

## **DRAFT EXPLANATORY MEMORANDUM**

### **Suggested text for a Directive on measures for reduction of use and impacts on health and environment from pesticides**

#### **1. JUSTIFICATION FOR THE PROPOSAL**

##### **1.1 Introduction**

According to the draft Commission Communication on the Sixth Environmental Action Programme, there is sufficient evidence to suggest that the scale and trends of problems caused by pesticides are serious and growing. Particular concerns include the contamination of groundwater and foodstuff, and the continuing accumulation of certain pesticides in plants and animals.<sup>1</sup> The effects of small quantities of pollutants that accumulate in human bodies are also poorly understood. There is consequently a need to protect vulnerable groups such as children and the elderly.<sup>2</sup>

Therefore, in order to guarantee a high level of protection and improvement of the quality of the environment (art 2 EC), environmental and human health-related problems linked to the use of pesticides must be addressed.

The Community has already adopted a number of legislative acts aimed at controlling adverse impacts from the use of pesticides, including Directive 91/414/EEC concerning the placing of plant protection products on the market (Directive 91/414) and Directive 98/8/EC concerning the placing of biocidal products on the market (Biocides Directive). These framework laws set in place harmonised systems for testing, evaluation and authorisation of pesticides for agriculture and other uses.

But the reviews of active ingredients being carried out under these two Directives are delayed. A five-year extension of the period for evaluation of the remaining substances under Directive 91/414/EEC is foreseen, so that completion is not expected before 2008. In the meantime, pesticide products of serious concern remain on the market. Even after the reviews of active ingredients have been completed, the intensive use of authorised products may undermine the benefits of Directive 91/414 for the environment and for humans' and animals' health.

Moreover, experience shows that the controls set in place by these acts are not sufficient to prevent contamination of water, air, and soil by pesticides. In fact, the use of pesticides in Europe is increasing, and represents a serious source of environmental pollution, with subsequent effects on biodiversity and phytotoxicity. In the meantime, pesticide contamination of foodstuffs poses risks to human health for both consumers and workers.

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<sup>1</sup> *Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions on the sixth environment action programme of the European Community 'Environment 2010: Our future, Our choice', Section 5.5 on pesticides.*

<sup>2</sup> *Id.*, Section 5.1 on environment and health issues.

The attached suggested text for a Directive would set in place measures aimed at achieving more sustainable practices with respect to pest control, including reductions in the use of pesticides. Such a Directive was already foreseen in the Fifth Environmental Action Programme (5<sup>th</sup> EAP), covering the period 1993 to 2000, which called for the EU to achieve a substantial reduction of pesticide use per unit of land under protection before the year 2000. The 5<sup>th</sup> EAP also called for the conversion of farmers to methods of integrated pest control, at least in all areas of importance for nature conservation, and it listed three actions for meeting the targets it had set; (i) registration of sales and use of PPS; (ii) control on sales and use of PPPs; and (iii) promotion of 'integrated control' (in particular training activities).

The draft Sixth Environmental Action Programme (6<sup>th</sup> EAP)<sup>3</sup> also recognises the need for Community-level action to address pesticide-related problems. The Common Position on a Decision laying down the Community Environmental Action Programme 2001-2010 calls for action to "reduc[e] the impacts of pesticides on human health and the environment and more generally to achieve a more sustainable use of pesticides as well as a significant overall reduction in risks and of the use of pesticides consistent with the necessary crop protection."

This suggested Directive would contribute to a high level of protection of human health and the environment and promote sustainability by laying down measures for a reduction of dependency on and, wherever possible, elimination of, the use of pesticides.

## 1.2 The Present Situation and Impacts on Health and Environment

### 1.2.1. Trends in sales and uses

According to Eurostat<sup>4</sup>, annual pesticides<sup>5</sup> sales have increased in EU countries, between 1992 and 1998, from 295,173 tons of active ingredients up to 322,315 tonnes and from 3.36 kg of active ingredients per hectare of agricultural area (arable crops + permanent crops) up to 3.88 kilogrammes. Sales are here used as a proxy for consumption and are assumed to equal the use on farmland.

Coverage of data may vary from one country to another and a number of factors such as weather conditions, seasonal factors, prices of pesticides, land set aside, may affect figures from one year to another. Nevertheless, from 1992 up to 1995, a slight decrease in consumption (up to 283,774 tonnes of active ingredients and 328 kilogrammes of active ingredients per hectare of agricultural area) can be observed. This may be partly explained as a response to changes introduced from 1992 to Common Agricultural Policy but also as a result of the increased use of new low dose pesticides and of specific policies developed for example in the Netherlands, Denmark and Sweden aimed at decreasing pesticide use. But, since 1996, there has been a general increase in the use of pesticides (expressed both in tonnes of active ingredients and in kilogrammes of active ingredients per hectare of agricultural area) in most EU countries. EU countries implementing an integrated pesticide use reduction programme show a decrease in use or only a very slight increase in pesticide consumption. This increase in pesticide consumption happens despite a clear trend in arable farming towards active ingredients which are effective at lower dosage rates (grammes instead of kilogrammes) than former standard products. However the effect on total pesticide

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<sup>3</sup> The decision-making procedure leading to its entry into force, is not over yet: the Programme is currently awaiting the European Parliaments' second reading.

<sup>4</sup> Eurostat/new Cronos, January 2002

<sup>5</sup> Pesticides refer to herbicides, fungicides, insecticides and other pesticides. Insecticides include nematocides, acaricides and molluscicides. Fungicides include bactericides and seed treatments. Herbicides include defoliant and dessicants. The "other pesticides" category covers a wide range of products such as growth regulators, soil desinfectants, rodenticides and varies from one country to another.

consumption of the increased use of low dose pesticides can, but only partly, be counterbalanced by a slight increase in the use of sulphur and copper products. These high dose pesticides, mainly used as fungicides, are key products in integrated crop protection, for disease control in vineyards, orchards, and on farms dedicated to organic farming practices.

The quantity of pesticides consumed does not necessarily reflect the risk presented by using pesticides. The real risks depend on factors such as type of product, toxicity, persistence, climate and soils conditions, water solubility, type of cultivation and application practices, and resulting exposure. New active substances can be applied far less copiously without necessarily resulting in a corresponding reduction of risk for health and environment. High dose pesticides are not necessarily likely to lead to an increase in these risks.

Ideally, a proper pesticide risk indicator would take into account all the above mentioned parameters. However, this would involve complex and contentious calculations. Data availability and the lack of a consensus on a calculation methodology do not yet allow the calculation of a "scientifically sound" pesticide risk indicator.

From Eurostat consumption data, it appears that there is a trend towards an increased dependency on pesticide products and hence an increase in exposure to pesticides, their "inert ingredients" and metabolites.

In order to avoid any likely further increase in the risk to health and environment from rising exposure to pesticides acting separately or in interaction, precautionary measures for pesticide use/dependency reduction must be implemented without further delay.

## 1.2.2. Residues in environment and food

### 1.2.2.1. Trends in water, soil and air contamination

According to a study on environmental trends released by the European Environment Agency (EEA) in 1995<sup>6</sup>, pesticides levels in groundwater are increasing and are estimated to exceed the target (maximum 0,5 µg/l for total amount of pesticides) in 75% (of EU/EFTA) agricultural land. Since the majority of Europeans (65%) rely on groundwater for their drinking water, this trend is of great concern. The EEA report states unequivocally that current EU policies are not sufficient to tackle a number of key issues, including pesticide pollution of groundwater.

According to a June 1998 EEA report<sup>7</sup>, "many pesticides are not found in groundwater, simply because they are not looked for. Once a pesticide is looked for, it is often found although the concentration may be below 0, 1 µg/l". Furthermore, recently released monitoring data<sup>8</sup> from 1997 and 1998 shows that one-third of waters used in France as sources for drinking water (surface and groundwater) contain pesticide levels high enough to require special treatment to remove the chemicals.

A survey carried out in 2001 by EUREAU, an organisation that represents the water industry associations across Europe, of the sources of drinking water shows that a number of EU member states have relatively high levels of pesticide residues.<sup>9</sup> Since as little as 100

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<sup>6</sup> Environment in the EU: Environmental trends, EEA, <http://org.eea.eu.int/documents/3-yearly/env95/en/env954en.htm>

<sup>7</sup> Europe's Environment: The Second Assessment, EEA, 1998

<sup>8</sup> France records high pesticide level in water, Ends Daily 28/08/00; see also French environment ministry at: <http://www.environnement.gouv.fr> or French Environment Institute at: <http://www.ifen.fr>

<sup>9</sup> Keeping raw drinking water resources safe from pesticides, EUREAU Position Paper, EU1-01-A56, 2001, <http://www.water.org.uk>.

grammes of some pesticides can contaminate up to one billion litres of water, pesticide removal is an expensive process right across the EU. For example, over the last ten years the UK water industry has spent £1 billion in capital expenditure. Moreover, the running costs to eliminate pesticides from water sources were about £ 100 million per year. This is not sustainable over the long-term as pesticide removal is an energy and resource intensive process. To protect human health, the EU has set a limit of 0.1µg/l (parts per billion) as the allowable residue of any single pesticide in drinking water.

The EUREAU report confirms that pesticide contamination is particularly acute in the UK, Belgium, France and the Netherlands. In all these countries a high proportion of the raw drinking water resources are contaminated with pesticide residue levels that regularly exceed the drinking water limit of 0.1 µg/l (parts per billion), often by a significant margin. In the most affected countries of Belgium, Denmark, France, Germany, Netherlands and UK between 5-10% of resources regularly contain pesticides in excess of 0.1 µg/l.

For the UK, the report cites a survey covering a water supply population of nearly 16 million people where 77% of raw surface water (from rivers and lakes) is contaminated with pesticides above the 0.1 µg/l limit. In some areas there is growing concern about the threat to future contamination of groundwater sources, as pesticide residues from historic use and current use pass through overlying rocks to the aquifer. The report cites a system for ranking those substances that most regularly cause problems. For groundwater the chemicals are – atrazine (and related products), bentazone, mecoprop, simazine; and for rivers – atrazine (and related products), chlortoluron, diuron, glyphosate (AMPA), isoproturon, MCPA and mecoprop.

Pesticides have also been found in European rainwater. Approximately half of the compounds analysed were detected. For those detected, most concentrations were below 100 ng/l, but larger concentrations, up to a few thousand nanograms per litre, were detected at most monitoring sites. The most frequently detected compounds were lindane (gamma-HCH) and its related isomer (alpha-HCH), which were detected on 90-100% of sampling occasions at most of the sites where they were monitored. In total, 44 pesticide active ingredients have been found in European rainwater from 1990 onwards. They include: alachlor, atrazine, carbaryl, 2,4-D, diazinon, isoproturon, MCPA, mecoprop, and simazine.<sup>10</sup>

Soil contamination may also result from the use of pesticides. They may accumulate and persist in soil to form products that are harmful to the soil. They can also have undesirable effects – such as killing non-target species or causing water pollution.

In the UK a government investigation<sup>11</sup> into the sustainable use of soil concluded: ‘The effects of pesticides on soil organisms may have implications for soil quality’. And as a result re-enforced the view that pesticides should be used as sparingly as possible and in conjunction with other control measures, with due regard for nature conservation.

#### 1.2.2.2. Contamination of food

DG SANCO’s report on pesticide residue in food in 1999 suggests that residue safety breaches are getting worse, compared to previous studies.<sup>12</sup> The EC has analysed the testing carried out by 17 national monitoring programmes in the European Union countries, as well as Norway and Iceland, of melons, peppers, cauliflowers and wheat. While 64% of the

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<sup>10</sup> IG Dubus, JM Hollis and CD Brown, Pesticides in rainfall in Europe, Environmental Pollution, Vol,110, 331-344, 2000.

<sup>11</sup> Royal Commission on Environmental Pollution, Sustainable Use of Soil, London, 1996.

<sup>12</sup> *Monitoring of pesticide residues in products of plant origin in the European Union, Norway and Iceland*, European Commission, SANCO/397/01, June 2001.

samples contained no detectable residues, nearly one-third (32%) of the food consumed is contaminated. Of this, 4.3% exceeds the approved maximum residue level (MRL). Of particular concern were the levels of residues of endosulfan and methamidophos in peppers and melons.

The EU report highlights the low level of residue testing for fruit and vegetables in the UK. Compared with 17 other European countries, the UK ranks 11th for number of samples taken and the lowest per capita: only 0.231 per 10 000 capita, compared with 3.44 samples per 10 000 capita in Sweden. However, UK samples in the monitoring programme showed 2.9% of the residues analysed as above the MRL, whereas 30% of samples in the Netherlands were above the MRL, 24% in Finland and 10% in Spain.

The report analysed data from each member state in order to identify which residues occurred most frequently. The organophosphate (OP) chlorpyrifos figured in 12 countries including the UK. Another frequently detected pesticide in the UK was DDT, despite having been banned for use there since 1984. The testing revealed that 14% of the samples contained residues of more than one pesticide, and in 2.2% residues of four or more pesticides were detected. In Finland 29% of samples contain multiple residues, and in France, one sample contained eight or more pesticide residues.

Because most residue limits are set on the adult bodyweight, children can consume a disproportionate level of pesticide residues. At the residue levels found across Europe, a toddler would consume 181% of the health-based acceptable daily level of endosulfan in peppers, over six times (681%) of the acceptable level of methamidophos. As a precautionary measure, the EC has greatly lowered the MRL for methamidophos on peppers. Both these pesticides are known to cause problems, particularly in developing countries. Many people died in Benin recently as a result of exposure to the pesticide endosulfan, and methamidophos is an OP nerve poison that can adversely affect those applying the insecticide.

DG SANCO latest report<sup>13</sup> on pesticide residues in food in 2000 confirms the worsening of the situation. Compared to previous years the percentage of fruit, vegetable and cereal samples with no detectable residues has remained about the same level (60-61%). The percentage of samples exceeding MRLs (national or EC-MRLs), however, has increased over the years 1996 to 2000 from 3% in 1996 to 4,5% in 2000. The trend of decreasing percentages of samples with multiple residues in fresh fruit, vegetables and cereals which was shown from 1996 to 1998 was not continued in 1999 and 2000, where percentages of samples with multiple residues rose from 14% in 1999 to 15% in 2000. In particular, the percentage of samples with four or more residues was higher than in the years before (2,8% in 2000 compared to 2,0 - 2,3% in 1997-1999).

### 1.2.3. Impacts on health

Concerning poisoning of workers or workers' health, few independent studies on workers' health have been carried out at the European level. In the late 1990s, the European Federation of Agricultural (EFA) workers carried out a survey of pesticide poisoning among its two million members.<sup>14</sup> A total of 1,230 questionnaires from individuals and organisations were analysed. The results showed that at least one person in five considers that they have been made ill or poisoned, or adversely affected by pesticides.

The survey revealed that workers are poisoned at different times during their work. Problems of usage represent 73% of incidents, in particular: handling of concentrates (6%); application

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<sup>13</sup> Monitoring of Pesticide Residues in Products of Plant Origin in the European Union, Norway, Iceland and Liechtenstein, 2000 Report, SANCO/687/02 final, April 2002.

<sup>14</sup> Health and safety concerns from European survey of operators, *Pesticides News*, No. 36, June 1997.

(39%); preparation and mixing (28%). Nevertheless the proportion of incidents arising after pesticide treatment is noticeable: washing after use (12%), operations involving contaminated equipment (7%) or containers after use (2%), working in areas previously treated (6%) making a total of 27%.

Among those poisoned, 53% informed their employer, but only 27% informed the competent authority. In 46% of cases, poisoning involved medical intervention, either a consultation or visit to a hospital. Symptoms most often reported by pesticide users included: headaches (67%); skin irritation (39%); stomach pains (33%); vomiting (30%); eye irritation (25%); diarrhoea (15%) [some reported more than one symptom]. Other symptoms occurred in 10% of cases: notably symptoms linked with the nervous systems such as fatigue, difficulty in concentration, difficulty in muscle control and co-ordination of movement; and the respiratory system.

*[section on chronic effects due to exposure via contaminated water and foods, to come]*

#### 1.2.4. Effect on biodiversity

Pesticides are known to have adverse impacts on a wide range of non-target organisms including birds, fish, and beneficial insects. For example, in-field biodiversity has been reduced by the use of herbicides for weed control, which some researchers claim has contributed to recent falls in the numbers of some bird species. A 1997 report<sup>15</sup> cited pesticide use as a major factor in the decline of many bird species over the last 30 years or so. The main examples were: tree sparrows (-89%), turtle doves (-77%), bullfinches (-76%), song-thrushes (-73%), lapwings (-62%), reed buntings (-61%), skylarks (-58%), linnets (-52%), swallows (-43%), blackbirds (-42%), starlings (-23%).

Several investigations in Germany verify that areas close to organic farms are characterised by a greater biodiversity than areas close to conventional farms. The variability of organisms can be up to 6 times higher in land in organic farming as compared to land in conventional agriculture.<sup>16</sup> One investigation found that species listed on the IUCN Red List of Threatened Species could be found in 79% of the agricultural areas sampled where organic farming had been applied for at least 25 years, whereas Red List species could be found on only 29% of land in conventional agriculture.<sup>17</sup> In a two-year study in Austrian soils<sup>18</sup>, beetles were 94% more abundant in organic fields than in the conventional ones. The number of beetle species was 16% higher.

Of the more than 130 different plants found naturally around Germany's agricultural land, half are currently considered endangered, and some have already disappeared.<sup>19</sup> Another

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<sup>15</sup> Campbell, L.H. and A.S. Cooke. The indirect effects of pesticides on birds, Joint Nature Conservation Committee, Peterborough, UK (1997).

<sup>16</sup> Frieben, B. & U. Köpke. Effects of farming systems on biodiversity, in: Isart, J. & J. J. Llerena (eds.): Biodiversity and Land Use: The Role of Organic Farming (1997). Proceedings of the first ENOF-Workshop, Bonn, 11-21; Van Elsen, Th: 1994: Die Fluktuation von Ackerwildkraut-Gesellschaften und ihre Beeinflussung durch Fruchtfolge und Bodenbearbeitungszeitpunkt. Diss. agr. Universität Gesamthochschule Kassel, 415 S.

<sup>17</sup> Frieben, B. 1990: Bedeutung des Organischen Landbaus für den Erhalt von Ackerwildkräutern (Relevance of the organic farming for the preservation of wild herbs organisms). Natur und Landschaft (65), Heft 7/8, 379-382.

<sup>18</sup> Cited in Commission Communication Towards a Thematic Strategy for Soil Protection 16-04-02, COM/2002/179 final

<sup>19</sup> MURL (Ministerium für Umwelt, Raumordnung und Landwirtschaft des Landes Nordrhein-Westfalen) 1988: Schutzprogramm für Ackerwildkräuter (protection programme for wild herbs on agricultural fields). 2. Fassung. Umweltschutz und Landwirtschaft. Schriftenreihe des Ministeriums für Umwelt, Raumordnung und Landwirtschaft Nordrhein-Westfalen, Heft 3.

German study calculated the cost of the loss of biodiversity in Germany through the use of pesticides at 10 million DM (~5 mil Euros) per year.<sup>20</sup>

The inappropriate use of pesticides, and in particular nematicides, can have very negative effects on soil biodiversity because of their poor selectivity. Some studies suggest that some herbicides considerably suppress soil bacteria and fungi activity<sup>21</sup>

Danish studies also stress the negative effects of pesticides on biodiversity. According to the Bichel Report, the effects of pesticide use on above-ground arthropods are significant, and a larger insect population could be expected in the event of a phase-out of pesticide use.<sup>22</sup> According to a 2002 report<sup>23</sup>, half and quarter dosages of herbicides and insecticides improve the "natural elements" of the fields with an increased number of weed species, increased proportion of flowering species and increased abundance of insects. Use of half the dose only creates negligible, if any, agricultural problems, especially if supplementary control of particular weed patches is carried out.

#### 1.2.5. Pest resistance

Most weed and insect pests have short life cycles, a wide geographic range, and large populations. Consequently, there is substantial genetic diversity found in pest populations. When these populations are all sprayed with the same toxic chemical, a few individuals are not killed because they are genetically resistant. These individuals survive to reproduce, quickly resulting in localized resistant populations which then spread.

Consequently, higher and higher doses are needed to kill pests and finally new chemicals must be developed. Then the cycle begins again, resulting in increased costs, increased amounts of chemical use and the ever-decreasing effectiveness of products.

Resistance has been reported in about 500 species of insects and mites, 100 species of plant pathogens, 50 species of weeds, 5 species of rodents and 2 species of nematodes.<sup>24</sup>

#### 1.2.6. Phytotoxicity

Many herbicides on the market will kill a wide range of crops and weeds alike. Herbicides are classed as 'selective' when they are used to kill weeds without harming the crop and as 'non selective' when the purpose is to kill all vegetation. Most of the urea herbicides are relatively non-selective. They include monuron, diuron and linuron, and are usually applied to the soil as herbicides that exert their effects prior to the emergence of the crop plant. There is thus a widespread potential for non-target plants species to be affected by herbicide applications.

### 1.3 Member State Experience with Pesticide Use Reduction programmes

A number of Member States have had pesticide use reduction programmes for more than a decade, e.g., Sweden since 1986, and Denmark since 1987. Several other European countries have followed their example (Norway 1991, Netherlands 1991, Finland 1993).

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<sup>20</sup>Waibel, H. Experience with Cost Benefit Studies of Pesticides in Germany.

<sup>21</sup>Ibid 18

<sup>22</sup>The Bichel Committee. Report from the main committee to assess the overall consequences of phasing out the use of pesticides, 1999.

<sup>23</sup>Esjberg, Peter and Petersen Bo Svenning, Effects of reduced pesticide use on flora and fauna in the agricultural fields, Pesticides research 58, 2002, Danish Environmental Protection Agency.

<sup>24</sup><http://www.cas.psu.edu/docs/casdept/ipm/history1.html>.

The three best-known programmes in Europe can point to concrete reductions in use of pesticides: Sweden achieved a 64% reduction in volume of active ingredients<sup>25</sup> from the reference period 1981-1985 until 1995, Denmark a reduction of 59% in volume of active ingredients and 25% reduction in application frequency between the reference period 1981-1985 and 2000, and Netherlands a reduction of 50 % volume between the reference period 1984 -1988 and 2000 .

Each country is quite different; e.g., Sweden is oriented more towards its forests than its agriculture, while the Netherlands is the third largest agricultural exporter in the world. However, the primary motivations for implementing pesticide use reduction programmes were similar for all three countries: concerns about adverse effects on the ecology as well as about contamination of water resources used for human consumption.

The success of the programmes is strongly linked to the targets set and measures taken, with experience showing that pesticide use reduction is more successful when higher and clearer goals are set.

Measures might differ depending on the situation of each Member State. For example, in one country it might be possible to extend farmer-information through computer-programmes and Internet, in others it is easier to reach people by personal contact. Some instruments are common to all three countries' programmes, e.g. mandatory training for professional sprayers in the correct use of pesticides and in alternative pest control. The possibility to use voluntary measures to achieve a reduction in use is easier in countries like Sweden where such programmes are widely supported by farmers.

An important measure used by Denmark is to create buffer zone areas to protect wet natural areas (targeted water courses and ponds/lakes over 100 m<sup>2</sup>). Bans on application of pesticide use in vulnerable zones, e.g., to protect water, are important in all three countries, but enforcement is not sufficient. Financial instruments such as taxes and levies on pesticide use have proved to be especially effective as well as financial support for ICM and organic farming practices.

#### **1.4 Current EU actions to control impacts from pesticides**

A number of Community measures to control impacts from pesticides have already been taken. The first legislation on the placing on the market and use of plant protection products was Directive 79/117/EEC (21 December 1978, OJ 1979 L 33), containing a 'negative ' list of active substances and banning or severely restricting the marketing and use of products based on these substances. It was not until 1991 that harmonised measures for the marketing and use of agricultural pesticides were set in place, through Directive 91/414/EEC). Measures for the marketing and use of non-agricultural pesticides were established in 1998 with the Biocides Directive (98/8/EC).

The classification, labelling and packaging of pesticide products has been regulated since the 1960s, through several subsequent directives.<sup>26</sup> These aspects are now covered by Directive 1999/45/EC on the classification, labelling and packaging of dangerous preparations.<sup>27</sup>

Residues in foodstuffs have been regulated since the 1970s in directives for selected fruits and vegetables (76/895/EEC, OJ 1976 L 340/26), cereals and cereal products (86/362/EEC, 24 July 1986, OJ 1986 L 221/36)), foodstuffs of animal origin (86/363/EEC, 24 July 1986, OJ

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<sup>25</sup> Calculated in total sale of pesticide active ingredients.

<sup>26</sup> Directive 67/548/EEC on classification, labeling and packaging of dangerous substances, as amended.

<sup>27</sup> 31 May 1999, OJ 1999 L 200/1.

1986 L 221/43) and products of plant origin, including fruits and vegetables (90/642/EEC, 27 November 1990, OJ 1990 L 350/71)). In the 1990s, special levels appeared to be necessary and have been set for baby food (Commission Directives 1999/39/EC, 6 May 1999, OJ L 124/8 and 1999/50/EC, 25 May 1999, OJ 1999 L 139/29).

Regulatory activities to protect the environment against pesticides have, to date, mainly focused on water. For example, discharges of certain dangerous substances were regulated to protect the aquatic environment and groundwater. The Framework Directive on Water (2000/60/EC, 23 October 2000, OJ 2000 L 327/1) now replaces these directives. For water intended for human consumption, concentration standards have been set for groundwater, where Directive 98/83/EC (3 November 1998, OJ L 330/32) replaces directive 80/778/EEC (15 July 1980, OJ 1980 L 229/11), and for surface water, where Directive 75/440 (16 June 1975, OJ 1975 L 194/26) only very basically gives standards for some three active substances for pesticides.

Several community measures with a wider scope also cover aspects of pesticide marketing and/or use, such as Directive 76/769/EC (27 July 1976, OJ 1976 L 262/201) giving restrictions on marketing and use of certain dangerous substances and preparations, Directive 90/220/EEC (23 April 1990, OJ 1990 L 117/15) on the deliberate release into the environment of genetically modified organisms, and Regulation (EEC) 3093/94 (15 December 1994, OJ 1994 L 333/1) on ozone-depleting substances, which covers the phasing-out of the active substance methylbromide.

Several aspects of the agricultural use of pesticide products have been regulated through agri-environmental measures, such as Regulation (EEC) 2078/92 (30 June 1992, OJ 1992 L 215/85) on agricultural production methods compatible with the requirements of the protection of the environment and the maintenance of the countryside.

*[paragraph on the Rural Development Regulation to come]*

In the early 1990s, the European Commission, together with the Dutch Ministry of Environment (VROM), carried out a multi-year project entitled “*Possibilities for future EC environmental policy on plant protection products*”. Two studies were carried out in Phase 1 of the project, and another six studies in Phase 2.<sup>28</sup> In May 1998, at the end of this multi-year research effort, the Commission and VROM presented the research findings at a Stakeholders’ Conference. The conference reached a broad consensus that additional EU level measures to control pesticides were needed, but agreement could be reached only on minimal specific measures.

Following the 1998 conference, a Commission Communication on Sustainable Use of Pesticides was drafted. This Communication was delayed, and its release is now anticipated sometime in mid-2002.

The 6<sup>th</sup> Environmental Action Programme promises, in addition, a Thematic Strategy on the sustainable use of pesticides no later than 2007. The Thematic Strategy should include a proposal for Community legislation.

## **1.5 The need for a specific directive on sustainable use**

Despite the above-mentioned EC measures, the current use of pesticides in the beginning of the 21st century is still a serious source of environmental pollution. Moreover, as scientific and technical knowledge develops, threats to public health as a result of pesticide use seem to be growing, for example because of the combined effects and of aggregate exposure to

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<sup>28</sup> The studies are available on the DG Environment website.

pesticides used. Therefore a more stringent prevention approach is needed. This requires a more sustainable use of pesticide products. Elements of such an approach can be seen in some of the above-mentioned measures. However, on the whole the measures do not focus on prevention and sustainable use. A directive specifically focussing on this preventative approach is therefore needed, as the 1998 Stakeholders Conference recognised.

This suggested directive, in contrast to many of the earlier measures, will regulate the largest source of pesticide pollution – the use stage. This stage is not yet covered by Community legislation.

## **1.6 The Objectives of the Proposed Directive**

The objective of the proposed Directive is, as a first priority, to contribute to a high level of protection of human health and the environment. It also aims to promote sustainability, through reduction and, wherever possible, elimination of the use of synthetic pesticides

## **2. CHOICE OF LEGAL BASE**

The aim of this directive primarily regards the protection of the environment and public health against adverse effects of pesticide use. The proposed measures relate to the sustainable use of pesticides in agricultural applications, as well as in non-agricultural applications, except in household use. The measures do not aim at attaining the objectives of the Common Agricultural Policy. The production and marketing of agricultural and non-agricultural pesticides in these fields are not the main objectives of this directive. The principal goal is the protection of the environment by stimulating a sustainable use of pesticide products. A more sustainable use will contribute to this goal by causing less residues in the environment and in agricultural products. The appropriate legal basis for this directive therefore is article 174 of the Treaty.

## **3. SUBSIDIARITY AND PROPORTIONALITY**

### **3.1 Objectives of the proposed action in relation to the obligations of the Community**

The measures pursuant to Directive 91/414/EC were set in place with a view to ensuring a high standard of protection. In particular, the Directive was aimed at preventing authorization of plant protection products where risks to health, groundwater and the environment and human and animal health outweighed the objective of improving plant production. The application of the prevention principle in the field of plant protection products and agriculture was also applied in the Uniform Principles (annex VI of Directive 91/414/EEC). For example, Uniform Principle C.1.3 (p. 102) requires Member States to ensure that authorized amounts are the minimum necessary to achieve a desired effect, even where higher amounts would not result in unacceptable risks to human or animal health or to the environment. The prevention principle is also applied in Part C, point 2.5.1.2., stating that an active ingredient cannot be authorised if its concentration in groundwater would exceed 0,1 µg/l.

Measures to reduce pesticide use, wherever possible, also follow from the prevention principle of Art. 174 (2) which the Community is obliged to apply in its environmental policy.

### **3.2. The Community dimension of the problem**

The harmonization of pesticide authorization practices through Directive 91/414/EEC is not sufficient for sustainable crop protection in the EU. This type of legislation may ensure a

process by which pesticide risks are reduced, but it is likely to have only limited effect on the quantity of pesticides applied. Moreover, the length of time for implementation of Directive 91/414/EEC is of serious concern, in that it is now proposed to move forward the original target date for completion of the process of reviewing all active ingredients, from 2003 to 2008.

The pesticide risk assessment procedures under Directive 91/414/EEC are insufficient for guaranteeing adequate protection of human health and the environment. Scientific studies on pesticide fate and behaviour show essential gaps in knowledge, *inter alia* dispersal of pesticides through air, effects of combined exposure, effects of chronic exposure to low concentration, and effects on vulnerable groups including foetuses, infants and children.

There is concern that over the long term, crop protection that relies heavily on pesticides may not be sustainable, even when pesticides have been assessed as having lower environmental risks. With the reduced number of pesticides that will be available because of stricter standards, build-up of pest resistance could be exacerbated.

These problems cannot be solved at the national level because the use in one country can cause environmental effects in another country (air and water pollution) and because agricultural products treated with pesticides are marketed in other Member States. Actions by single Member States could cause distortions of the market. An EU policy promotes fair competition between farmers. Moreover, certain policy instruments, e.g. financial instruments, can be implemented most effectively at the EU level. These elements make it clear that the proposed action can be achieved better on Community scale and is in line with the principle of subsidiarity.

A Community approach is therefore necessary to bring all Member States towards a more sustainable use. This has already been recognised in the Fifth Environmental Action Programme 1992-2002. The proposed Sixth Environmental Action Programme 2002-2010 confirms the importance of aiming at a more sustainable use of pesticides at EU level.

### **3.3. Subsidiarity**

Preventative measures for the use of pesticides cannot be sufficiently achieved by the Member States. Because of transnational aspects, such as cross-border health and environmental effects, for example by import and export of products treated with pesticides and by transboundary water pollution, measures by Member States will be less effective than concerted action. Therefore, Community measures will satisfy the subsidiarity principle. Because measures at Member State level could contribute to trade restrictions, the measures at Community level will also be beneficiary from an economic point of view. A minimum level of sustainable use requirements, throughout the Community, will be more effectively achieved by Community legislation.

### 3.4. Costs

The European Environment Agency estimates that European agriculture's negative externalities are substantial. Externalities are technically defined as the costs or benefits from production (or consumption) experienced by people other than the producers (or consumers). Modern agriculture has been hugely successful at increasing output, yet it has done so by depleting both natural capital (nature's goods and services) and social capital (the social cohesion, trust, and connectedness) in rural areas. Externalities have been calculated for the transport sector and they are massive—some 4% of Europe's GNP. But an equivalent figure for agriculture's total externalities has not yet been calculated. It may, indeed, be impossible, as it means putting a cost on damage to things like biodiversity and the aesthetic value of the countryside.

For those things that can be measured, the numbers are worrying. Gerd Fleisher and colleagues at the University of Hanover have estimated the minimum externalities of pesticides in Germany in excess of DM 250 million annually. The total is about 25% of the private costs to farmers of using pesticides. This is considered to be a minimum because there is much that the researchers have been unable yet to measure.

In the UK, the annual cost of cleaning up pesticide residues in drinking water alone is £121 million. Following £1 billion of investment by water companies, this puts the annual hidden subsidy to pesticide users who pollute at some £7.57 per kg of active ingredient, or £20-22 per hectare of arable land. Farmers spend £490 million on pesticides each year—so these external costs account for 25% of the private costs—already equal to the German figure even without accounting for other costs. Other studies in Denmark, Poland, Belgium, and Scotland confirm that the external costs of modern agriculture are high.

A tax on pesticide inputs (of possibly 25%) would help to cover these external costs. All such taxes would need to be hypothecated, i.e., the income raised would be best returned to agriculture as an incentive to those with more sustainable practices.

### 3.5. Proportionality

The measures chosen in this Directive do not go beyond what is necessary to achieve the objectives of the Directive concerning health and the protection of the environment. The Member States are empowered to introduce more stringent measures where they consider this necessary. Where possible, flexible provisions are encouraged to enable the Member States to apply the principle of proportionality.

## **4. RESULTS OF CONSULTATION WITH INTERESTED PARTIES**

At the May 1998 stakeholder meeting on possible strategies and policy instruments for an additional EU policy concerning plant protection products, organised by the European Commission and the Dutch Ministry of Environment (VROM), participants concluded that additional EU pesticide risk reduction policy instruments were needed.

## **5. DETAILED EXPLANATION OF THE PROPOSAL**

### **Article 1: Objective**

The Directive aims firstly at contributing to a high level of protection for human health and the environment throughout the whole EU territory from impacts related to the use of

pesticides. It also aims to promote sustainable development by reducing dependency on and, wherever possible, eliminating the use of pesticides for pest control.

Because impacts from pesticides are linked to their release in the environment in the course of applications for pest control purposes, the Directive sets forth a number of mandatory measures to eliminate unsafe pesticide use practices, including minimum training requirements for pesticide dealers and pesticide operators. It also sets EU wide targets for reducing frequency of applications of pesticides, including *inter alia* by requiring the mandatory application of integrated pest management (IPM) in all pest control situations and of integrated crop management (ICM) in the cultivation of all agricultural crops throughout the EU territory.

## **Article 2: Scope**

Community legislation already covers the authorisation of pesticides for plant protection, requires measures for the protection of workers, and establishes quality standards for the ambient environment and for water and food destined for human consumption.

This Directive covers the missing link – the stage of pesticide use. It focuses on those pesticides currently authorised for use for plant protection purposes. It covers only professional handling and use of pesticides, e.g., applications for commercial purposes or by a public authority. It does not cover use of pesticides by the general public.

## **Article 3: Definitions**

A few of the definitions in this Proposal copy are inspired by definitions which already exist in Community legislation, in particular Directive 91/414/EEC on the authorisation of plant protection products. A number of other definitions have been inspired by Member State legislation, such as the definition of ‘frequency of application’ which is a concept used in the Danish pesticide use reduction programme’.

## **Article 4: Principles**

In order to achieve a high level of protection of human health and the environment from harmful impacts of pesticides, preventive measures are necessary. This proposal for a Directive therefore aims to reduce the use of pesticides. This is in accordance with the principles in the Treaty of prevention of pollution by reduction at the source, as well as the precautionary principle.

The ‘substitution principle’, though not specifically mentioned in this proposal for a Directive, is also a fundamental principle for control of harmful impacts from chemicals. Unfortunately, it is often used to refer only to the substitution of a harmful chemical by a less harmful chemical, whereas the first aim should be to substitute a non-chemical system, method or practice.

Therefore, to avoid confusion, the proposal is based on the ‘none, unless...’ principle. This principle, taken directly from the Dutch pesticide use reduction programme, means that pesticides are not to be used unless there is no other method, practice, or system available to prevent unreasonable pest damage.

## **Article 5: Designation of competent authority**

The Directive requires each Member State to establish which authority or authorities will have responsibility for implementing the various obligations and tasks in the Directive.

## Article 6: Mandatory pesticide use reduction target

Those Member States with pesticide use reduction programmes already in place have found pesticide use reduction targets to be important tools for focusing policies and for selecting implementing measures. The targets have typically been linked to specific indicators used for measuring progress.

We do not suggest use of **pesticide volume reduction targets**, since this has been widely criticised as an insufficient indicator of use reduction. This parameter can be influenced by a decrease in the farmed area, change in cropping patterns, yearly variation in pest problems, or changes in formulations. In most countries with pesticide reduction programmes, the reduction in the volume of pesticides used was greatly influenced by the rising use of low dose pesticides. Moreover, a simple reduction in volume does not necessarily equate to a reduction in risk because the lower dose chemicals are more biologically active and may pose an equal, or even greater, risk to the environment and health. Equally, growers can also switch to high volume products (e.g. used by organic growers) with a reduction of risk as a consequence. However, when used in conjunction with other indicators and targets, pesticide volume reduction targets have been useful.

Instead, the text suggests **targets based on frequency of application**. Frequency of application is a type of indicator for "environmental load". It is an expression of the average number of times an agricultural area can be treated with the prescribed dose, based on the quantities sold.<sup>29</sup> The advantage of this parameter as a measure of use reduction is that it excludes the effects of changing to pesticides that are effective at lower doses. Since a frequency of application parameter includes the effect of individual agents, it can express the intensity of spraying and the potential biological effect. Experience in Denmark has shown a good correlation between frequency of application and effects in the aquatic environment or population size of farmland birds. While the frequency of application may still be influenced by changes in cropping pattern, it is nevertheless considered to be the best indicator for pesticides load on the environment. In Denmark it has been estimated that the frequency of application can be reduced by nearly 40% in 5-10 years without economic losses to farmers and society.

Concerning the suggested baseline year, those Member States that set targets for their pesticide use reduction programmes also typically designed a year or time period before the programme was implemented as a baseline year, e.g. 1981-1985 for Denmark and Sweden, 1984-1988 for the Netherlands, and 1987-1991 for Finland. For the purposes of this Directive, the baseline year has been set in the future, i.e., one year after the Directive comes into effect. The reasons for this are two-fold. First, the process of reviewing active ingredients set in place under Directive 91/414/EEC is expected to eliminate a large number of pesticides currently on the market. This process is still under way, and will probably be extended until 2008. Second, as the Bichel Report documents for Denmark, even those countries with pesticide use reduction programmes in place for many years can achieve even further reductions.

Frequency of application is primarily a measurement of pesticide use. Because it may not necessarily reflect the relative toxicity of various pesticides, it is not suitable by itself for measuring the impact of pesticides on human health and the environment. The suggested text for a Directive recognises that frequency of application may need to be supplemented by additional indicators for monitoring risks to human health and the environment. Since the

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<sup>29</sup> Treatment frequency is calculated by dividing the volume sold for each particular product divided by the recommended dosage per hectare for a particular use. The results of these calculations for each pesticide and crop are then aggregated, and divided by the total number of hectares in cultivation.

development of indicators in these areas is already underway in international forums such as the OECD, this article directs the Commission and the Member States to continue working on additional tools for determining if the measures in this Directive achieve the aim of a high level of protection.

#### **Article 7: National pesticide use reduction programmes**

In recognition of the principle of subsidiarity, this article requires Member States to determine which combination of measures to achieve a reduction in pesticide use are most appropriate for its national situation. The first step is for each Member State to carry out a national study to provide a baseline of information concerning how pesticides are used at present. The national study should estimate the consequences of various use reduction targets, and include evaluations of the economic benefits (including reduction in hidden costs) as well as the costs of further pesticide use reductions, with one scenario being a total phasing out of the use of pesticides. Finally, it should recommend the national pesticide use reduction targets for specific crops and non-agricultural pest control situations that will enable the Member State to meet the mandatory reduction goals set in Article 6 and to achieve further use reductions over time. The specific elements to be covered in the national studies are set forth in more detail in Annex 1, Part A. The Bichel Report prepared for Denmark's pesticide use reduction programme could serve as a model for studies to be prepared by other Member States.

The article then foresees a process of balanced stakeholder consultation, in order to discuss the findings and recommendations of the scientific study, and to consider which measures should be taken nationally and locally to enable the Member State to meet the mandatory reduction goals of Article 6.

The national study and the stakeholder consultation are to provide the basis for a national pesticide use reduction programme. Article 7(3) stipulates a number of obligatory elements for such programmes, including qualitative and quantitative goals for specific reductions, the specific measures to be taken to achieve the established goals, and consideration of the financial resources that will be needed to implement the programme. The national programmes are also required to designate pesticide vulnerable zones where use of pesticides is banned or severely restricted, according to criteria to be proposed by the Commission using a regulatory committee procedure. Annex II lists some of the types of goals and measures that can be taken at national level to meet the mandatory use reduction targets.

The article also establishes a schedule for periodic review of the effectiveness of the pesticide use reduction programmes and for periodic improvement of the programmes themselves. Finally, the article requires Member States to submit their national programmes to the Commission, so that they can be communicated to the other Member States for information.

#### **Article 8: Mandatory requirements for use of pesticides**

Integrated pest management, or IPM, is the internationally recognised standard covering all pest control situations. Similarly, integrated crop management (ICM) is widely recognised throughout Europe as the standard that should be followed by all agricultural producers. This text therefore suggests that IPM should become the mandatory standard for all pest control situations, with ICM as the minimum mandatory standard for all cultivated land in non-organic agriculture in the EU territory.

In recognition of the varying conditions in the Member States and in accordance with the subsidiarity principle, the Directive obliges each Member State to define the ICM standards that are to apply nationally for each major crop or crop rotation. The standards are to be defined by independent expert bodies, and to take into account the elements set forth in Annex III of the suggested text.

It is suggested also that Member States report their IPM and ICM standards to the Commission, so that it can review the coherence of the standards in place across the Community. If large variances are found in the IPM and ICM standards set in place by the various Member States, the Commission may propose Community-wide ICM and IPM standards, using the regulatory committee procedure set forth in Article 19. This mechanism to allow for the need to bring national standards set under the subsidiarity principle to be brought into Community-wide coherence is also found in the Directive on integrated pollution prevention and control (IPPC).

In order to ensure the implementation and enforcement of IPM and ICM standards throughout the Community, the article requires Member States to set in place systems for supervising the application of the mandatory standards, including sanctions for violations. Member States are free to choose how such systems are to be organised. They could base such systems in the competent authorities designated under Article 5 or use other administrative structures already in place. The use of private systems is another possible option not excluded by this article.

As a final mechanism to support the Community-wide coherency of the obligation to apply IPM and ICM standards, the article requires the Commission to promote and to coordinate both national and Community-level research on ICM on crops of Community importance and on reduction of the use of pesticides.

#### **Article 9: Promotion of organic farming**

This article aims to promote further application of organic farming as a key method for reducing dependency on pesticides. It sets positive targets for the amount of cultivated land within the national territories to be farmed using organic farming methods.

Though Community and national programmes are already in place in most Member States to promote organic farming, these programmes are still under-funded. This article requires further financial support to be provided by Member States to support farmers in the process of conversion from conventional agriculture to organic farming. It also requires further financial support from both Member States and the Commission for additional research programmes to support development of organic farming techniques and better access to information about organic farming techniques, particularly through extension programmes.

#### **Article 10: Measures to eliminate unsafe pesticide practices**

This article aims to eliminate those practices with respect to use of pesticides that are considered unsafe. It prohibits the aerial application of pesticides. It requires Member States to set in place systems for periodic inspection of pesticide dealers and pesticide operators with respect to a number of elements listed in Annex IV. It also requires annual inspection of pesticide application equipment to ensure technical soundness, including re-calibration of spraying equipment, as needed.

This article also addresses the problem of used pesticide packaging and obsolete pesticides by placing responsibility on pesticide producers to set in place systems for safe collection and environmentally sound disposal of the used packaging and obsolete pesticides. The systems must meet the approval of the competent authority designated as per Article 5.

Moreover, it sets in motion the development of European standards for minimum technical requirements for pesticide application equipment, as well as minimum requirements for storage of pesticides and application equipment, and for pre-application preparations and post-application cleaning of equipment.

In addition, it provides for Community-level research programmes to develop less hazardous techniques for pesticide handling and application.

#### **Article 11: Minimum requirements for pesticide dealers and pesticide operators**

This article sets in place minimum requirements for the training of all pesticide dealers, crop protection advisors, extension officers and pesticide operators, as a condition for carrying out professional activities with respect to pesticide use. Pesticide dealers would be required to receive accreditation verifying that they had received training on all of the items set forth in Annex V, including pesticide safety and toxicity, environmental and health impacts from pesticides, and poisoning symptoms. Crop protection advisors and extension officers would be required to have training in addition on alternative pest control methods, including principles of ICM and IPM.

Pesticide operators would be required to obtain licenses valid for a maximum period of three years verifying that they had received minimum training on all of the aspects detailed in Annex V.

To ensure coherence in the training of pesticide dealers, crop protection advisors, extension officers and pesticide operators throughout the Community, the Commission is asked to propose guidelines for best practices in training on the items listed in the annex.

#### **Article 12: Reporting on the production, import, export, sales, distribution and use of pesticides**

This article aims to fill the gaps in information concerning the placing on the market and use of pesticides within the Community. It requires the Commission, in cooperation with Eurostat, to establish a reporting system based on a central pesticide label database with unique EU registration numbers and EU barcodes for each individual pesticide product. The effort to develop the reporting system would be advised by a pesticide stakeholder working group with a balanced representation.

Once the system is developed, each pesticide producer will be required to place the unique EU registration number and EU barcode onto the label of each pesticide product. The EU registration numbers and EU barcodes are to form the core of a comprehensive system for annual reporting of information on the production, import, export, sales and distribution and use of pesticides. Member States will be required to report the information they collect to the Commission on an annual basis, and the Commission in turn will issue an annual report containing information on the amounts and kinds of pesticide active ingredients used per crop, per non-agricultural use, and by geographical area.

Member States are also required to verify the accuracy, reliability and validity of the information they receive by providing for independent review of the pesticide use data and collection procedures.

#### **Article 13: Record-keeping**

This article sets in place specific record-keeping requirements for pesticide dealers and pesticide operators. Pesticide dealers would be required to keep records showing the receipt, sale, delivery or other disposition of all pesticides and application equipment for a minimum of two years.

All pesticide operators would be required to keep journals recording all applications of pesticides, when and where the applications were made, and any observations on the

environmental impacts of those applications. The competent authority would be able to inspect the pesticide application journals on demand.

#### **Article 14: Monitoring and collection of data on impacts from pesticide use**

This is aimed at ensuring that sufficient data is gathered to enable a determination of the impact of pesticides on health and environment through the observation of pesticide poisoning and pollution incidence and their consequences on exposed species and the environment. It requires Member States to regularly monitor and collect information on species exposed to pesticides and on pesticides in the environment, including residues on foodstuffs, and to carry out systematic analyses to determine the presence and impact of pesticides. This information is to be gathered by the Commission into an annual report.

Health and environmental risk indicators shall also be developed and used in efforts to monitor the impacts of the measures required under this Directive.

To ensure comparability of information, the Commission is to develop a strategic guidance document on monitoring and surveying of impacts on human health and the environment from pesticide use. In addition, Member States are to carry out long-term research programmes on impacts to human health and the environment from pesticide use, including studies on high-risk groups, biological diversity and combination effects.

#### **Article 15: Access to information; public participation**

This article is aimed at ensuring that requests from the public for certain information on pesticides held by public authorities are not refused, and that public interest bodies have access as observers to all meetings of regulatory committees and advisory bodies taking decisions related to pesticides and their use, and to all documents issued by such bodies. All requests for restriction of information regarding pesticides on the basis of commercial confidentiality will need to be backed up by evidence that revealing that information would be prejudicial to the financial or competitive interests of the person holding the proprietary information.

#### **Article 16: Reporting obligations**

This article provides a three-yearly reporting obligation for Member States, in line with similar reporting requirements adopted in other Community legislation in the field of environment. The information provided by Member States on the experience gained in their pesticide use reduction programmes is to be gathered by the Commission into a report for presentation to the European Parliament and the Council.

#### **Article 17: Adaptation to scientific and technical progress**

The Commission, assisted by a regulatory committee comprising Member State representatives, will be able to make certain changes to the annexes of the Directive, in order to keep up with new knowledge on the impact of pesticides and new developments enabling further reductions in pesticide use.

#### **Article 18: Regulatory procedure**

This article will establish a Regulatory Committee comprising representatives from the Member States to assist the Commission in adapting the contents of specific annexes to scientific and technical progress.

**Article 19: Implementation**

The laws, regulations and administrative procedures necessary to comply with the Directive shall enter into force before [24 months after the entry into force of the Directive].

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