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Application of the Dangerous Preparation Directive: consequences on plant protection products in the internal market

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Summary. Legislative Decree March 2003, n. 65 brought about implementation of Directive 1999/45/EC of the European Parliament and of the Council dated 31 May 1999 and Directive 2001/60/EC of the Commission dated 7 August 2001 concerning laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations come into force. Directive 1999/45/EC brought about a series of modifications representing the new regulatory framework for dangerous preparations. The above-mentioned Decree supplies the criteria for the evaluation of hazardous preparations, regardless of their intended use, and completes previously undertaken steps, in strict connection with the analogous Directives of the EU, for the problematic complexity of the classification, packaging and labelling of dangerous substances and preparations. The applicative importance of Directive 99/45/EC derives directly from these innovations. Among these, for the first time, the category of "dangerous for the environment" has been extended also to preparations. Moreover, also for the first time, the scope of the Directive is extended to plant protection products and biocides. This paper provides an overview on the results of the hazard classification procedure carried out at national level for plant protection products in light of the new rules and the outcomes in terms of variations of the labels through comparison between previous and new classification. Furthermore the most significant issue which come up during the classification process and the criteria applied for their solution are also reported.

Key words: plant protection products, classification, product labeling, dangerous preparations.

Riassunto *(Applicazione della Direttiva Preparati Pericolosi: conseguenze sui prodotti fitosanitari nel mercato nazionale)*. Con il Decreto Legislativo 14 marzo 2003, n. 65 è stata data attuazione alla Direttiva n. 1999/45/CE del Parlamento Europeo e del Consiglio del 31 maggio 1999 e alla Direttiva 2001/60/CE della Commissione del 7 agosto 2001 concernente il riavvicinamento delle disposizioni legislative, regolamentari ed amministrative degli Stati membri relative alla classificazione, imballaggio ed etichettatura dei preparati pericolosi. La Direttiva 1999/45/CE apporta una serie di modifiche rappresentando la nuova normativa quadro in materia di preparati pericolosi. Il Decreto in oggetto fornisce i criteri per la valutazione di pericolosità dei preparati, indipendentemente dalla loro destinazione d'uso e completa l'azione intrapresa, in stretto collegamento con le analoghe direttive dell'UE, per regolamentare la complessa problematica della classificazione, imballaggio ed etichettatura dei preparati pericolosi. Le ricadute applicative della Direttiva 99/45/CE derivano direttamente dalle novità di rilievo introdotte. Tra queste, viene inserita per la prima volta, anche per i preparati, la categoria di "Pericoloso per l'ambiente". Inoltre, sempre per la prima volta, il campo di azione della Direttiva viene esteso ai preparati fitosanitari ed ai biocidi. Nel testo vengono indicate, attraverso una panoramica sulle classificazioni di pericolo effettuate per i preparati fitosanitari alla luce della nuova norma, le risultanze in termini di variazioni delle etichette tramite il confronto tra la vecchia e la nuova classificazione. Vengono inoltre presentate le più significative problematiche di rilievo incontrate durante la procedura di riclassificazione ed i criteri utilizzati per la loro soluzione.

Parole chiave: preparati fitosanitari, classificazione, etichettatura di prodotti, preparati pericolosi.

INTRODUCTION

Legislative Decree n. 65 dated 14 March 2003 [1] brought about implementation of Directive 1999/45/EC of the European Parliament and Council dated 31 May 1999 [2] and Directive 2001/60/CE of the Commission dated 7 August 2001 [3] relative to legislative, regulamentory and administrative regulations of Member States in reference to classification, packaging, and labelling of dangerous preparations. Directive 1999/45/EC introduced a series

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of modifications becoming the new reference norms in terms of dangerous preparations. The above-mentioned Decree provides criteria for classifying hazardous preparations, regardless of their intended use, and completes the process, in strict adherence to similar EU Directives, aimed to regulate the complex regulations regarding classification, packaging and labelling of dangerous preparations. Requirements which aim to ensure better protection of individuals who come in contact with dangerous preparations, whether as part of their work or during personal use, are furthermore outlined.

New classification of plant protection products became necessary to abide by a European Directive which harmonized the various national norms and equated plant protection preparations with other dangerous preparations. Italy is among the European countries to have acted more quickly, preceded only by Northern European countries, which however had far fewer products to assess and have more resources involved in this task.

REPERCUSSIONS OF THE APPLICATION OF DIRECTIVE 99/45/EC

The repercussions of the application of this Directive derive directly from major introduced changes.

These include the introduction, for the first time, of the classification as "Dangerous for the environment" also for preparations. A Safety Data Sheet (SDS) may be provided also for preparations considered not dangerous, and not destined to the general public, which contain at least one substance dangerous for health or for the environment if its concentration is equal to or higher than 1% or for which EU has established a limit of exposure in workplaces. Other repercussions of the Directive are: the requirement to report on the label of certain preparations not classified as sensitizing; the chemical name of the substance officially or self-classified as sensitizer if contained in concentrations of 0.1% or greater; the establishment of the principle that the "conventional" classification system should prevail over the experimental test.

For liquid preparations having a flash point higher than 55 °C and containing halogenated hydrocarbons and flammable or easily flammable substances in concentrations greater than 5% it will become mandatory to label that the substance may easily become flammable during use. On the label it should be included the phrase R67 (Vapors may cause drowsiness and dizziness), where the substance or substances labeled with phrase R67 are present in concentrations of minimum 15%, unless the compound is packaged in small containers or is already classified, for acute toxicity, as dangerous by inhalation. For the first time, it includes within the scope of application of issues of classification, packaging and labelling of dangerous preparations, plant protection products, (except for what regulated by Legislative Decree 194/1995 dated 17 March 1995 [4]), and subsequent modification, as well as biocidal products (except for what regulated by Legislative Decree 174/2000 [5]), and subsequent modification. Labelling becomes mandatory whenever cement or cement preparations not classified as sensitizing, but containing more than 2 ppm of chrome VI, warning of the risk of allergic reaction. For the first time, procedures for distance sales are defined.

Rules for the possibility of avoiding disclosure of the composition of a dangerous substance while informing only the authorities and poison centers of the complete product's composition are introduced.

INNOVATIVE ASPECTS OF DIRECTIVE 99/45/EC

Innovative aspects of the Directive are:
- assessment of dangers for the environment;
- rules for SDS [6];
- specific labelling criteria for certain categories of preparations;
- possibility of reporting the names of substances using an alternative identification;
- report for the archive of dangerous preparations;
- norms regulating correspondence sales [7];
- requirement for vertebrate protection [8];
- introduction of plant protection preparations and biocides in the area of application [9].

Among those the first important innovative element is the introduction of environmental classification for preparations containing substances classified for the aquatic environment, and it could be even stated that the first hypothesis of revision of the former Directive on Preparations 88/379/EEC [10] originated from the need to extend the classification of substances also to the environmental sector. The new Directive, infact, calls for the creation of a procedure similar to the one used for human health, to be used for the environmental classification of substances, such as the concept of sum of concentrations for the same effect, the concept of percentage limitations and the concepts of "dilution" or "degradation" of classification upon reduction of the concentration. The environmental classification of preparations occurs as a consequence of the concentration and the environmental classification of the substances of which they are made. As an alternative to the methods of calculation, there is the possibility of carrying out a test on the preparation, but contrary to what so far recommended, this choice is not supported, in part due to the need for saving but also in support of trends called for by new orientations on the safeguard of species test, in particular vertebrates. The classification resulting from the application of the methods of calculation, whenever considered excessively penalizing and/or not responsive to the ecotoxic properties of the preparation, can be disproved by results of tests on the preparation, but it will be necessary to obtain

negative results from all three tested species (fish, daphnia, algae). There is no possibility of conducting tests on the preparation regarding the long-term effects such as persistence, biodegradation, bioaccumulation. As a matter of fact, properties such as biodegradation and the bioaccumulation potential cannot be tested on preparations since these peculiar aspects are strictly correlated to the intrinsic properties of the single components. For the the first time the conventional method is given priority over testing. According to bulletin dated 7 January 2004 of the Ministry of Health, a "new experimental test can be conducted on a preparation only it if can be proved that by applying the system of calculation or the reference to studies already conducted do not reflect the real properties of the preparation". Therefore if the person responsible for introducing the preparation on the market is able to scientifically prove that the toxicological properties of the preparation cannot be correctly determined either through calculation or on the basis of tests already conducted on animals, experimental methods can be used assuring that steps are taken to safeguard the animals used for experimental or other scientific purposes and that good laboratory practices are used.

APPLICATION TO PLANT PROTECTION PRODUCTS

Plant protection products (PPPs) are subject to registration procedures outlined in Directive 91/414/EEC acknowledged in Italy through Law Decree n. 194 dated 17 March 1995. Within the scope of this procedure, the hazard classification and the corresponding labelling is not up to the person responsible for registering it but lies within the duties of the central Authority. Furthermore the Ministry of Health and the Istituto Superiore di Sanità proceeded to revise the current classification, in accordance with new criteria, of all plant preparations available on the domestic market. Comparison of the old and the new classification, through a presentation of the new classifications of PPP obtained in respect of the new norm, are hereby provided. Some of the criteria utilized in approaching specific problems which came up during reclassification are listed below.

The procedure involved:
- about 250 firms/manufacturers;
- about 4900 preparations;
- about 600 (new and existing) active substances;
- over 1000 counter deductions presented by firms following the first proposal of the ISS, of which 25% were accepted.

PECULIAR ASPECTS AND SOME SPECIFIC APPLIED CRITERIA

Some aspects and applications of the Directive 99/45/EC are listed below.

Coformulants and solvents. The term coformulating agent refers to any other ingredient present in a PPP, in addition to the active ingredient, which does not have the property of destroying, repelling or inhibiting a harmful organism. Based on expected use, PPPs contain large quantities of coformulanting agent and solvents, some times more dangerous that the active ingredient itself. For the first time in the sector of PPPs, coformulating agent and solvents are taken into account in determining classification of the preparation, in accordance with enforcement of Directive 99/45/EC. If considered as dangerous (thus present in concentrations above accepted limits) their chemical name is reported on labelling, with the exclusion of irritating substances, dangerous for the environment substance and dangerous substances for their chemical-physical properties.

Quality of studies presented. Toxicity studies conducted before 1985 and studies not performed under good laboratory practice have not been taken into consideration in determining classification.

Active ingredients not included in Annex I to Directive 67/548/EEC. Information reported in the corresponding SDS submitted by firms was used for preparations containing the approximately 140 active ingredients which are either new or not officially classified by Directive 67/548/EEC [11]. In the event of SDS provided by different firms which refer to the same active ingredients but presenting contradictory data, validation was conducted using data obtained through bibliographical and on-line research. In these cases, the classification previously produced by the group of experts in the EU pending formalization in the 30th ATP [12] and the national classifications approved by the Commission on Plant Protection Products (Commissione Consultiva Prodotti Fitosanitari, CCPF) were also taken into consideration.

Products dangerous for their chemical-physical properties. In order to determine the chemical-physical characteristics for the classification of dangerous products due to their possible flammable, explosive or combustive properties, in absence of a test on the preparation, a conservative approach was adopted, selecting an indicative perceptual limit of 30% for flammable, explosive or combustive components.

Products containing petroleum-based solvents. Classifications provided by Annex I of Directive 67/548/EEC, integrated with classifications reported in a document produced by the Concawe (The Oil Companies European Organization for Environment, Health and Safety) [13], were applied to products containing petroleum-based solvents. Phrases R66 (Repeated exposure may cause skin dryness or cracking) and R67 (Vapours may cause drowsiness and dizziness) were also added to a preparation if the solvents characterized by these phrases were present in the formula in concentrations over 15%.

Products containing nonilphenol. Directive 2003/53/EC dated 18 June 2003 [14], which modified for the 26th time Directive 76/769/EEC with reference to restrictions to introducing products on the market, and

the use of certain substances and dangerous preparations (nonilphenol NP, ethoxylated nonilphenol NPE, etc.) has been taken into account. The Directive introduces harmonized regulations regarding the sale of NP, NPE and cement (NP is used come intermediate during the production of NPE, such as in detergents and paints), in the production of resins and plastics. Furthermore it is used as a stabilizer in producing polymers, in the production of phenol oxidide and certain paints. This Directive prohibits the use of nonilphenol and of ethoxylated nonilphenol in concentrations equal to or higher than 0.1% in biocides and plant protection products.

Products containing category 1 or 2 CMR substances. The decision consolidated by CCPF according to which "Substances in 1 or 2 for carcinogens, mutagens or teratogens (CMR) cannot be present in plant protection preparations" was adopted.

In the case of substances which have not yet been included in Annex I of Directive 91/414/EEC, this precautionary approach has been adopted, expressed various times by the CCPF and upheld by the National Competent Authority during the EU evaluation of said substances as well as at the time of selection for possible inclusion in 91/414/EEC Annex I of of active substances for PPPs classified as CMR 1 and 2. Consequently, for preparations containing category 1 and 2 CMR substances not yet included in Annex I or for preparations for which the process of the EU's revision has not yet been finalized, the precautionary approach of non-admissibility on the basis of the hazard assessment carried out in relation to the intrinsic properties of the substances, required by the consolidated decision of the CCPF, has been confirmed. On the other hand, for preparations containing substances already included in Annex I of Directive 91/414/EEC and classified in CMR categories 1 and 2, one has proceeded, abiding by with the commonly accepted principles, with the quantitative and qualitative risk assessment considered case by case, in agreement with the criteria laid out in Directive 91/414/EEC.

In this case, a proper quantitative risk assessment has been carried out only in the case in which the available data allowed it, taking into consideration the mechanism of toxic effects with or without a threshold (for example carcinogenic and genotoxic substances). The acceptance of preparations classified as CMR category 1 or 2 (depending on the concentration of active CMR substance they contain, according to what is indicated in Directive 99/45/EC and in the subsequent Legislative Decree n. 65 dated 2003) has been carefully examined by the CCPF also with regard to the real and actual national agronomic needs and by the absence of valid alternatives. The approval of some category 1 or 2 substances in Europe indicates how their use in normal agricultural practices carries negligible risk.

Products containing copper compounds. For preparations based on the following compounds: copper sulphate, copper oxychloride, copper hydroxide, copper oxide and bordeaux mixture, it was decided to use the classification proposed by the Copper Task Force, which revealed the following problems for some of the above compounds:

- acute inhalatory toxicity: T R23 (Toxic by inhalation) o Xn R20 (Harmful by inhalation);
- acute oral toxicity: Xn R22 (Harmful if swallowed);
- ocular irritation: Xi R41 (Risk of serious damage to eyes) o Xi R36 (Irritating to eyes).

All the copper compounds have furthermore been classified as N R50-53 (Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment), in accordance with what has been proposed by the EU's classification and labelling group of technical experts.

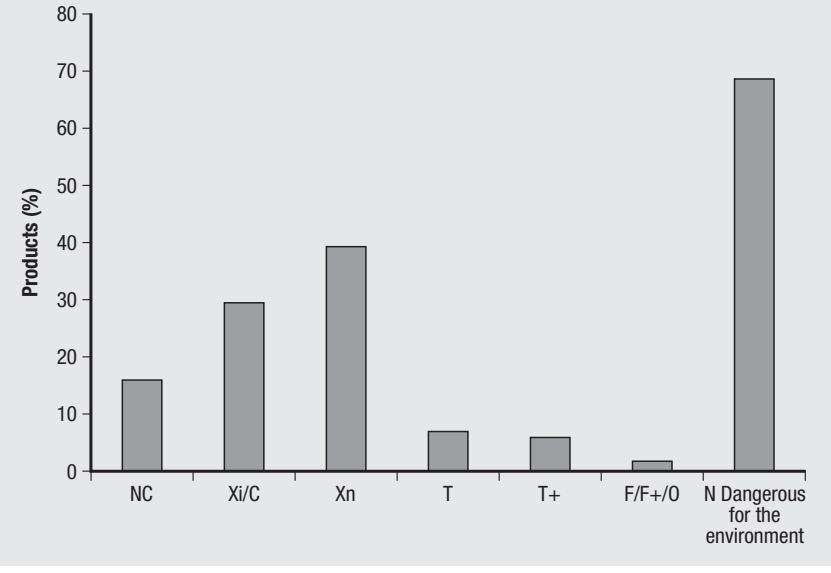

Fig. 1 | *Results of the Istituto Superiore di Sanità classifications with regard to Directive 99/45/EC.*

NC = Not Classified;
Xi/C = Irritant/Corrosive;
Xn = Harmful;
T = Toxic;
T+ = Very Toxic;
F/F+/O = Extremely Inflammable/ Highly Inflammable/Explosive when mixed with combustible material;
N = Dangerous for the environment.

RESULTS OF THE RECLASSIFICATION PROCEDURE

The results of the reclassification procedure are illustrated in the two following figures.

Results in *Figure 1* highlight that

for human health:

- about 17% of the PPPs tested resulted as Not Classified (NC);
- about 30% of the PPPs tested resulted as Xi/C (Irritant/Corrosive);
- about 40% of the PPPs tested resulted as Xn (Harmful);
- about 7% of the PPPs tested resulted as T (Toxic);
- about 6% of the PPPs tested resulted as T+ (Very Toxic).

for the chemical-physical properties:

- about 0.5% of the PPPs was F R11 (Highly Inflammable);
- about 0.8% of the PPPs was F+ R12 (Extremely Inflammable);
- about 0.3% of the PPPs was O R9 (Explosive when mixed with combustible material).

For the environment:

- about 70% of the plant protection products resulted classified for its effects on the environment and only 30% still results unclassified;
- about 35% resulted classified as N R50-53 (Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment);
- about 20% resulted classified as N R51-53 (Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment);
- about 5% resulted classified as N 50 (Very toxic to aquatic organisms);
- about 10% resulted classified as R52-53 (Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment);
- less than 1% resulted classified as N R59 (Dangerous for the ozone layer).

Results in *Figure 2* highlight the variations between the previous classification and the new one respecting the application of the Directive on preparations, which show:

- a 2.3% increase in products classified as T+ (Very Toxic);
- a 2.7% increase in products classified as di prodotti classificati T (Toxic);
- an 18.5% increase in products classified as Xn (Harmful);
- a 4.9% increase in products classified as Xi/C (Irritant/Corrosive);
- a 29.4% decrease in products not classified;
- a 70% increase in products classified as dangerous for the environment.

CONSEQUENCES ON THE DISTRIBUTION SYSTEM

The application of the Directive 99/45/EC have caused the following consequences on the distribution system:

- whereas a license was required for the purchase of 26.6% of the preparations, it is now required for 50.2% (+23.6%);
- a possible need for greater spaces for storage of products classified as T+ (Very Toxic), T (Toxic), Xn (Harmful);
- about 10% of resale (> 5 tons of T+), may be subject to the Seveso 2 [15];
- the possible increase in flammable products may require application of fire prevention norms (L. D. 626/94) [16];
- probable increase in the number of products subject to the ecotax, the "Contribution to the food products safety, reference Art.123, Law n. 388 dated 23 December 2000 [17] and Art. 59, Law n. 488 dated 23 December 1999" [18]. This contribution corresponds to 2% of the previous year's turnover, aimed at sup-

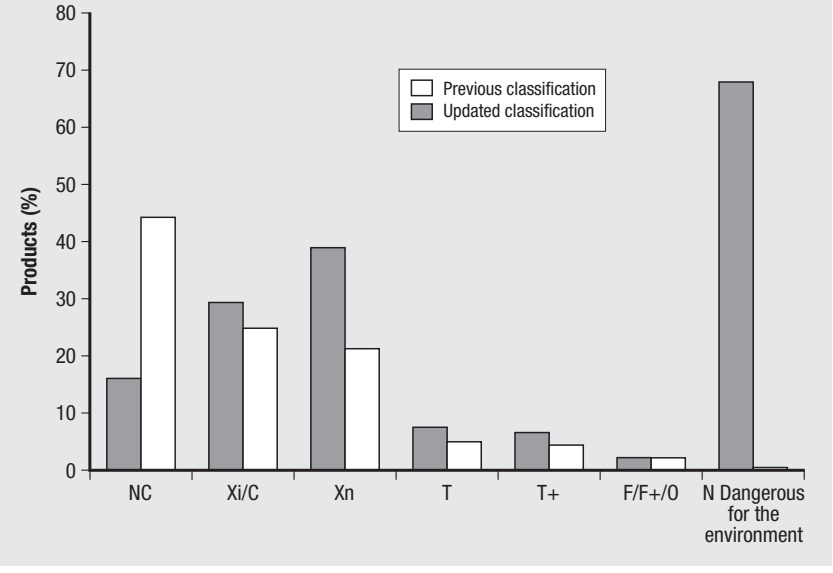

Fig. 2 | *Comparison between previous and updated classification.*
NC = Not Classified;
Xi/C = Irritant/Corrosive;
Xn = Harmful;
T = Toxic;
T+ = Very Toxic;
F/F+/O = Extremely Inflammable/ Highly Inflammable/Explosive when mixed with combustible material;
N = Dangerous for the environment.

porting biological and high-quality agriculture, and is applied to products labelled with: R62 (Risk of impaired fertility); R60 (May impair fertility); R50 (Very Toxic to aquatic organisms); R49 (May cause cancer by inhalation); R45 (May cause cancer); R40 (Limited evidence of a carcinogenic effect); R33 (Danger of cumulative effects); R28 (Very toxic if swallowed); R27 (Very toxic in contact with skin); R26 (Very toxic by inhalation); R25 (Toxic if swallowed); R24 (Toxic in contact with skin); R23 (Toxic by inhalation).

ADAPTATION TO TECHNICAL PROGRESS (ATP) FOR DIRECTIVE 67/548/EEC

Every time an update to the classification of dangerous substances is published, the norm also calls for regularization of the classification of substances which are contained in the Annex.

The 30th ATP (Directive of the Commission 2008/58/EC) contains numerous substances which show specific concentration limits for the environment most of them ppp classified as N R50-53.

Some plant protection substances have been classified as "Toxic Reproductive 2" with phrase T R61 (May cause harm to the unborn child), such as Dinocap, and will therefore be subject to the above mentioned limitations within national criteria. The 31th ATP (Directive of the Commission 2009/2/EC) [19] contains new scientific data used to establish the classification for the Nichel compounds.

SECOND ATP FOR DIRECTIVE 99/45/EC

The 2nd ATP has been acknowledged on March 2007 *(Directive of the Commission 2006/8/EC)* [20] *and implemented by Ministerial Decree 3/4/2007* [21] and contained several changes such as:

- definition of criteria of application of environmental SCL for N R50-53 substances having LC50 less than 1 mg/l not yet included in Annex I of Directive 67/548/EEC;
- application of symbol "N" to phrase R59 (Dangerous for the ozone layer);
- special indications for some types of preparations (such as some Safety "S" phrases for aerosols);
- identification of a 1% limit of concentration for phrase R33 (Cumulative effects);
- some specific phrases for preparations containing lead, cyanoacrylates, isocyanides, chlorine, epoxy constituents and chromium.

Following the implementation of the Directive 2006/8/EC (2nd ATP of the Directive 99/45/EC) a national Decree by Italian Ministry of Health has been published. After that, a further revision of the labels of ppps was necessary, in order to introduce the new criteria, mostly related to environmental highly toxic substances.

These new criteria concerned mainly the following aspects:

- preparations composed of more than one substance being classified in Annex I to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labeling of dangerous substances as carcinogenic, mutagenic and/or toxic for reproduction must currently be labelled with risk phrases (R-phrases) to indicate both category 1 or 2 and category 3 classification. However, providing both R-phrases sends a conflicting message. Preparations should therefore only be classified and labelled with the higher category;
- for substances very toxic to the aquatic environment (classified as N) and assigned the R-phrases R50 or R50-53, specific concentration limits (SCLs) were currently applied to substances listed in Annex I to Directive 67/548/EEC in order to avoid an underestimation of the hazard. This measure created distortions between preparations containing substances listed in Annex I to Directive 67/548/EEC, to which SCLs are applied, and those preparations containing substances not yet included in Annex I, but classified and labelled provisionally in accordance with Article 6 of Directive 67/548/EEC and to which no SCLs are applicable. It was therefore necessary to ensure that SCLs are applied in the same way to all preparations containing substances very toxic to the aquatic environment;
- the necessity of applying the symbol N to those preparations classified as R59 "Dangerous for the ozone layer".

In order to revise the labels of all the preparation on the national market containing at least one substance classified as very toxic for the aquatic compartment (R50 or R50-53) or dangerous for the ozone layer (R59), a new classification proposal have been asked to manufacturers, for all preparations fitting the above mentioned new criteria and obviously not yet classified as R50-53.

Two different lists have been presented by the manufacturers, one containing products to be newly classified because fitting the new criteria introduced by Directive 2006/8/EC, and one list containing products excluded by these criteria, even containing at least one substance classified as R50 or R50-53.

Obviously, preparations tested for aquatic compartment with negative results for all three target species (fish, daphnia, algae) were not taken into consideration. Within September 2007, a new classification proposal has been presented by the manufacturer and evaluated by Istituto Superiore di Sanità within February 2008. An official approval granted by Ministry of Health has been released by the end of March 2008.

SOME CONSIDERATIONS

Plant protection products included in the list to be revised were approximately 700, related to about 120 manufacturers. For those products containing substances not included in the Annex I of the Directive 67/548/EEC (about 140), a provisional classification has been made on the basis of the test results reported on safety data sheets or found in open literature. Among these, 65 out of 140 showed an LC/EC

50 value below 0.1 mg/l in at least one of the three target organisms. Most of the classification has been made through conventional method (calculation), while for some big Enterprises, test on formulations have been provided and consequently evaluated. 450 out of 700 products resulted in a more severe environmental classification respect to the one attributed following the application of the first Directive 99/45/EC.

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