Classification of Listed Substances for the Purposes of the EC Groundwater Directive (80/68/EEC)

Technical Report

ENVIRONMENT AGENCY

Classification of Listed Substances for the Purposes of the EC Groundwater Directive (80/68/EEC)

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Technical Report

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EXECUTIVE SUMMARY

The Environment Agency and the Scottish Environment Protection Agency are the competent bodies required to implement the UK legislation designed to complete transposition of the EC Groundwater Directive (80/68/EEC). Included in the implementation is the classification of substances likely to be discharged to or to otherwise pollute groundwaters.

The Groundwater Directive National Advisory Group (GDNAG) was set up to produce a suitable classification system. The system is required to classify substances as either List I (discharge to groundwater unacceptable) or List II (discharge to be controlled to prevent pollution).

The classification procedure includes the selection of relevant substances for consideration and then the assessment of whether a substance is a carcinogen, mutagen or teratogen and its aquatic and mammalian toxicity, persistence (in groundwater and soil) and bioaccumulation properties. Lists of priority substances were produced by the group and also suggestions for substance-property criteria for classification of which the aquatic and mammalian toxicity criteria were agreed.

The aquatic toxicity criterion was that a substance falling within the List I Families/Groups with stringent, robust test data indicating an LC50 or equivalent data of less than 10 mg l^{-1} should remain on List I. Test data used in the classification have to meet defined quality targets based on the results being obtained in a reliable test done to a recognised protocol and on a suitable aquatic species. For less robust test data, information from more than one test are required in order to classify a substance. Aquatic toxicity data on 165 substances were assessed and 79 substances were provisionally classified as List I.

KEY WORDS

Groundwater Directive, classification of substances, toxicity, persistence, bioaccumulation criteria, validity of classification data.

1. INTRODUCTION

The EC Groundwater Directive (80/68/EEC) was produced with a view to protecting all groundwaters from pollution by certain toxic, persistent and bioaccumulable substances. The Directive classified substances, not as particular substances, but as Families and Groups and presented these families and groups in List I and List II. Substances in List I are required to be prevented from being introduced into groundwater. List II substances are required to have their introduction into groundwater limited to avoid pollution. (The List I and List II definitions of families and groups are included in Section 2.2 of this report.)

The Department of the Environment (DoE), now the Department of the Environment, Transport and the Regions (DETR), and the Welsh Office (WO) considered the implementation of the Directive in England and Wales including the issue of classifying substances. The three main documents specifying the objectives of the classification process were:

- DoE/Welsh Office Joint Circular (DoE 20/90, WO 34/90; dated 29.10.90)
- DoE/Welsh Office Consultation Paper (dated October 1990) "A Proposed National Classification Scheme of Listed Substances for the Purposes of EC Groundwater Directive (80/68/EEC)
- Direction of 13/7/92 (under Water Resources Act 1991) to the NRA in relation to the EC Groundwater Directive

In England and Wales the National Rivers Authority (NRA), now succeeded by the Environment Agency, was appointed as the competent authority responsible for classifying particular substances as List I or List II. To assist carrying out this task the NRA set up and convened a Groundwater Directive National Advisory Group consisting of members from the Government, industry and regulatory authorities.

Paragraph 2 of the Direction of 13/7/92 states that the Authority shall act in accordance with criteria in the Schedule of the direction to decide which substances are appropriate to List II families and groups having regard to their toxicity, persistence and bioaccumulation. The Groundwater Directive (80/68/EEC) allows individual substances on List I to be treated as List II on the basis of low risk of these properties. The Direction of 13/7/92 includes the consideration of substances which, in terms of definition of their chemical composition, might be List I but which should be considered for reclassification as List II on the basis of their toxicity, persistence and bioaccumulation all being low according to specified criteria. The Schedule (Table 1.1) specifies the "low" criteria to be used.

This report is a summary of the substance classification issues addressed and the decisions made by the Groundwater Directive National Advisory Group (GDNAG) and the substance information considered by the Group. It will assist further development of the classification system and its employment by UK authorities in the control operations required for the protection of groundwater. In this report references are made to papers presented at GDNAG meetings; these are presented as "GDNAG\meeting-number\document-number". Appendix A presents the agreed terms of reference for GDNAG and the list of GDNAG members.

The Groundwater Regulations 1998 (Statutory Instrument 2746) were made in November and complete transposition of the Groundwater Directive. The Regulations cover England, Wales and Scotland and supersede the existing Direction in a number of ways. Under the Regulations, the Agency has the duty to determine whether or not an individual substance is appropriate to List I. The Secretary of State may review any decision of the Agency in relation to classification of substances.

Table 1.1 Direction 13/7/92 Schedule for Criteria for Classifying Dangerous Substances in List II of the Annex to Council Directive 80/68/EEC

Criteria for low toxicity

1. A substance shall be classified as having low toxicity if and only if:

   a) it is not included in a list of carcinogenic, mutagenic or teratogenic substances supplied from time to time by the Secretary of State;
   b) sufficient data exist to carry out tests to establish whether it meets the criteria referred to in sub-paragraphs (c) and (d);
   c) according to the most stringent data obtainable its acute oral LD50 (rat) toxicity exceeds 200 mg/kg body weight; and
   d) according to the most stringent data obtainable it meets each of the following criteria for acute aquatic toxicity for which sufficient data exist:-
      i) its 96-h LC50 (fish) exceeds 10 mg/l;
      ii) its 48-h EC50 (daphnia) exceeds 10 mg/l or
      iii) its 72-h IC50 (algae) exceeds 10 mg/l.

Criteria for low persistence

2. A substance shall be classified as having low persistence if and only if:

   a) its half-life in sediments in the dark is less than 3 months;
   b) where no data exist for the purpose of paragraph (a), the half-life of the substance in water (preferably freshwater rather than saline) in the dark is less than 30 days; or
   c) where no data exist for the purposes of paragraphs (a) or (b), the half-life of the substance in soil is less than 30 days.

Criteria for low bioaccumulation

3. A substance shall be classified as having low bioaccumulation if and only if:

   a) its measured bioconcentration factor (BCF) is less than 100 on whole body weight, or less than 1000 on fat (lipid) content of aquatic organisms or aquatic plant tissue;
   b) where no data exist for the purposes of paragraph (a), the log Kow or log (n-octanol/water partition coefficient) of the substance is not more than 3.0.

2. SUBSTANCE CLASSIFICATION ISSUES

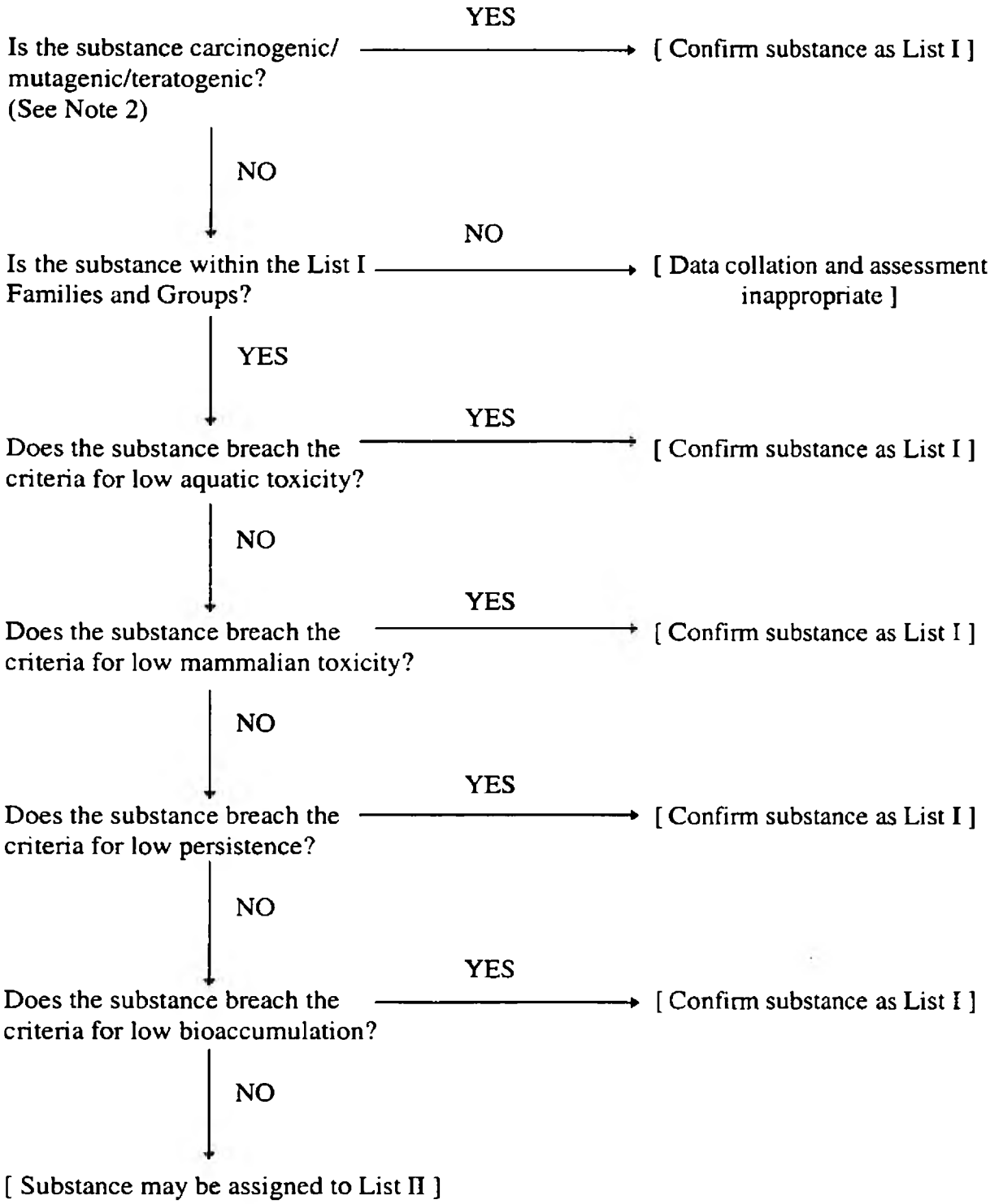
Substance classification can be divided into two major areas where the Group had to make decisions. The areas are:

- defining the substance information, including its validity, needed to make List I/List II decisions,
- selection of substances to be considered for classification.

The work of GDNAG on these two areas is summarised in following sections (2.1 and 2.2).

Consideration of the decisions under these topics about specific substances will be applied to the basic classification procedure, the latest version of which (GDNAG\7\1 - Appendix C) is illustrated as a flow diagram in Figure 2.1. (Note 2 refers to the production of a Government list of carcinogenic, mutagenic or teratogenic substances which was not available at the time of preparing the procedure. The other notes refer to the variety of decision issues discussed by GDNAG and summarised in this report.)

Figure 2.1 Procedure for data collation and reliability assessment for classification of substances (of List I Families/Groups) under the Groundwater Directive



2.1 Substance-information criteria

Information needed to classify substances should be "stringent" and "robust". The most stringent data is the information indicating the lowest concentrations or doses producing the LC50 (the concentration estimated to cause 50% mortality of test organisms for the test duration specified) or equivalent data in aquatic and mammalian toxicity tests. Robust data have to meet recognised toxicity test protocols and standards of conduct.

In order to reclassify an apparent List I substance to List II it is clear that the most stringent information must be reliably identified. When reliable data indicate a breach of the aquatic or mammalian thresholds then it is not necessary to ensure that the most stringent data have been found because the substance has been confirmed as List I, the worst case.

Any substance identified as a mammalian carcinogen, mutagen or teratogen in or *via* the aquatic environment should be included on List I. The Carcinogens, Mutagens and Teratogens Group (CMTG) was established to provide information on the identification of carcinogen/mutagen/teratogen substances which are possible groundwater contaminants. The aim was to produce a Government list of the substances. GDNAG concluded (GDNAG\7\1, section 2.3.2 ii) that possible groundwater contaminants listed by IARC as Class 1 or Class 2 carcinogens should be included on the list and that mutagenicity should be assessed by the Department of Health tiered approach.

For aquatic toxicity, mammalian toxicity, persistence and bioaccumulation the threshold concentrations or values had been specified by the Direction 13/7/92 Schedule (Table 1.1).

For aquatic toxicity the threshold concentration is 10 mg l^{-1} for the 96-h LC50 for fish or the 48-h EC50 for daphnia or the 72-h IC50 for algae. Thus, if any reliable data demonstrate an LC50, EC50 or IC50 below 10 mg l^{-1} then the substance should be retained on List I. Originally, the ideal requirement would be to use data on native, freshwater species. However, because only limited information was available for the wide range of substances under consideration, it was necessary to widen the range of test species and even include marine species. Also, because much of the available data did not exactly agree with the three definitions in the Direction Schedule, it was considered necessary for such data on lethal, effect and inhibition concentrations to be considered by experts in relation to the Schedule requirements. The main areas where the differences from the Schedule specification occur are the time periods for the tests (e.g. 24-h LC50 instead of 96-h LC50) and the species involved. "Effect" may be on mobility, reproduction or behaviour and "inhibition" of growth may be determined according to recognised protocols in terms of biomass or growth rate. However, some published reports and reviews do not make clear the precise meaning of the results.

The threshold for mammalian toxicity is 200 mg l^{-1} for acute oral LD50 for rats. For mammalian toxicity it was suggested that decision data in the 100 to 300 mg l^{-1} range should be supported by additional information.

Persistence thresholds could be decided on the basis of half-lives in sediments (3 months), fresh water (30 days), or in soil (30 days). Substances with persistence greater than these values would be retained on List I.

Bioaccumulation decisions could be made on a bioconcentration factor (BCF) of 100 on whole body wet weight or 1000 fat (lipid) content of aquatic organisms or aquatic plant tissue. If no such data exist then a log octanol-water partition coefficient (log K_{ow}) of 3 could be applied. Bioaccumulation figures higher than these would lead to retention of List I classification.

Details of test criteria for aquatic and mammalian toxicity, carcinogenicity, mutagenicity and teratogenicity, persistence and bioaccumulation are presented in Appendix B.

The robustness of available experimental data on aquatic and mammalian toxicity were graded in four levels (GDNAG\7\1). Levels A, B, C and D were finally defined as:

Aquatic toxicity

A. - all criteria for acceptability or standard international protocols are met.

B. - main criteria for acceptability are met.

C. - a body of data (e.g. reviews) exist though quality/reliability may not be known.

D. - limited (or no) data are available and key criteria are not met.

For Level A data, one or more points or references may be used for classification. For Levels B and C, provided GDNAG accepts the balance of probability, two or more (B) or an undefined number (C) of data points/references may be used. If only Level D data are available the substance cannot be classified.

At one stage, recognising the potential variability in biological data, it was suggested that Grade A data with results within a factor of 10 of the aquatic toxicity threshold should require confirmation from an additional source, in view of uncertainties associated with experimental variations. It was not considered necessary to apply this criterion to data generated so far.

Mammalian toxicity

A. - full details of experimental method available and these indicate that studies have been carried out to acceptable protocols and an acceptable standard.

B. - some details of the experimental method are available which indicate that acceptable protocols have been followed.

C. - insufficient information is available to determine acceptability.

D. - the data are shown not to meet acceptable standards of quality.

For Levels A, B and C the number of data points required are at least 1, 2 or 3 respectively but for Levels A and B if the values are in the range 100 to 300 mg/kg then 2 (A)or 3 (B) points are required.

Acceptability conditions for persistence data were not finalized. However a report (Reynolds *et al*, 1996) has been produced and a draft of the paper was presented at the seventh meeting.

The paper included reviews of national and international procedures and guidelines. The technical part of the summary of the report is included in this report (Appendix B4).

For bioaccumulation, consultation with DoE suggested that the Discharge of Certain Dangerous Substances Directive 76/464/EEC might provide a basis for acceptability criteria. However, acceptance criteria were not finalized.

2.2 Choice of substances

GDNAG agreed (GDNAG\7\2) on the definition of six of the List I Families and Groups from the Groundwater Directive. The definitions of these six Families and Groups (numbered as in the Groundwater Directive Annex with, in brackets, the additional Directive text defining Family/Group number 1) are:

1. Organohalogen compounds (and substances which may form such compounds in the aquatic environment): any organic compound which contains one or more covalently bound halogen atoms.
2. Organophosphorus compounds: any organic compound which contains one or more covalently bound phosphorus atoms.
3. Organotin compounds: any organic compound which contains one or more covalently bound tin atoms.
5. Mercury and its compounds: mercury and any compound of mercury.
6. Cadmium and its compounds: cadmium and any compound of cadmium.
8. Cyanides: free cyanide and any compound capable of releasing cyanide in solution.

Two other families/groups were defined as List I in the Groundwater Directive but no definitive decisions were made about the definition of these by GDNAG:

- Family/Group 4: Substances which are carcinogenic, mutagenic or teratogenic in or via the aquatic environment would be included on the provisional UK List. However, the identification and listing of such substances needs further consideration (by CMTG, chaired by DETR).

- Family/Group 7: Mineral oils and hydrocarbons require a workable definition. This was agreed to need careful consideration and to match the Hazardous Wastes Directive. Vegetable oils and hydrocarbons which are gaseous at room temperature should be excluded.

GDNAG did not reconsider the definitions of List II substances. In the Groundwater Directive Annex the List II Families/Groups are:

1. The following metalloids and metals and their compounds: zinc, copper, nickel, chrome, lead, selenium, arsenic, antimony, molybdenum, titanium, tin, barium, beryllium, boron, uranium, vanadium, cobalt, thallium, tellurium and silver,

2. Biocides and their derivatives not appearing in List I.

3. Substances which have a deleterious effect on the taste and/or odour of groundwater, and compounds liable to cause the formation of such substances in such water and to render it unfit for human consumption.

4. Toxic or persistent organic compounds of silicon, and substances which may cause the formation of such compounds in water, excluding those which are biologically harmless or are rapidly converted in water into harmless substances.

5. Inorganic compounds of phosphorus and elemental phosphorus.

6. Fluorides.

7. Ammonia and nitrites.

Clearly many biocides (List II family/group 2) are members of the List I organohalogen, organophosphorus and organotin groups. Three organohalogen biocides, two herbicides (bromoxynil and bromoxynil octanoate) and an insecticide (chlorpyrifos) had been included in List I following the discussion of a groundwater incident between the UK government and the European Commission.

Substances to be considered by GDNAG for classification under the Groundwater Directive were derived from the following lists and sources covering individual compounds.

- Substances from the 132 on the Priority List for classification as List I substances drawn up under the Discharge of Certain Dangerous Substances Directive (76/464/EEC),
- UK Red list,
- 3rd North Sea Conference: Annex 1A list of 36 substances (overlap with 76/646/EEC and UK Red list), 8 pesticides from Annex 1B and some of the Annex 1D list of 170 substances.
- Specific UK site information was obtained from existing dicharge consents and waste disposal site licences supplied by NRA regions (GDNAG\2\4 Appendix A),
- carcinogens, mutagens and teratogens - DoH provided a list of substances of groups 1 and 2 of the IARC classification. (GDNAG\1\12),
- associated with particular agricultural and industrial activities that may result in discharge to groundwater.

Many of these substances were considered unnecessary for classification under the Groundwater Directive, e.g. because they were banned or did not fall within the chemical definition of the List I groups. The 165 substances investigated so far, for classification according to aquatic toxicity information, are listed in Appendix C.

3. SUBSTANCE CLASSIFICATION BY AQUATIC TOXICITY

This part of the work was undertaken largely by the WRc National Centre for Environmental Toxicology under contract to NRA. A list was produced of possible sources of toxicity data which could be readily searched (GDNAG\2\5). This document also included information sources for mammalian toxicity, physical-chemical properties, fate and behaviour.

A search procedure was established to collate the minimum amount of appropriate data to enable classification decisions, taking into account the robustness of the data. Thus if a single Grade A result, two Grade B results or three Grade C results of less than 10 mg l^{-1} were found in the primary sources the search would stop. If insufficient information was found from the primary sources three further sets of sources were searched. In the early phases the preferred test species were those suitable for the UK freshwater environment. The range of acceptable test species was extended to include non-native species for cases where List I status was being confirmed. However, for re-classification to List II using a single-data point to demonstrate low risk, the test must be on a native species.

The primary data sources were Environmental Quality Standard (EQS) reports, DoE Hazard Assessments and other WRc reports. The second source was the WRc National Centre for Environmental Toxicology INSTAB database, the third source was searching reference texts and the final source was on-line databases.

The format of the tables containing the information was:

- name,
- yes/no for carcinogen, mutagen or teratogen,
- summary of acute aquatic toxicity information,
- acceptability level of each piece of toxicity information,
- comments,
- note of reference/source of information.

The work was undertaken in several phases. The reasons for submitting substances for aquatic toxicity assessment are presented in the "Substances for Assessment" documents discussed at the GDNAG meetings. The phases are either a chemical or use class of substances, e.g. chloroalkanes or insecticide, or groups of classes or uses derived from the sources of information mentioned in section 3.2, e.g. substances from NRA discharge consents.

The information submitted to GDNAG is summarised in the table in Appendix C. This table also includes identification ("List I" in comments column) of the 79 substances which GDNAG has provisionally classified as List I. These substances are listed separately in alphabetical order in Appendix D. The classification of a substance as List I was made by identification of robust, stringent data failing the aquatic toxicity criteria in Direction 13/7/92 Schedule (see Table 1.1, item 1-d) and the extensions of these criteria discussed in Section 2.1 required because of the lack of information defined in item 1-d.

For the remaining substances there was either insufficient information to classify the substance or the aquatic toxicity data were robust enough to indicate that the most stringent

data did not breach the threshold and therefore information of the acute mammalian toxicity, persistence and bioaccumulation will be required to continue the classification process.

REFERENCES

Department of the Environment/Welsh Office (1990a) EC Directive on Protection of Groundwater Against Pollution Caused by Certain Dangerous Substances (80/68/EEC): Classification of Listed Substances, Circular 20/90 (DoE)/34/90(WO).

Department of the Environment/Welsh Office (1990b) A Proposed National Scheme for Classification of Listed Substances for the Purpose of EC Groundwater Directive (80/68/EEC): A Consultation Paper.

Harris, R.C. and Leaf, S. (1994) Groundwater quality standards and objectives, *Environmental Policy and Practice*, **4**, No. 2, 85-92.

Reynolds, P., Comber, S. and Rogers, H. (1997) Development of Quality Assessment Criteria for Persistence Data. WRc Report No.: EA 4330.

APPENDIX A GROUNDWATER DIRECTIVE NATIONAL ADVISORY GROUP

The Groundwater Directive National Advisory Group (GDNAG) was set up in 1993 to address the classification of substances for List I and List II of the Groundwater Directive (80/68/EEC). The background to the agreed objectives of the classification process arose from various consultations and Government decisions which were summarised by Harris and Leaf (1994). Although the NRA and GDNAG were authorised to address the issues for England and Wales relevant authorities in Scotland and Northern Ireland were also informed of the work of GDNAG.

A1 TERMS OF REFERENCE

The terms of reference for GDNAG derived from the documents mentioned in the Introduction and discussions at the early meetings are (Annex to GDNAG\4\1):

1. To make recommendations to the NRA on the classification, for the purposes of the Groundwater Directive, of dangerous substances which are or may be discharges directly or indirectly to groundwaters within England and Wales, so that the Authority, after consultation with interested parties and discussion with the Department of the Environment (DoE), may finalise the classification and make public the outcome.

2. To utilise, in undertaking the classification assessment, the criteria (for low toxicity, persistence and bioaccumulation) laid down in the Direction to the NRA of 13/7/92.

3. To make recommendations to the NRA on data requirements relating to the assessment of toxicity, persistence and bioaccumulation of the substances classified, and to assist if required in collating robust data.

4. To consider whether and how various related issues, affecting the implementation of the Groundwater Directive, could be incorporated within the classification scheme. These issues include "de minimis" i.e. negligible quantities or concentrations, no effect concentrations, the mobility of substances, and transformation products.

5. To consider relevant implementation issues, of the type outlined in 4 above, so that the NRA may raise these, where it considers appropriate, with the Department of the Environment.

6. To assist the Department of the Environment, as required, and through the NRA, in the formulation of the Government list of carcinogens, mutagens and teratogens referred to in the Direction to the NRA of 13/7/92.

At the seventh GDNAG meeting it was noted that the terms of reference were still under discussion between the NRA and DoE for minor modifications.

A2 GDNAG MEMBERS

ORGANISATION:	REPRESENTATIVES:
NRA Head Office	P Chave (Chairman), P Bird
NRA Head Office	S Leaf (Technical Secretary), H Wilkinson,
NRA Severn Trent Region (Groundwater Protection Centre)	R Harris, C Harris
NRA Thames Region	S Killeen, S Hennings
DoE Water Resources & Marine Division	A Sheils, L McDonnell, R Moxon
DoE Waste Technical Division	P Hinchcliffe, J Gronow
DoE Water Quality Division	I MacDonald
MAFF Pesticides Safety Division	A Craven
DoH Environment & Food Division	M Waring, A Patel
Her Majesty's Inspectorate of Pollution (HMIP)	T Graham, P Douben
AEA Harwell	W McKay, G Dollard
WRc Medmenham	J Fawell
Institute of Waste Management	P Greifenberg (Cheshire CC), N Nesbitt, D Forster
Chemical Industries Association	M Bell (ICI Chemicals & Polymers)
Confederation of British Industry	M Carter, P Smart, M Cliff, D Taylor
National Association of Waste Regulation Officers (NAWRO)	A Cooper, A Holmes
Health and Safety Executive (HSE)	J Chadwick

APPENDIX B TEST CRITERIA

B1. AQUATIC TOXICITY TEST CRITERIA

B1.1 Levels of data acceptability

A. - all criteria for acceptability or standard international protocols are met. (The substance may be classified on the basis of one or more data points/references of this quality.)

B. - main criteria for acceptability are met. (The substance may be classified on the basis of two or more data points/references of this quality providing the Group is happy with the balance of probability.)

C. - a body of data (e.g. reviews) exist though quality/reliability may not be known. (The substance may be classified on the basis of such data points/references providing the Group is happy with the balance of probability.)

D. - limited (or no) data available and key criteria not met. (The substance cannot be classified on the basis of the data considered.)

B1.2 General requirements of reliable laboratory studies

1 Basic experimental design

- There should be a minimum of three (usually five) test concentrations, ideally with one at a concentration expected to cause no effects.
- ◊ Intervals between test concentrations should be less than one order of magnitude.
- Suitable controls should be included as well as test concentrations, including a carrier control if a carrier solvent is used in the tests.
- ◊ All controls and treatments should preferably be replicated.

2 Measured concentrations

- ◊ Exposure concentrations should be analysed preferably at the start, end and some point in the middle of the study.
- ◊ Analytical technique should be appropriate.

3. Maintenance of test conditions

- Test concentrations should be maintained at reasonably constant levels, unless specifically investigating effects of intermittent of fluctuating exposures.
- ◊ Flow-through studies are usually better at maintaining test concentrations than static studies due to regular replenishment of test substance(s).
- ◊ Closed, silanised vessels should be used where necessary.

4. Other aspects of test procedure

◊ If possible the study should follow a standard test procedure (e.g. OECD, APHA/ASTM, ISO, USEPA).

◊ The stocking density should be appropriate.

◊ The test should incorporate an appropriate feeding regime (where necessary).

- Extraneous sources of stress should be eliminated, i.e. lighting, vibrations.

◊ The test organism should be of suitable age, sex and health.

◊ Use of incompatible materials in test apparatus should be avoided, e.g. some sealants could lead to high control mortalities. (If concentrations are analysed and control, mortalities are reported, this becomes less important.)

- Suitable test species should be used, i.e. temperate - salmonid, sub-tropical - blue gill sunfish and fat head minnow.

5 Peripheral data

- Peripheral test data should be measured and reported, i.e. pH, dissolved oxygen, temperature and preferably hardness, type of water.
- The above test parameters should not add to the stress of the organisms (e.g. low dissolved oxygen, high temperature) or otherwise affect the test.

6 Analysis of the results

- Control results should be low (e.g. less than or equal to 10% in acute tests using adult fish and less than or equal to 20% in acute tests for algae).
- Ideally the results should show a concentration dependent effect and the results should be analysed for confidence limits or statistical significance.
- The results should not be extrapolated outside the range of test concentrations.

Tests meeting all the above criteria merit a level A acceptability mark. Test meeting the bolded bullet points merit a level B acceptability mark.

Further specific test criteria (i.e. for algae, daphnia and fish) are listed in Appendix B of GDNAG\7\1.

B2. MAMMALIAN TOXICITY TEST CRITERIA

B2.1 Levels of data acceptability

A. - full details of experimental method available and these indicate that studies have been carried out to acceptable protocols and an acceptable standard. (The substance may be classified on the basis of one data point/reference of this quality. However, if the value is within the range 100 - 300 mg/kg body weight then an additional confirmatory data point of the same quality is required.)

B. - some details of the experimental method are available which indicate that acceptable protocols have been followed. (The substance may be classified on the basis of two or more data points/references of this quality. However, if any value is within the range 100 - 300 mg/kg body weight then a minimum of three confirmatory data points are required.)

C. - insufficient information is available to determine acceptability. (The substance may be classified on the basis of three or more confirmatory data points/references.)

D. - the data are shown not to meet acceptable standards of quality. (The substance cannot be classified on the basis of the data considered

In levels "A" to "C" confirmatory data points are those which give the same compliance result (i.e. "pass" or "fail") against the low toxicity criterion of 200 mg/kg body weight.

B2.2 General requirements of reliable laboratory studies

Information is acceptable from a number of standard protocols for acute oral rat toxicity tests, in particular the OECD and the new limit tests proposed by the British Toxicology Society.

B3 CARCINOGENICITY, MUTAGENICITY AND TERATOGENICITY CRITERIA

These criteria were presented by J Fawell (GDNAG\4\2) and included the following general comments:

Evaluation of these test protocols is more difficult than for the aquatic and mammalian toxicity protocols because they are relatively recent innovations.

In some cases, such as pesticides, commercial in-confidence data classified as to quality by regulatory authorities will be available through those authorities.

Classification cannot rely on simple numerical data or on a positive or negative result. The data themselves will require interpretation. With regard to carcinogenicity this will be simplified if there is no need to determine the mechanism of action, i.e. genotoxic or non-genotoxic. However it is important to consider whether tumours only occur at high doses, and if they are only associated with tissue damage.

B3.1 Carcinogenicity

Studies should be carried out to internationally recognised protocols and standards. Classification as possessing carcinogenic properties should follow the recognised classification of IARC and for the purposes of this exercise only those substances in Classes 1 and 2 will be accepted as carcinogenic.

In cases where a substance has not been considered by IARC or substantive new data are available, the following is proposed.

1. Data from adequate epidemiological studies indicate there is causal relationship between the agent and cancer in man (i.e. observed association is unlikely to be due to bias, confounding or chance).

2. Sufficient evidence of carcinogenicity in animals (there is an increased incidence of malignant tumours in multiple species or strains, in multiple experiments with differing routes of exposure or dose levels, or the incidence, site of type of tumour or age at onset is unusual).

B3.2 Mutagenicity

Classification of mutagenicity should follow the DoH approach.

It is inappropriate to classify a substance as mutagenic on the basis of bacterial assays alone and a tiered approach to testing reflects this. The following broad criteria are suggested as a basis for classification.

1. The substance has been shown to cause either a dose related increase in chromosome aberrations or micronuclei in rat or mouse bone marrow or a dose related increase in unscheduled DNA synthesis in rat liver *in vivo* when carried out to an internationally accepted protocol.

2. The substance has been shown to cause a dose related increase in two of the four following studies carried out to internationally recognised protocols.

   - Chromosome aberrations in mammalian cells *in vitro*.
   - Unscheduled DNA synthesis in mammalian cells *in vitro*.
   - Mouse lymphoma assay.
   - Sex linked recessive lethal mutations in Drosophila.

3. The substance has been shown to cause a dose related increase in point mutations in a bacterial assay carried out to an internationally recognised protocol and to cause either chromosome aberrations in mammalian cells *in vitro* or unscheduled DNA synthesis in mammalian cells *in vitro* or sex linked recessive lethal mutations in Drosophila.

B3.3 Teratogenicity

This is taken to mean the induction of permanent structural or functional change in developing offspring and does not include embryotoxic effects from which recovery is possible, e.g. delayed ossification. Studies should be carried out to internationally recognised protocols including appropriate statistical analysis of the data and should normally demonstrate a dose response.

B4 PERSISTENCE DATA CRITERIA

Technical Summary of Reynolds *et al* (1997)

In order to assess the persistence of a chemical in the environment, both abiotic and biotic degradation and transformation processes must be considered. Many factors affect the rate of degradation in the environment such as the presence and adaption of micro-organisms, concentration of substance in the environment, physico-chemical parameters such as pH and environmental conditions including temperature, availability of oxygen and light conditions (although the latter is not important for groundwater environments). A detailed explanation of all the processes which may potentially affect the persistence of a chemical are reviewed in this report.

The various methods available for measuring persistence have been outlined according to their advantages and disadvantages. In addition, an assessment has been made of all available National and International guidelines for determining persistence of chemicals in soils, sediments and groundwaters. The relevance of these tests with respect to the Groundwater Directive has been discussed. Although many of the standard methods adopted by the European Commission and other such bodies are undertaken in accordance with strict guidelines for test procedure and monitoring, they do not mimic the conditions likely to occur in groundwaters; for example, aerobic biodegradation tests differ from the natural environment with respect to elevated temperatures (studies are often undertaken at 15-25 °C), substrate concentration and nutrient levels, as well as maintenance of aerobic conditions.

A list of quality criteria for the assessment of persistence studies in sediments, soils and water have been derived. The list of criteria has been designed in such a way that they can be checked whilst the data are being reviewed. The criteria cover the basic experimental design, considerations regarding test chemical and controls, maintenance and measurement of test

conditions, and the reporting of results. Using this list of criteria, the reliability and accuracy of persistence studies can be determined, along with the suitability of a test for the classification of a chemical's persistence.

Based on these criteria, a 4-tiered approach has been derived. Studies can be classified as Level A (reliable studies which meet certain quality criteria) to Level D (fail to meet certain quality criteria), and this, in turn, enables substances to be classified according to their persistence in the environment.

B5 BIOACCUMULATION TEST CRITERIA

For bioaccumaulation consultation with DoE suggested that the dangerous substances Directive 76/464/EEC might provide a basis for acceptability criteria. Among the suggestions for test criteria for BCF determinations are (GDNAG\7\1, appendix B(4)):

- Test animals should be exposed to at least three concentrations for the time necessary to reach a steady-state plateau.
- Concentrations in both water and test organism should be measured and expressed as wet weight.
- The depuration rate constant should be measured.
- Animals should not be fed during the uptake phase but should be during depuration.

APPENDIX C SUMMARY OF AQUATIC TOXICITY DATA

The table in this Appendix is a summary of the aquatic toxicity data provided to NRA to classify chemicals in relation to the Groundwater Directive (80/68/EEC). The information was produced in five phases plus continuations to phases 3 and 5 and a repeated search on some of the substances.

The "Search Phase" column indicates where the full information on a substance can be found in the original documents supplied and the complete list of information (in preparation). The abbreviation "RS" is for the Repeated Search phase.

The column titles "Breaks Aq.Toxicity Limit 10 mg l^{-1}" is the indication of whether a substance may be classified as a List I or List II substance. "Y" means that a toxicity test is reported as producing an LC50 or equivalent result of less than 10 mg l^{-1} and "N" means that the result is greater than 10 mg l^{-1}. (For a substance given an "N", classification data on its other criteria must also meet the List II requirements.) The abbreviation "nd" in this column means that either no relevant information was found in the search or that the information was insufficient to classify the substance. Where a substance has information from more than one search phase the location of the particular "Y", "N" or "nd" is indicated by the phase number or abbreviation in brackets.

The "Data Grade" column indicates the class of the "Y" and "N" decisions as defined in Section 3.3 of this report.

In the "Comments" column "List I" = provisional confirmation as List I at the time of the end of the seventh GDNAG meeting (8 March 1996). There are 79 substances with provisional List I classification. These substances are listed in Appendix D.

SUBSTANCE	SEARCH PHASE	BREACHES AQ. TOXICITY LIMIT 10 mg/l?	DATA GRADE	COMMENTS
Chlorpyrifos	1	Y	A	List I
Bromoxynil octanoate	1	Y	A	List I
Hexachlorocyclohexane	1	Y,Y	B,B	List I
DDT	1	Y,Y	B,B	List I
Pentachlorophenol (PCP)	1	Y,Y	B,B	List I
Hexachlorobutadiene (HCBD)	1	Y,Y	B,B	List I
Aldrin	1	Y,Y	B,B	List I
Dieldrin	1, 4	Y,Y (1); Y(4)	B,B; A	List I
Endrin	1	Y,Y	B,B	List I
Isodrin	1	Y	C	Only one result
Polychlorinated Biphenyls (PCBs)	1	Y,Y	B,B	
Dichlorvos	1	Y,Y	B,B	List I
Atrazine	1, RS	Y,Y,Y(1); Y,Y(RS)	C,C,C; A,A	List I
Trifluralin	1	Y,Y	B,B	List I
Fenitrothion	1	Y,Y	B,B	List I
Azinphos-methyl	1	Y	A	List I
Malathion	1	Y,Y	B,B	List I
Endosulfan	1	Y,Y	B,B	List I
Bromoxynil (as Bromoxynil-phenol)	2	Y,Y,Y,Y	C,C,C,C	List I
Cadmium	2	Y	A	List I (Chloride salt)
Carbon tetrachloride	2, RS	N,N(2); N,N(RS)	C,C; D,C	
Chloroform	2, RS	N,N(2); N,N,N(RS)	B,B; B,B,C	
1,2-Dichloroethane	2, RS	N,N,N(2); N,N,N,N(RS)	C,B,C; D,D,C,C	
Hexachlorobenzene	2	Y,Y,Y	C,C,C	List I
Mercury	2	Y	A	List I (Mercury(II) nitrate)

(continued)

SUBSTANCE	SEARCH PHASE	BREACHES AQ. TOXICITY LIMIT 10 mg/l?	DATA GRADE	COMMENTS
Simazine	2	Y,Y,Y	C,B,C	List I
Tetrachloroethylene	2	Y	A	List I
Tributyl tin oxide (TBTO)	2	Y	A	List I
1,2,4-Trichlorobenzene	2	Y	A	List I
Trichloroethylene	2	Y	A	List I
Triphenyl tin oxide (TPTO)	2	Y,Y	B,B	List I
Chlorothalonil	3	Y,Y	B,B	List I
Cypermethrin	3	Y,Y	B,B	List I
Diuron	3	Y,Y	B,B	List I
Flutriafol	3	N	D	Only one item of grade C data
Monolinuron	3, 5, RS	Y,Y (3); N(5) Y,Y,N,N,N(RS)	D,- ; - ; D,D,C,C,C	"Y" results are for a variety of algal tests, "N" results are for Daphnia and fish.
Paclobutrazol	3	N	D	Only one data item
Permethrin	3	Y,Y	B,B	List I
Pirimiphos-methyl	3	Y,Y	D,-	
Diazinon	4	Y,Y	B,B	List I
Chlorofenvinphos	4	Y,Y	B,B	List I
Coumaphos	4	Y,Y	B,B	List I
Fenchlorphos	4	nd	D	
Flumethrin	4	nd	D	
Propetamphos	4	Y,Y	D (C,C)	Insufficient data
Dichlofluanid	4	Y,Y,Y	D(C,C,C)	List I
5-Chloro-2-methyl-4-iso-thiazolin-3-one	4	nd(4); Y,Y,Y(RS)	D; C,C,C	
3-Iodo-2-proponyl n-butyl carbamate (IPBC)	4, RS	nd	D	List I
1-Chlorohexane	5, RS	N(5); nd (RS)	- ; -	Limited dataset; Insufficient data
1,1-Dichloroethane	5, RS	N(5); N,N(RS)	- ; B,C	

(continued)

SUBSTANCE	SEARCH PHASE	BREACHES AQ. TOXICITY LIMIT 10 mg/l?	DATA GRADE	COMMENTS
1,6-Dichlorohexane	5, RS	N(5); nd (RS)	- ; -	Limited dataset; Insufficient data
Dichloromethane (methylene dichloride)	5, RS	N(5); N,N,N(RS)	- ; C,C,C	
1,2-Dichloropropane	5, RS	N(5); N,N,N(RS)	- ; B,C,C	
Hexachloroethane	5	Y	A	List I
Pentachloroethane	5	Y	A	List I
Tetrabromoethane	5	nd	-	
1,1,2,2-Tetrachloroethane	5, RS	N(5); N,N,N(RS)	- ; B,B,C	Some data close to limit (5)
1,1,2-Trichloroethane	5, RS	N(5); N,N,N(RS)	A; D,B,B	
1,1,2-Trichlorotrifluoroethane	5	nd	-	
Chloroethene (vinyl chloride)	5, RS	N(5); N(RS)	- ; D	Insufficient data to classify
3-Chloropropene (allyl chloride)	5, RS	N(5); N,N,N(RS)	- ; C,C,C	
2-Chloro-1,3-butadiene (chloroprene)	5, RS	N(5); nd (RS)	- ; -	Insufficient data to classify (RS)
1,1-Dichloroethene	5, RS	N(5); N,N,N(RS)	- ; C,C,C	
1,2-Dichloroethene	5, RS	N(5); N,N,N(RS)	- ; C,C,C	
1,3-Dichloropropene	5	Y,Y(5)	B,B	List I
2,3-Dichloropropene	5	nd		
2-Chloroanthraquinone	5	nd		
Chloronaphthalene	5	nd		
Fluoranthene	5, RS	Y(5); N,N(RS)	C; C,B	Needs review and decision
Hexachloronaphthalene	5	nd	-	
Hexachloronorbornadiene	5	Y,Y,Y(5)	C,C,C	List I
2-Chloroaniline	5	Y	A	List I
3-Chloroaniline	5, RS	N(5); Y,Y,N(RS)	A; B,B,C	Needs review and decision
4-Chloroaniline	5, RS	N(5); Y,Y,Y(RS)	A; C,C,C	Needs review and decision
Dichloroaniline	5	Y	A	List I
4-Chloro-2-nitroaniline	5	nd	-	

(continued)

SUBSTANCE	SEARCH PHASE	BREACHES AQ. TOXICITY LIMIT 10 mg/l?	DATA GRADE	COMMENTS
2,4-Dichlorophenoxy-4-aniline	5	nd	-	
Bis(2-chloroisopropyl)ether	5	nd	D	
Chloroacetic acid	5, RS	N(5); Y,Y(RS)	C/D; B,B	Insufficient data to classify (5)
2-Chloroethanol	5, RS	N,N(5); - (RS)	B,B; -	RS produced no further information.
1,3-Dichloro-2-propanol	5, RS	N(5); N,N,N(RS)	- ; C,C,C	
2,2-Dichloropropanoic acid	5, RS	N(5); N,N,N(RS)	- ; C,C,C	
Epichlorohydrin	5, RS	N(5); N,N,N(RS)	- ; C,B,C	
Trichloroacetic acid	5, RS	N(5); N,N,N,N(RS)	- ; D,C,C,C	
Trichloroethanal	5	nd	D	
Chloroaminotoluene (chlorotoluidine)	5	nd	D	
Chloronitrotoluene (all isomers)	5, RS	nd(5); Y,Y,Y(RS)	- ; C,C,C	RS tests were on 3 different isomers
2-Chlorotoluene	5	Y,Y,Y	C,C,C	List I
3-Chlorotoluene	5, RS	nd, Y*(5); Y*(RS)	D, - ; A	Y*s from the same confidential data;
4-Chlorotoluene	5	nd	D	
α-Chlorotoluene	5	Y,Y,Y	C,B,C	List I
α,α-Dichlorotoluene (benzylidene chloride)	5	nd	D	
α-Trifluoro-2-nitrotoluene	5	nd	D	
α-Trifluoro-3-nitrotoluene	5	nd	D	
α-Trifluoro-3-nitro-4-chloro-toluene	5	nd	D	
α-Trifluoro-4-nitrotoluene	5	nd	D	
Trichlorophenol (all isomers)	5	Y,Y,Y	C,C,C	List I
2-Amino-4-chlorophenol	5	nd	-	
2-Benzyl-4-chlorophenol	5	nd	-	
2-Chlorophenol	5	Y,Y,Y	B,C,C	List I
3-Chlorophenol	5	Y	C	Insufficient data to classify
4-Chlorophenol	5	Y,Y	B,C	

(continued)

SUBSTANCE	SEARCH PHASE	BREACHES AQ. TOXICITY LIMIT 10 mg/l?	DATA GRADE	COMMENTS
4-Chloro-3-methylphenol	5	Y,Y,Y	C,C,C	List I
2,3-Dichlorophenol	5	nd	-	
2,4-Dichlorophenol	5	Y,Y,Y	B,C,C	List I
Cresyldiphenyl-phosphate	5	nd	-	
Tributyl-phosphate	5	Y,Y,Y	C,C,C	List I
Tricresyl-phosphate	5	nd	-	
Trioctyl-phosphate	5	nd	-	
Triphenyl-phosphate	5	Y,Y,Y	C,C,C	List I
Tris(2,3-bromo-1-propyl) phosphate	5	nd	-	
Trixylenyl-phosphate	5	nd	-	
Dichlorobenzidine	5	nd	D	
N-(4-bromophenyl)methyl-1,2-ethanediamine	5	nd	D	
2,4,6-trichloro-1,3,5-triazine	5	nd	D	
Chlorobenzene	5	Y,Y,Y	C,C,C	List I
Chlorodinitrobenzene (mixed isomers)	5	nd	-	
Chloro-2-nitrobenzene	5	Y,Y,Y	C,C,B	List I
Chloro-3-nitrobenzene	5	Y,Y,Y	B,C,C	List I
Chloro-4-nitrobenzene	5	Y,Y,Y	C,C,C	List I
Chloro-2,4-dinitrobenzene	5	Y,Y,Y	C,C,C	List I
1,2-Dichlorobenzene	5	Y,Y,Y	C,C,B	List I
1,3-Dichlorobenzene	5	Y,Y	B,B	List I
1,4-Dichlorobenzene	5	Y,Y	B,B	List I
Dichloronitrobenzene (all isomers)	5	Y,Y,Y	C,C,C	List I
1-Fluoro-4-isocyanatobenzene	5	nd	-	
Pentachlorobenzene	5	Y,Y	B,B	List I
1,2,4,5-Tetrachlorobenzene	5	Y,Y,Y	B,C,C	List I

(continued)

SUBSTANCE	SEARCH PHASE	BREACHES AQ. TOXICITY LIMIT 10 mg/l?	DATA GRADE	COMMENTS
Demeton	5	Y,Y	B,B	List I
Dibutyltin salts	5	Y,Y,Y	C,C,C	
2,6-Dichlorobenzonitrile (Dichlobenil)	5, RS	Y,Y,Y(5); Y(RS)	C,C,C; B	
2,4-D	5, RS	Y,Y(5); Y,Y(RS)	C,C	5) Other, unstated data = N;
Dichlorprop	5	Y,Y,Y	C,C,C	List I
Dicofol	5	Y,Y	B,B	List I
Dimethoate	5	Y	A	List I
Linuron	5	Y,Y	B,B	List I
Methamidophos	5, RS	N(5); N,N,N(RS)	- ; C,C,C	
MCPA	5, RS	N(5); N,N,N,N(RS)	- ; C,C,C,B	
Mecoprop (MCPP)	5, RS	N(5)	-	
Mevinphos	5	Y,Y	B,B	List I
Omethoate	5, RS	Y,Y,Y(5); Y	C,C,C; C	
Oxydemeton-methyl	5	Y,Y	B,B	List I
Propanil	5	Y,Y,Y	B,C,C	List I
Pyrazone	5	nd	-	
Triazophos	5	Y,Y,Y	C,C,C	List I
Trichlorfon.	5	Y,Y	B,B	List I
Dibutyl bis(oxylauroyl)tin	5	Y	A	List I
Dibutyltin oxide	5	nd	D	
Tetrabutyltin,	5	Y	A	List I
Diphenyl chloroarsine	5	nd	D	
Ethyl dichloroarsine	5	nd	D	
Hexaconazole	3(cont)	Y,Y,Y	C,C,C	List I
Lambda-cyhalothrin	3(cont)	Y,Y	(C),(C)	Insufficient data to classify
Diclobutrazol	3(cont)	nd	-	

(continued)

SUBSTANCE	SEARCH PHASE	BREACHES AQ. TOXICITY LIMIT 10 mg/l?	DATA GRADE	COMMENTS
Azinphos-ethyl	5(cont)	Y,Y	B,B	List I
Fenthion	5(cont)	Y,Y	B,B	List I
Parathion	5(cont)	Y,Y	B,B	List I
Parathion-methyl	5(cont)	Y,Y	B,B	List I
1,1,1-Trichloroethane	5(cont),RS	Y(5); N,N(RS)	D; B,B	Both "N" results for the same species.
Dioxins	5(cont)	nd	D	
Chloropicrin	5(cont)	nd	D	
Heptachlor	5(cont)	Y,Y	B,B	List I
Chlordane	5(cont)	Y,Y	B,B	List I
1,2-Dibromoethane	5(cont)	Y,Y	(C),(C)	Insufficient data to classify
Quintozene	5(cont)	Y	(C)	Insufficient data to classify

APPENDIX D THE 79 LIST I CLASSIFIED SUBSTANCES

- Aldrin
- Atrazine
- Azinphos methyl
- Azinphos-ethyl
- Bromoxynil (as Bromoxynil-phenol)
- Bromoxynil octanoate
- Cadmium
- 2-Chloroaniline
- Chlorobenzene
- Chlordane
- Chloro-2,4-dinitrobenzene
- Chlorofenvinphos
- 4-Chloro-3-methylphenol
- Chloro-2-nitrobenzene
- Chloro-3-nitrobenzene
- Chloro-4-nitrobenzene
- 2-Chlorophenol
- Chlorothalonil
- 2-Chlorotoluene
- α-Chlorotoluene
- Chlorpyrifos
- Coumaphos
- Cypermethrin
- DDT
- Demeton
- Diazinon
- Dibutyl bis(oxylauroyl)tin
- Dichlofluanid
- Dichloroaniline
- 1,2-Dichlorobenzene
- 1,3-Dichlorobenzene
- 1,4-Dichlorobenzene
- Dichloronitrobenzene (all isomers)
- 2,4-Dichlorophenol
- 1,3-Dichloropropene
- Dichlorprop
- Dichlorvos
- Dicofol
- Dieldrin
- Dimethoate
- Diuron
- Endosulfan
- Endrin
- Fenitrothion
- Fenthion
- Heptachlor
- Hexachlorobenzene
- Hexachlorobutadiene (HCBD)
- Hexachlorocyclohexane
- Hexachloroethane
- Hexachloronorbornadiene
- Hexaconazole
- 3-Iodo-2-proponyl n-butyl carbamate (IPBC)
- Linuron
- Malathion
- Mercury
- Mevinphos
- Oxydemeton-methyl
- Parathion
- Parathion-methyl
- Pentachlorobenzene
- Pentachloroethane
- Pentachlorophenol (PCP)
- Permethrin
- Propanil
- Simazine
- Tetrabutyltin
- 1,2,4,5-Tetrachlorobenzene
- Tetrachloroethylene
- Triazophos
- Tributyl tin oxide (TBTO)
- Tributyl-phosphate
- Trichlorfon
- 1,2,4-Trichlorobenzene
- Trichloroethylene
- Trichlorophenol (all isomers)
- Trifluralin
- Triphenyl tin oxide (TPTO)
- Triphenyl-phosphate