

## **Summary of the European Directives Regulating the Placing of the Biocorrosion and Corrosion Inhibitors on the Market.**

Biocides used in cooling water systems are divided into oxidising agents and non-oxidising ones. The use of oxidising agents could lead to the increase of the physicochemically induced corrosion of metallic materials. Under these conditions, industry must remedy the situation and treat plants with classic corrosion inhibitors. So, the biocorrosion treatments use in fact two families of products: on the one-hand, classic corrosion inhibitors which treat the physicochemically induced corrosion, and on the other hand the biocides, which kill or control the development of the micro-organisms responsible for a biologically induced corrosion.

These products, until May 1998 had to conform to the laws, regulations and administrative provisions of the modified Directives 67/548/EEC relating to dangerous substances, 88/379/EEC relating to dangerous preparations and 76/769/EEC relating to restrictions on the marketing and use of dangerous substances and preparations.

But, since May 1998, date of entry into force of the Directive 98/8/EC of February 1998 concerning the placing of the biocidal products on the market, the Member States moreover regulates their placing on the market by particular provisions.

So, it appears that Microbiologically Influenced Corrosion control will be well regulated in Europe and that in future all chemicals will have to abide by one of the Directives mentioned above.

### **I- SUMMARY OF THE DIRECTIVE 67/548/EEC ON THE APPROXIMATION OF THE LAWS, REGULATIONS AND ADMINISTRATIVE PROVISIONS OF THE MEMBER STATES RELATING TO THE CLASSIFICATION, PACKAGING AND LABELLING OF DANGEROUS SUBSTANCES**

The objective of this principal Directive is to harmonise the legislation of the various Member States as regards tests, classification, packaging and labelling of dangerous chemicals towards human or environment.

The Directive makes a distinction between "new" and "existing" chemicals. The existing chemicals are those which were introduced on the Community market before September 1981 and which are reproduced on the list of the European Inventory of Existing commercial Chemical Substances (EINECS)." The new "chemical substances are those which do not appear in the EINECS list.

A producer or an importer who places a new chemical substance on the market and markets it for the first time in the European Community after September 1981 must present a dossier of notification on the chemical to her or his proper national authority 45 days at least before the date of the introduction on the market. The existing chemicals are free from this notification.

This common core data set is intended to identify the dangers for health and environment. It contains physicochemical data, toxicological and ecotoxicological tests, quantities to be produced, the intended uses, measures necessary to protect man, animals and the environment, and the means for making the substance inoffensive.

Toxicological and ecotoxicological tests required depend on the annual sale tonnage. Additional information can also be required before these levels of production are reached.

All the chemicals classified as dangerous by the Community in accordance with the Directive are listed in Annex I, which is regularly updated. The Commission publishes in the Official Journal of the European Communities a list of the new chemicals, which were notified in accordance with this Directive. This list is called the ELINCS list for European List of New Chemical Substances.

## **II- SUMMARY OF THE DIRECTIVE 88/379/EEC ON THE APPROXIMATION OF THE LAWS, REGULATIONS AND ADMINISTRATION PROVISIONS OF THE MEMBER STATES RELATING TO THE CLASSIFICATION, PACKAGING AND LABELLING OF DANGEROUS PREPARATIONS**

The Directive adapts and extends the procedures and the standards for the classification and labelling of dangerous chemicals of Directive 67/548/EEC to the dangerous preparations marketed in the Community. A preparation is a mixture of two or several chemical substances.

The Directive applies to the preparations which are put on the Community market and which contain at least one substance classified or considered as dangerous. Annex II defines the particular conditions of labelling for certain products containing lead, cyanoacrylates, isocyanates, epoxydic compounds, aerosols, active compounds containing cadmium and chlorine. The preparations must be classified according to the greatest identified risk.

### **III- THE DIRECTIVE 98/8/EC CONCERNING THE PLACING OF THE BIOCIDAL PRODUCTS ON THE MARKET**

The European Community is concerned at the lack of harmonised provisions for biocides, formerly known as " non-agricultural pesticides ". For memory, the definition which is given in the Directive 98/8/CE of the biocidal product is very large since the biocidal products are "active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means".

It is considered that biocidal products are necessary for the control of organisms that are harmful to human or animal health and for the control of organisms that cause damage to natural or manufactured products. However biocides can pose risks to human, animals and the environment in a variety of way due to their intrinsic properties and associated use pattern.

The Directive 98/8/CE of the European Parliament and of the Council concerning the placing of biocidal products on the market was:

- Adopted on : 16 February 1998,
- Published in O.J. : L 123 of 24 April 1998 p.1,
- Entered into force on : 14 May 1998,
- And, it will be implemented in Member State on 14 May 2000.

#### **1. THE ANNEXES I AND V OF THE DIRECTIVE 98/8/CE**

An exhaustive list of 23 product types with an indicative set of descriptions within each type is given in annex V of the biocidal product directive (BPD). These 23 type products are

grouped into 4 groups.

K Group 1 : Disinfectants and general biocidal products (Type 1 to 5) :

➤ Type 2 : Private area and public health area disinfectants and other biocidal products (ex: Swimming pools, air conditioning systems).

K Group 2 : Preservatives (Type 6 to 13) :

➤ Type 6 : In-can preservatives (containers),

➤ Type 10: Masonry preservatives.

K Group 3 : Pest control (Type 14 to 19) :

➤ Type 16 : Molluscicides.

K Group 4 : Other biocidal products (Type 20 to 23) :

➤ Type 21 : Antifouling products (microbes and higher forms of plants or animal species).

The purposes of this Directive are various but the most important for the MIC mitigation is that this Directive draws up a Community list, constituting Annex I, reviewed periodically, of the active substances approved for inclusion in biocidal products. This list is empty initially and filled by reviews and submissions of new active substances. The conditions of entry in the list are a dossier satisfying data requirements, no unacceptable effects on man or the environment, effectiveness, and that analytical methods will be available.

This Annex is separated in three parts. Annex I establish the list of active substances with requirements agreed at Community level for inclusion in biocidal products, these substances can be regarded as “substance of concern”. They would be normally a substance classified as dangerous and present in biocidal product at a concentration leading the product to be regarded as dangerous. Annex IA draws up the list of the active substances with requirements agreed at Community level for inclusion in low-risk biocidal products. Annex IB draws up the list of the basic substances with requirements agreed at Community level of which the principal use is not that of a pesticide but which is used incidentally as biocide (ex: CO<sub>2</sub>, N<sub>2</sub>, ethanol, 2-propanol, acetic acid, kieselguhr...).

It is also to remark, like written in article 10.5 of the BPD, that an entry of an active substance in Annex I and, where relevant, IA or IB may be refused or removed if there is another active substance on Annex I for the same product type which, in the light of scientific

or technical knowledge, presents significantly less risk to health or to the environment.

## **2. THE TIME SCHEDULES**

Concerning the time schedules, an identification of existing active substances, which represents approximately 2000 substances, have been done by member states. All non-listed substances will be forbidden to use as biocide or in a biocide product after the 14 May 2000 and all non-listed substances will be considered as new substances and will require a full dossier.

The producers will have then 18 months to indicate if they support or not one or more of these substances and for what type. After this delay, all non-supported substance will be extract from the market.

Then, to review the dossier of each product, an identification of priority product types will be done. The first will be certainly "wood preservatives" and "rodenticides" types. It is planned that the examination of all the dossiers will take approximately 10 years.

In a second phase, for end 2002, but more certainly after, a final filled list of existing active supported substances (200 - 900?) will be establish. For some substances a possible limitation of use would be added (only for closed circuits for example).

## **3. THE COSTS OF THE BPD FOR THE PRODUCERS**

The costs of the BPD for the producers will be relatively expensive since:

- The dossier requirements (data): 5 M Euro/Active Substance,
- The complementary data necessary for products: 70 K Euro/Product,
- The costs of dossier: 225 K Euro/Dossier (1 person/year/product),
- The registration costs: 3 K Euro/Product/State.

## **CONCLUSION**

In this conditions, it is foreseeable that few substances will be supported as biocides and, after examination of their dossier and the risk evaluation, very few of them will be retain as authorised substance for biocide activity.