information. The combined use of this information will aid in identifying processes and/or practices that are the source of toxicity.

4.4.2 Toxicity tracking

Following the agreement of the toxicity reduction programme the discharger will investigate the source of toxicity. General procedures for this have been published in the United States (e.g. Mount and Anderson-Carnahan, 1989; Mount, 1989; Norberg-King *et al.*, 1991). Research is proceeding within Europe to refine these methods.

These procedures may include:

Facility performance evaluation

It may be possible that a procedural, mechanical or electrical failure in the running of a plant may cause toxicant release that would not occur during 'normal' plant performance. In this case there may be a requirement for improvements in staff training and/or the replacement of plant hardware and/or changes in operational procedures.

Toxicant identification

If it is not clear which chemicals are contributing to the majority of any observed toxicity in an effluent then a programme of toxicity identification may be required. This is a process of effluent fractionation using chemical or physical manipulation combined with toxicity testing and chemical analysis to identify, sequentially, the chemicals responsible for the observed toxicity. It is often adequate to only identify general classes of chemicals that are responsible for the observed toxicity since similar chemicals often operate through the same general modes of action. Additionally, similar classes of chemical can often be treated by the same processes to remove them from the effluent. The identification of classes of toxic chemicals with their subsequent reduction/substitution/treatment will result in a more financially directed and environmentally-efficient toxicity reduction programme.

Source identification

A complex effluent that is discharged into receiving waters is often a composite of effluents produced from numerous processes in a plant. Effluents may vary according to temporal

changes in processes (or batch processing). This often means that a programme of source evaluation can be conducted to identify processes that are contributing to all, or the major portion of, toxicity in the final effluent. Once the source is identified, a directed, and potentially more cost-effective programme of toxicity reduction can be mounted. Toxicity source evaluation is performed using toxicity tests (preferably rapid tests) to trace toxicity within the plant and to assess treatment options or process modifications. If the toxicity of the final effluent is variable as a result of batch production then the process which produces a toxic effluent can be identified. The use of bench scale simulation models of processes may aid in identifying the source of effluent toxicity, particularly where by-products or degradation products are involved.

4.4.3 Remedial action (toxicity reduction)

Once the remedial action necessary to reduce toxicity has been identified, this must be agreed with the Environment Agency and the original timescales of the toxicity reduction plan may be modified. A toxicity reduction programme will consider the various environmental options, the available technology, and costs for achieving reductions in toxicity. The definition of what is 'excessive cost' will be decided through agreement between the Agency and the discharger. The toxicity reduction plan may identify a remedial action as simple as improved 'housekeeping', more complex modifications to processes or the introduction of effluent treatment (USEPA, 1989; Homlan and Gray, 1991; USEPA, 1994b). It is the responsibility of the discharger to take remedial action as part of the agreed toxicity reduction programme.

Remedial action to reduce toxicity may include the following:

- Chemical substitution; exchanging toxic chemicals for less toxic but functionally similar or identical chemicals. It may also be possible to use substitutes that degrade more rapidly.
- Improving process management (good housekeeping). The quantities of certain chemicals may be reduced in a process without affecting the process; i.e. reducing levels to those that leave no excess. Some chemicals can be recovered and re-used, with good economic returns.
- Improving laboratory waste handling procedures.

- Improving process and plant maintenance, chemical storage and clean-down areas.
- Improving plant efficiency and performance, updating outdated technology.
- Improving or installing effluent treatment (abatement plant).

Consultation issue
It is proposed that the toxicity reduction plan be devised by the discharger.

4.5 Costs of toxicity reduction programmes and remedial action

The cost of toxicity reduction programmes vary greatly according to the complexity of the individual toxicity issue. Approximate costs from case studies in the US may range from thousands to hundreds of thousands of pounds. Toxicity reduction measures may have minimal cost if, for instance, the remedy is chemical replacement or good-housekeeping. However costs may be considerably higher if treatment is required to reduce the toxicity. The Environment Agency would agree reasonable timescales in which the discharger was expected to complete these investigations and subsequently reduce toxicity.

In the longer term, many case studies in the United States have suggested that toxicity reduction improvements not only reduce the release of toxicants to receiving waters but also provide positive financial benefits resulting from improving plant management and efficiency, updating technology, recycling useable or saleable resources, replacing raw materials with cheaper alternatives and installing more cost-effective treatment options (e.g. Looney, 1996). Toxicity conditions may also provide the incentive for waste minimisation programmes which have proved highly successful in reducing the emission of toxicants and reducing costs to industry (Holman and Gray, 1991; North Carolina Office of Waste Reduction, 1993; NRA, 1995; Solutions '96 Survey, 1996). However, the work required will be site-specific and may be costly in certain instances.

4.6 Post toxicity reduction compliance monitoring, licence issue or re-issue and environmental monitoring

The discharge will be characterised again following a toxicity reduction programme to ensure that the measures taken have achieved the desired of toxicity goal. This process is described in **Section 3.3**. If the PEC over this period is less than or equal to the PNEC, a licence containing toxicity-based conditions can be issued or re-issued and compliance monitoring will proceed **(Section 3.4)**.

Environmental benefit as a result of toxicity-based controls will be assessed by biological survey and the Direct Toxicity Assessment of the receiving waters.

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