

**EUROPEAN WATER ASSOCIATION (EWA) POSITION PAPER ON THE
REGULATION OF THE INTRODUCTION OF NEW CHEMICALS
INTO THE ENVIRONMENT.**

**EWA IS TAKING THE OPPORTUNITY OF EXPRESSING ITS VIEWS AS A
RESPONSE TO THE EUROPEAN COMMISSION PROPOSAL FOR A
REGULATION CONCERNING THE REGISTRATION EVALUATION
AUTHORISATION AND RESTRICTION OF CHEMICALS, ESTABLISHING
A EUROPEAN CHEMICALS AGENCY AND AMENDING DIRECTIVE
1999/45/EC AND REGULATION ON PERSISTENT ORGANIC
POLLUTANTS**

1 SUMMARY

- 1.1 EWA is very much aware of the problems in the current regulation of industrial chemicals and the impact that these materials can have on the water environment. Hence EWA broadly welcomes the Commission's proposals and suggests that there should be close cooperation between the programmes for developing REACH and the establishment of the proposed European Chemicals Agency with the programmes for applying the Water Framework Directive and the work in developing a Sustainable Soil Strategy and the promotion of utilisation of biosolids as agricultural fertilisers
- 1.2 EWA would be pleased to elaborate on any of the points made and responses may be directed to the Hennes office.

2 BACKGROUND

- 2.1 On the 29 October 2003, the European Commission published proposals for new regulations controlling the manufacture, use or import of chemicals into the EU. The proposed new EU chemicals strategy (known as the REACH system – Registration, Evaluation and Authorisation of Chemicals) suggests a single system to gather hazard information, assess risks, classify, label, and restrict the marketing and use of individual chemicals and mixtures.
- 2.2 The draft proposals are:
- A Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) {on Persistent Organic Pollutants}; and
 - A proposal for a Directive of the European Parliament and of the Council amending Council Directive 67/548/EEC in order to adapt it to Regulation (EC) of the European Parliament and of the Council concerning the registration, evaluation, authorisation and restriction of chemicals.

3 OVERVIEW

- 3.1 EWA is well placed to observe the risks of chemicals to the water environments. The failings of the current system are well recognised and EWA supports the development of a new approach that is fast and effective in identifying and taking action on chemicals of most concern.
- 3.2 REACH will bring many changes to the way chemicals are managed in the EU, many of which will need interim arrangements to be made in preparation.

A new approach

- 3.3 EWA welcomes initiatives that will lead to a better understanding of Chemicals and how they are used and enter into the environment, but feels information is required at national level to help inform other pollution control activities. EWA believes that sorting and selecting potential chemicals of concern is essential to ensure that action is prioritised to chemicals of highest concern first.

Administrative arrangements

- 3.4 EWA recognises that there may be a requirement for administrative arrangements to change in the future, not least as a consequence of the introduction of REACH and the creation of a European Chemicals Agency. EWA suggests that there may be advantages to be gained in increased co-ordination and leadership in chemicals management at national levels in the EU countries.

Integrating Environmental Monitoring

- 3.5 EWA considers that improvements in the available data on chemicals, which will help to better target monitoring programmes, are required. It also recognises the importance of surveillance monitoring of chemicals and biota and of using the wealth of information on biota generated by voluntary organisations to identify the often-unexpected impacts of chemicals. It is likely that existing Regulators are not, however, specifically funded to undertake this activity and additional resources are needed. Where appropriate, EWA urges that measures should be adopted which would facilitate the introduction of specific post-authorisation monitoring by industry, as this would help assess the effectiveness of risk management measures.

4 SPECIFIC RECOMMENDATIONS

EWA comments on the main issues of concern are highlighted in the following sections.

4.1 **A new approach**

4.1.1 *List of Marketed Chemicals*

EWA welcomes initiatives that will lead to a better understanding of Chemicals and how they are used and enter into the environment, but feels information is necessary at national level to help inform other pollution control activities. However, we recognise that because of the complexity of the supply chain this may not be achievable in detail for all chemicals. The new EU Chemicals

Strategy will eventually lead to a database of chemical substances manufactured and supplied in the EU over a certain tonnage and may go some way to fulfilling this recommendation. However, we have reservations about the use of very broad descriptions of chemical types that relate poorly to use, as we believe these would not provide appropriate information that could help in formulating risk management strategies.

EWA believes that sorting and selecting potential chemicals of concern is essential to ensure that action is focussed on these chemicals first. Bodies such as OSPAR and the European Commission – are already proactive in identifying possible chemicals of concern and have been using many of the screening techniques e.g. using the criteria for persistence (P), bioaccumulation potential (B) and toxicity (T).

Although REACH has some limitations, EWA is of the opinion that predictive techniques (such as Quantitative Structural Activity Relationships, QSARs) and in vitro testing rather than animal data, will contribute significantly to the data made available by industry, at least for environmental effects. It is recommended that the existing database EUCLID, operated by the European Chemicals Bureau at the Joint Research Centre in Ispra, Italy, is considered as a starting platform for the European Chemicals Agency in order to minimise duplicate work in the data collection and data banking.

EWA urges that early consideration should be given to how data gathered under REACH can contribute to the future development of QSARs and other predictive techniques.

EWA supports the public availability of hazard information on chemicals.

As chemical management is organised at an international level, EWA believes that we should seek international harmonisation of criteria to sort chemicals of concern.

In general, EWA supports the need for a more systematic use of environmental monitoring data and observation in the assessment of chemicals (see further comments later). EWA considers that chemicals found in unexpected environmental compartments or at unexpected concentrations, or associated with unusual biological phenomena, should be selected for further investigation.

4.1.2 *Evaluation of Selected Chemicals and Risk Management Action*

EWA supports the identification of chemicals of highest concern followed by swift appropriate action to control the risks from these chemicals. It believes that the proposed system of authorisation under REACH, which includes persistent, bio-accumulative and toxic (PBT) and very persistent and very bio-accumulative (vPvB) substances (as well as those of equal concern and endocrine disrupters), if delivered in a workable manner, will help to achieve these aims. EWA supports the views expressed that there is a need to continue pressing for a workable and effective system of authorisations under REACH.

EWA is concerned about the current proposals for testing requirements for substances that are produced in quantities between 1 and 10 tonnes. The testing

requirements for these substances in the current proposal are inadequate to identify whether these substances are dangerous to the environment. The lack of obligations on downstream users for the safe use of these chemicals also means that REACH does not address the environmental concern of these chemicals. EWA would therefore like to see higher testing requirements for these substances and requirements on downstream users to ensure that they are used safely.

EWA is very clear that all practicable steps should be taken to avoid the use of higher animals as test organisms.

4.1.3 *Risk Management Action*

EWA believes that information available from monitoring in all compartments should be evaluated and considered to assist in managing risks from chemicals.

EWA believes REACH should take account of the aims of other legislation when forming risk reduction strategies. For example Environmental Quality Standards or the elimination of emissions of priority hazardous substances in Annex Ten of the Water Framework Directive may not be achievable without some form of marketing and use control.

4.2 **Administrative arrangements**

The experience of professionals engaged in water cycle management is that the management of risks of industrial chemicals is regulated in rather a fragmented fashion. We recognise that there may be a requirement for administrative arrangements to change in the future, not least as a consequence of the introduction of REACH and the creation of a European Chemicals Agency.

EWA suggests that there may be advantages to be gained in increased co-ordination and leadership in chemical management at national levels in the EU Countries. Whatever the form of future administrative arrangements, EWA suggests that these should include:

- an increased level of co-ordination between experts in chemical policy, regulation and science so to deliver an improvement in the protection of human health and the environment
- an improved and co-ordinated interface with external experts and bodies for example in the EU and OECD (particularly in light of the development of REACH)
- a transparent, meaningful and effective dialogue with all interested stakeholders
- improved co-ordination of research activities in the field of chemical management
- improved co-ordination and integration of monitoring activities in the management of chemicals whilst retaining the responsibility for monitoring within the expert bodies

4.3 **Integrating Environmental Monitoring**

4.3.1 *Monitoring*

EWA believes that better data on chemicals would improve the targeting of monitoring programmes. This would include information on production, use, and biological effects. This information is essential to ensure the design of cost-effective monitoring programmes.

It also recognises the importance of surveillance monitoring for chemicals and biota and of using the wealth of information on biota generated by voluntary organisations to identify the often-unexpected impacts of chemicals. In future development of databanks at the European or international level, there is a potential for including substance-specific data needed for modelling of environmental fate.

EWA suggests that industry could play a role in monitoring in a framework governed by Regulators. It is recognised that Directives rather than a strategic evaluation of potential impacts in the environment drive too many monitoring programmes. Many Regulators will be funded to carry out monitoring to assess compliance with Directive requirements but not to do exploratory and general surveillance work. Additional resources are required for this important work.

4.3.2 *Post-authorisation monitoring*

EWA would welcome measures that would facilitate the introduction of specific post-authorisation monitoring by industry where appropriate e.g. set as a condition of granting approval. This would help assess the effectiveness of risk management measures.

4.4 **Towards Environmentally Sustainable Products and Processes**

4.4.1 *Substitution*

EWA believes that the every effort should be made to substitute chemicals of concern with safer alternatives and that substances subject to authorisation should be phased out whenever feasible. EWA is therefore very supportive of the inclusion of persistent, bio-accumulative and toxic (PBT) and very persistent and very bio-accumulative (vPvB) substances (as well as those of equal concern such as endocrine disrupters) for authorisation under REACH as a way of achieving this aim. EWA is also supportive of further encouraging innovation in safer substitutes and substitution by authorising substances for a limited time period only (both first and second track authorisations).

EWA recognises the importance of Green Chemistry (both in terms of improved technological processes but also focussing on improved product design) and welcomes initiatives that promote it.

4.4.2 *Information Transfer through the Supply Chain*

EWA believes that better information provision through the supply chain is essential to ensure adequate risk management of chemicals.

European Water Association



The European Water Association (EWA) is an independent non-governmental and non-profit making organisation dealing with the management and improvement of the water environment. It was founded on 22 June 1981 as the European Water Pollution Control Association. The scope of EWA was enlarged in 1999 with the change of name to the European Water Association.

It is one of the major professional associations in Europe that covers the whole water sector, wastewater as well as drinking water and water related waste. With member associations from nearly all European Countries EWA includes most of the current European Union Member States, Norway, Switzerland and the majority of the future EU members from Central and Eastern Europe.

The aim of EWA is to provide a forum for the discussion of key technical and policy issues affecting the growing European region. This is done through conferences, workshops, meetings and special working groups of experts all organised on an international basis together with regular publications.

EWA informs its members on the development of EU legislation and standardisation and seeks to influence the drafting when appropriate. It has close contacts with the European Commission (DG Environment), the European Committee for Standardization (CEN), the European Environment Agency (EEA) and the European Parliament.

Through this exchange of knowledge the objective of EWA is to contribute to sustainable water management, a safe water supply and the protection of the water environment.

Today, EWA consists today of about 25 European national associations each representing professionals and technicians for wastewater and water utilities, academics, consultants and contractors as well as a growing number of corporate member firms and enterprises. EWA thus represents about 55,000 professional individuals working in the broad field of water management.

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