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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 5.9.2008
COM(2008) 535 final

2008/0172 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

**on machinery for pesticide application, amending Directive 2006/42/EC of 17 May 2006
on machinery**

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

Grounds for and objectives of the proposal

The European Parliament and the Council have recognised, in the Decision adopting the 6th Community Environment Action Programme¹, that the impact of pesticides on human health and the environment must be further reduced. As a first stage, this objective concerns plant protection products. The purpose is to achieve a more sustainable use of pesticides along with a reduction of the risks to human health and the environment resulting from their use, consistent with the necessary crop protection. The approach outlined for this purpose included full implementation and appropriate revision of the relevant legal framework and the development of a Thematic Strategy on the Sustainable Use of Pesticides. Since then, the European Commission has adopted the strategy (hereafter, the Thematic Strategy)², and proposed a Directive of the European Parliament and of the Council establishing a framework for Community action to deal with the main legislative aspects of its implementation (hereafter, the Framework Directive)³.

The Thematic Strategy sets out five main objectives:

- to minimise risks to health and the environment from the use of pesticides;
- to improve controls on the use and distribution of pesticides;
- to substitute the most dangerous pesticides with safer alternatives;
- to encourage low-input or pesticide-free cultivation;
- to establish a transparent system for reporting and monitoring progress.

Regarding the objective mentioned first in the list, and in particular pesticide application equipment, the proposed Framework Directive introduces requirements for Member States to set up a system for the regular maintenance and inspection of equipment in use. However, in order to complete the legislative measures relating to the equipment, complementary measures are needed to establish the environmental protection requirements to be fulfilled by new pesticide application equipment before it is placed on the market and put into service.

In its Thematic Strategy, and in the preamble as well as in the explanatory memorandum to the proposed Framework Directive, the Commission has made a commitment to introduce the necessary environmental protection requirements for new pesticide application equipment into a separate proposal. For this purpose, the

¹ Decision No 1600/2002/EC of the European Parliament and of the Council of 22 July 2002 laying down the Sixth Community Environment Action Programme (OJ L 242, 10.9.2002, p. 1–15).

² COM(2006) 372 final – Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of Regions – *A Thematic Strategy on the Sustainable Use of Pesticides*, available at: http://ec.europa.eu/environment/ppps/pdf/com_2006_0372.pdf

³ COM(2006) 373 final – Proposal for a Directive of the European Parliament and of the Council establishing a framework for Community action to achieve a sustainable use of pesticides, available at: http://ec.europa.eu/environment/ppps/pdf/com_2006_0373.pdf

⁴ Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast) (OJ L 157, 9.6.2006, p. 24–86).

Commission is now proposing a Directive amending Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery (hereafter, the Machinery Directive)⁴.

General context

Well designed, constructed and maintained machinery for pesticide application plays a significant role in reducing the adverse impacts of pesticides on human health, in particular on the operators of the machinery, and on the environment. The objective of the proposal is to ensure that new machinery for pesticide application does not endanger the environment unnecessarily. To this end, the proposal introduces supplementary essential environmental protection requirements that must be fulfilled by new machinery for pesticide application before it is placed on the market and/or put into service in the Community. Harmonisation of requirements for such machinery is a prerequisite for ensuring a high standard of protection while ensuring the free movement of such products in the Community.

Existing provisions in the area of the proposal

The Machinery Directive 98/37/EC sets out the essential health and safety requirements that machinery placed on the Community market must meet if they are to benefit from free movement within the Community and the procedures required to assess conformity with these requirements. Directive 98/37/EC will be repealed by Directive 2006/42/EC that will be applicable as from 29 December 2009. The Machinery Directive applies to machinery for pesticide application with respect to the protection of the health and safety of users of such machinery and other persons exposed to risks due to its operation. Environmental protection requirements are not currently covered by the Machinery Directive. However, several Member States have introduced national provisions setting out environmental protection requirements for pesticide application equipment. Furthermore, three European standards have been adopted in this area.

Consistency with the other policies and objectives of the Union

The proposal is fully consistent with the objectives and aims of the Sixth Community Environment Action Programme, the European Union Sustainable Development Strategy, the Lisbon Strategy, and the Thematic Strategy on the Sustainable Use of Pesticides. The proposal also contributes to other policies such as, in particular, the improvement of the protection of the health and safety of workers and of consumers. The proposal is also in line with the Inter-institutional Agreement on Better Law-Making.

2. CONSULTATION OF INTERESTED PARTIES AND IMPACT ASSESSMENT

Consultation of interested parties

Consultation methods, main sectors targeted and general profile of respondents

In order to give all stakeholders concerned the possibility to contribute to the development of the Thematic Strategy, the Commission organised an extensive consultation process involving the European institutions, Member States and other interested parties. It included four rounds of consultation, and the minimum standards

for consultation were fully respected.

In July 2002, the Commission adopted the Communication ‘Towards a Thematic Strategy on the Sustainable Use of Pesticides’⁵, which presented a list of possible measures to achieve the specific objectives of the Thematic Strategy. The Communication was submitted to the European Parliament, the Council, and the Economic and Social Committee, and published on the internet for consultation of the general public. More than 150 contributions were received during this consultation. In addition, in November 2002, the Commission organised a Stakeholders Conference with more than 200 participants from all relevant stakeholder groups such as the pesticide industry, farmer organisations, authorities, consumer and environmental organisations.

In 2004, the Commission contracted a study to an external consultant (BiPRO) on the impacts of the legislative aspects of the Thematic Strategy. This study was elaborated on the basis of surveys and interviews among the Member States (22 answered) and key stakeholders. It was accompanied by an inter-services group involving all relevant Directorates-General and its final report was published on the Commission’s website (hereafter BiPRO Report)⁶. 28 organisations submitted comments on the conclusions of the study⁷.

A final Interactive Policy Making consultation was conducted from 17 March until 12 May 2005. It built on the results of the previous stakeholder consultations and outlined the main measures to be included in the Thematic Strategy. The Commission received 1767 responses from the public and stakeholders.

Summary of responses and how they have been taken into account

A detailed summary of the consultation process and its outcome can be found in the Commission staff working paper on the Impact Assessment of the Thematic Strategy on the Sustainable Use of Pesticides (hereafter, the Impact Assessment)⁸. The conclusions of the Council, the Resolution of the Parliament, the opinion of the Economic and Social Committee as well as public contributions are summarised in Annex 1 to the Impact Assessment. All comments are also available on the internet⁹. The responses received in the final Interactive Policy Making consultation are summarised in Annex 2 to the Impact Assessment¹⁰.

Collection and use of expertise

Scientific/expertise domains concerned

Agriculture, plant protection, machinery and engineering (pesticide application

⁵ COM(2002) 349, available at: http://europa.eu.int/comm/environment/ppps/1st_step_com.htm

⁶ “Assessing economic impacts of the specific measures to be part of the Thematic Strategy on the Sustainable Use of Pesticides”, Final report, October 2004, Beratungsgesellschaft für integrierte Problemlösungen (BiPRO), available at: http://ec.europa.eu/environment/ppps/pdf/bipro_ppp_final_report.pdf

⁷ These are available at: http://ec.europa.eu/environment/ppps/2nd_step_react.htm

⁸ SEC(2006) 894 – Commission staff working paper on the Impact Assessment of the Thematic Strategy on the Sustainable Use of Pesticides, available at: http://ec.europa.eu/environment/ppps/pdf/sec_2006_0894.pdf

⁹ For all comments, see http://ec.europa.eu/environment/ppps/1st_step_consul.htm. The documents and reports from the Stakeholder consultation are available at: http://ec.europa.eu/environment/ppps/1st_step_conf.htm

¹⁰ The results are also available on the internet at http://ec.europa.eu/environment/ppps/pdf/stats_consult.pdf

equipment, in particular sprayers and related equipment), aerial spraying, analysis of economic, social and environmental impacts.

Methodology used

The methods used for collecting and using of expertise included bilateral consultations with stakeholders, organising meetings, participating in conferences, and contracting a study to an external consultant.

Main organisations/experts consulted

The main organisations consulted include Member State authorities, the pesticide industry, the pesticide application equipment industry, farmers' organisations, academia, the European Committee for Standardization (CEN), and environmental organisations.

Summary of advice received and used

With respect to new machinery for pesticide application, the advice confirmed that it is necessary to establish environmental protection requirements for new machinery for pesticide application with which it must comply before being placed on the market and/or put into service.

Means used to make the expert advice publicly available

The expert advice has been made available on the internet¹¹.

Impact assessment

- The proposal for an amendment to the Machinery Directive (2006/42/EC) on machinery for pesticide application is based on the BiPRO Report and the Impact Assessment of the legislative proposals based on the Thematic Strategy.

Policy options considered

The Impact Assessment deals with the policy options relating to pesticide application equipment in section 4.1.2 entitled “Standards for control and certification of application equipment”. In the Impact Assessment, the term ‘control’ refers to the maintenance and periodic inspection of pesticide application equipment that is the subject of measures proposed in the Framework Directive. The term ‘certification’ refers to the design, construction and conformity assessment of new pesticide application equipment that are the subject of this proposal. With respect to the certification of new pesticide application equipment, the Impact Assessment considered the following policy options:

- No action at Community level (identified in the Impact Assessment as option 5)¹²;
- Introduction of a voluntary certification system (identified in the Impact Assessment as option 6)¹³;

¹¹ See http://europa.eu.int/comm/environment/ppps/2nd_step_tech.htm

¹² See note 8 above, p. 38.

- Obliging the Member States to set up a mandatory certification system at national level (identified in the Impact Assessment as option 1)¹⁴;
- Introduction of a mandatory certification system for new application equipment at Community level (identified in the Impact Assessment as option 2, first paragraph)¹⁵.

The conclusion of the Impact Assessment, set out in section 6.2.2 and tables 6-45 and 6-46 of the document¹⁶, is that introducing a mandatory certification system for new pesticide application equipment at Community level is the only option that is able to attain the desired objectives of the Thematic Strategy in terms of protection of the environment and human health. Furthermore, the other policy options would perpetuate divergent national provisions that constitute obstacles to the free movement of goods within the Community (see below, section 3 - *subsidiarity principle*).

Potential impacts

In the BiPRO Report, the possible impacts of introducing requirements for the placing on the market of new pesticide application equipment are discussed¹⁷. It is expected that EU-wide harmonisation of such requirements will generally raise standards for new machinery with respect to environmental protection. As a consequence, average production costs for manufacturers of machinery for pesticide application equipment could rise. The possible cost increase would be unevenly distributed, since many manufacturers already provide machinery that is at a satisfactory level in order to comply with regulations or certification schemes in force in some Member States, while others would have to raise their product standards significantly. For the former, harmonisation of the environmental protection requirements at Community level would have the advantage of ensuring of fair competition in the internal market.

The possible increase in compliance costs for manufacturers who would have to upgrade their machines can be separated into two elements: a one-off cost due to adaptation of designs and tooling and a production cost due, for example, to the incorporation into the machinery of additional or more complex control devices and systems. Neither of these costs can be estimated with precision, since manufacturers do not generally distinguish between cost factors linked to compliance with legal requirements and cost factors linked to the regular updating of their designs to meet market demand for improved performance and other customer requirements. However, the costs that may be incurred by those manufacturers who would have to raise their product standards significantly will probably be transferred to users, in so far as the market conditions allow, via increased prices.

The Impact Assessment, assuming an average lifetime of 12–15 years per sprayer, estimates that approximately 125,000–250,000 new sprayers per year are purchased in the Community. Due to greater efficiency, sprayers that comply with the new

¹³ See note 8 above, p. 38..

¹⁴ See note 8 above, p. 37.

¹⁵ See note 8 above, p. 37.

¹⁶ See note 8 above, p. 143 to 146.

¹⁷ See note 6 above, in particular, Section 4.5 – p. 72 to 74, Impacts: Section 10 – p. 218 to 258.

¹⁸ See note 8 above, in particular, Policy opinions: Section 4.1.2 – p. 37, Impacts: Section 6.1.2 – p. 90 to 98, Comparing the options: Section 6.2.2 – p. 143 to 146, and Comments received: Section 9.10 – p. 197 to 198.

environmental protection requirements are likely to consume less pesticide and reduce losses of pesticide during mixing, loading, spraying and cleaning operations. The resulting average annual reduction of pesticide use is difficult to estimate, however, it will certainly lead to savings for users which are likely to compensate the possible increase in prices for some spraying equipment. On the other hand, the reduced use of pesticides can lead to losses in turnover for the pesticide industry which could lead to job losses.

In the long run, it is expected that introducing environmental protection requirements for new machinery for pesticide application will have positive impacts on human health and the environment via the expected decrease in exposure to pesticides and the reduction of adverse effects on human health and the environment due to such exposure.¹⁸

3. LEGAL ELEMENTS OF THE PROPOSAL

Summary of the proposed action

This proposal introduces new environmental protection requirements for the placing on the market and/or putting into service of new machinery for pesticide application in the EEA. These supplementary essential requirements are mandatory provisions intended to ensure that the products do not endanger the environment unnecessarily.

Legal basis

The legal basis of the proposal for an amendment to the Machinery Directive is provided by Article 95 of the EC Treaty, which sets out the principles for the establishment of the internal market. The Machinery Directive ensures the free movement of machinery falling within its scope that satisfies the essential health and safety requirements and conformity assessment procedures laid down by the Directive.

Subsidiarity principle

The subsidiarity principle applies, insofar as the proposal does not fall under the exclusive competence of the Community.

The objectives of the proposal cannot be sufficiently achieved by the Member States for the following reasons:

Certain Member States have already introduced mandatory environmental protection requirements and conformity assessment procedures for pesticide application equipment. Other Member States have announced draft regulations in this field. To leave the setting of environmental requirements for machinery for pesticide application to a voluntary certification scheme or to certification schemes established by the Member States at national level would have the effect of perpetuating, or indeed multiplying divergent national provisions and procedures having similar objectives. This generates undue costs for industry and constitutes obstacles to the free movement of goods within the Community.

Community action will better achieve the objectives of the proposal for the following reasons:

Harmonisation of the environmental protection requirements and conformity

assessment procedures at Community level is the only way to achieve the desired environmental protection objective while ensuring an equivalent level of protection throughout the Community, fair competition between manufacturers and the free movement of goods in the internal market.

The proposal therefore complies with the subsidiarity principle.

Proportionality principle

This proposal does not go beyond what is necessary in order to achieve its objective, and is therefore in accordance with the principle of proportionality, as set out in Article 5 of the Treaty.

The proposal is limited to the essential requirements with which machinery for pesticide application must comply before being placed on the market and/or put into service, while the European standardisation organisations are responsible for drawing up technical standards providing detailed specifications enabling manufacturers to comply with these requirements. Application of these harmonised standards remains voluntary, but confers a presumption of conformity with the essential requirements they cover.

The administrative burden falling upon the Community and upon national authorities is minimised by including the environmental protection requirements for machinery for pesticide application in the Machinery Directive as proposed. The Member States would have a one-off administrative burden linked to implementation of the amending Directive into national law. However, once the amendment is implemented, the administrative burdens for Member States and the Community entailed by management and enforcement of the new environmental requirements (market surveillance, administrative cooperation, organisation of and participation in the Machinery Committee and Working Group, management of standards etc.) would be essentially unchanged compared with those linked to the management and enforcement of the existing Machinery Directive as a whole.

Compliance with the new requirements set out in the Machinery Directive as proposed would also have the advantage of minimising the administrative burden for manufacturers of machinery for pesticide application. The manufacturer's technical file would have to be updated, but the EC Declaration of conformity that must accompany each machine would also cover the new environmental protection requirements – the only modification needed would be to add a reference to the relevant harmonised standards applied. The possible increase in costs linked to application of new harmonised requirements is largely outweighed by the reduction of the existing and foreseeable future costs resulting from non-harmonisation, in other words the design and production costs and the administrative burden for manufacturers incurred when applying divergent national regulations and procedures in an increasing number of Member States.

Choice of instruments

Proposed instrument: directive.

New machinery for pesticide application is already subject to the Machinery Directive with respect to the protection of the health and safety of operators and other exposed persons. From the perspective of better regulation, it is considered preferable to set out

all the requirements applicable to a given category of products in a single piece of legislation, thereby avoiding overlapping or contradictory requirements and providing for a unique conformity assessment procedure. For this reason it is proposed to incorporate the environmental protection requirements for machinery for pesticide application into the Machinery Directive by means of an amending Directive.

The proposal is thus in line with the Inter-institutional Agreement on Better Law-Making.

4. BUDGETARY IMPLICATION

The proposal has no implication for the Community budget.

5. ADDITIONAL INFORMATION

Correlation table

The Member States are required to communicate to the Commission the text of national provisions transposing the Directive as well as a correlation table between those provisions and this Directive.

European Economic Area

The proposed act concerns an EEA matter and should therefore extend to the European Economic Area.

Detailed explanation of the proposal

The preamble to the proposal includes three Recitals. The first two recitals give the background and state the objective of the proposal. The third recital explains why it is proposed to introduce environmental protection among the objectives of the Machinery Directive. This Recital also indicates that, in this proposal, the environmental protection requirements are limited to machinery for pesticide application and to the risks for the environment covered by the proposed new essential requirements to Annex I of the Directive.

Appropriate amendments are proposed to certain Articles of the Directive in order to introduce environmental protection among its objectives.

Article 2 gives definitions of certain key concepts used in the Directive. It is proposed to add a new definition of ‘essential safety and health requirements’ to this Article. Including the protection of the environment, where appropriate, in the definition of ‘essential health and safety requirements’ avoids the need to amend the numerous references to essential health and safety requirements in the Directive.

The objective of protection of the environment is also mentioned in appropriate amendments to Articles 4 (1), 9 (3) and 11 (1).

Annex I sets out the essential health and safety requirements applicable to machinery. The first General Principle set out in introduction to the Annex is amended to include the obligation for manufacturers of machinery for pesticide application, where appropriate, to estimate the risks of damage to the environment.

It is proposed to include the environmental protection requirements for machinery for

pesticide application in Part 2 of Annex I. Part 2 sets out supplementary essential health and safety requirements for several categories of machinery. It is proposed to add a reference to machinery for pesticide application to the first paragraph defining the scope of Part 2. The new supplementary environmental protection requirements are introduced in a new Section 2.4.

The requirements set out in the proposed new Section 2.4 of Annex I apply to machinery for pesticide application. A definition of ‘machinery for pesticide application’ is given in a first subsection 2.4.1. The definition makes it clear that the requirements apply to machinery intended for applying plant protection products¹⁹ and biocidal products for pest control²⁰, in line with the scope of the Thematic Strategy and the Framework Directive.

Machinery for pesticide application includes self-propelled machinery, towed, vehicle-mounted and semi-mounted machinery, airborne machinery as well as stationary machinery intended for pesticide application, both for professional and consumer use. It also includes powered portable and handheld machinery and manually-operated portable and handheld machinery for pesticide application with a pressure chamber. However, the requirements set out in section 2.4 do not apply to manually-operated portable or handheld pesticide application equipment without a pressure chamber or to simple pesticide application equipment without moving parts, since such equipment is not in the scope of the Machinery Directive.

Subsections 2.4.2 to 2.4.8 set out essential requirements that aim to ensure that machinery for pesticide application is designed and constructed in order to minimise damage to the environment and is accompanied by the necessary instructions relating to its correct use, maintenance and inspection.

It should be noted that the proposed new essential requirements apply to machinery for pesticide application equipment in addition to all the other relevant requirements of Annex I, including the requirement set out in section 3.5.3 relating to the protection of the operator of machinery against the risk of exposure to hazardous emissions, in accordance with General Principle 4 set out in introduction to Annex I.

The proposed new essential requirements are intended to be supported by technical specifications of harmonised standards for the various categories of machinery for pesticide application. To that end, the Commission will give an appropriate mandate to the European Standardisation Organisations.

¹⁹ See amended proposal for a Regulation of the European Parliament and of the Council concerning the placing of plant protection products on the market, 11 March 2008, COM(2008) 93 final.

²⁰ See product-types 14 to 19 as set out in Annex V to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market - OJ L 123, 24.4.1998 p.1 (as last amended by Directive 2007/47/EC (OJ L 247, 21.9.2007, p. 21).

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on machinery for pesticide application, amending Directive 2006/42/EC of 17 May 2006 on machinery

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof

Having regard to the proposal from the Commission²¹,

Having regard to the opinion of the European Economic and Social Committee²²,

Acting in accordance with the procedure laid down in Article 251 of the Treaty²³,

Whereas:

- (1) The use of pesticides is recognised as posing threats both to human health and the environment. In its Communication 'A Thematic Strategy on the Sustainable Use of Pesticides'²⁴, the Commission has adopted a strategy which aims at reducing the risks to human health and the environment from pesticides use. Furthermore, the Commission has proposed a Directive of the European Parliament and of the Council establishing a framework for Community action to achieve a sustainable use of pesticides²⁵ (hereinafter the "Framework Directive").
- (2) The design, construction and maintenance of machinery for pesticide application play a significant role when aiming at reducing adverse impacts of pesticides on human health and on the environment. Regarding pesticide application equipment already in professional use, the Framework Directive introduces requirements for the inspection and maintenance to be carried out on such equipment.
- (3) The requirements for the protection of the health and safety of persons and, where appropriate, domestic animals and property are already covered by Directive 2006/42/EC of the European Parliament and the Council of 17 May 2006 on

²¹ OJ C , , p. .

²² OJ C , , p. .

²³ OJ C , , p. .

²⁴ COM(2006) 372 final

²⁵ COM(2006) 373 final

machinery²⁶. In order to ensure the consistency of that Directive with the Framework Directive, it is appropriate that essential environmental protection requirements for the design and construction of new machinery for pesticide application are included in the Directive 2006/42/EC.

- (4) For this purpose, it is also necessary to include a reference to the protection of the environment in the provisions of Directive 2006/42/EC while limiting this objective to the category of machinery and to the risks subject to specific environmental protection requirements.
- (5) Directive 2006/42/EC should be therefore amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Amendment of Directive 2006/42/EC

Directive 2006/42/EC is amended as follows:

1. in Article 2, the following point (m) is added:
“(m) ‘essential health and safety requirements’ means mandatory provisions to ensure that products do not endanger the health or safety of persons and, where appropriate, domestic animals, property or the environment.”
2. Article 4 (1) is replaced by the following:
“1. Member States shall take all appropriate measures to ensure that machinery may be placed on the market and/or put into service only if it satisfies the relevant provisions of this Directive and does not endanger the health and safety of persons **or, where appropriate, domestic animals, property or the environment,** when properly installed and maintained and used for its intended purpose or under conditions which can reasonably be foreseen.”
3. In Article 9 (3), the first subparagraph is replaced by the following:
“In the cases referred to in paragraph 1, the Commission shall consult the Member States and other interested parties indicating the measures it intends to take, in order to ensure, at Community level, a high level of protection of the health and safety of persons **and, where appropriate, of domestic animals, property or the environment.**”
4. Article 11 (1) is replaced by the following:
“1. Where a Member State ascertains that machinery covered by this Directive, bearing the CE marking, accompanied by the EC declaration of conformity and used in accordance with its intended purpose or under conditions which can reasonably be foreseen, is liable to **endanger** the health and safety of persons **or, where appropriate, domestic animals, property or the environment,** it shall take all appropriate measures to withdraw such machinery from the market, to prohibit the

²⁶ OJ L 157, 9.6.2006, p. 24.

placing on the market and/or putting into service of such machinery or to restrict free movement thereof.”

5. Annex I is amended as follows:

(a) in the General Principles, point 1 is replaced by the following:

“1. The manufacturer of machinery or his authorised representative must ensure that a risk assessment is carried out in order to determine the health and safety requirements which apply to the machinery; the machinery must then be designed and constructed taking into account the results of the risk assessment.

By the iterative process of risk assessment and risk reduction referred to above, the manufacturer or his authorised representative shall:

- determine the limits of the machinery, which include the intended use and any reasonably foreseeable misuse thereof,
- identify the hazards that can be generated by the machinery and the associated hazardous situations,
- estimate the risks, taking into account the severity of the possible injury or damage to health **and, where appropriate, to the environment** and the probability of its occurrence,
- evaluate the risks, with a view to determining whether risk reduction is required, in accordance with the objective of this Directive,
- eliminate the hazards or reduce the risks associated with these hazards by application of protective measures, in the order of priority established in section 1.1.2(b).”

(b) Part 2 is amended as follows:

(i) the first paragraph is replaced by the following:

“Foodstuffs machinery, machinery for cosmetics or pharmaceutical products, hand-held and/or hand-guided machinery, portable fixing and other impact machinery, machinery for working wood and material with similar physical characteristics, **and machinery for pesticide application** must meet all the essential health and safety requirements described in this chapter (see General Principles, point 4).”

(ii) the following Section 2.4. is added:

“2.4. MACHINERY FOR PESTICIDE APPLICATION

2.4.1. Definition

'Machinery for pesticide application' means machinery specifically intended for the application of plant protection products as defined in Regulation (EC) N° [...] ²⁷ or of biocidal products for pest control belonging to product types 14 to 19 as defined in Annex V to Directive 98/8/EC²⁸.

²⁷ Regulation (EC) N° [...] on plant protection products – OJ L [...], [...], p. [...].

²⁸ Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market – OJ L 123, 24.4.1998 p.1 (as last amended by Directive 2007/47/EC) – OJ L 247, 21.9.2007, p. 21.

2.4.2. General

Machinery for pesticide application must be designed and constructed so that it can be operated, adjusted and maintained without damaging the environment unnecessarily.

2.4.3. Controls and monitoring

It must be possible to control and monitor the operation of the machinery from the operating positions.

2.4.4. Filling and emptying

Machinery must be designed and constructed to facilitate precise filling and complete emptying and to prevent any unintentional dispersal of pesticide during these operations.

2.4.5. Application

2.4.5.1. Application rate

The machinery must be fitted with means of adjusting the application rate easily, accurately, and reliably.

2.4.5.2. Distribution and deposition

The machinery must be designed and constructed to ensure an even distribution and homogeneous deposition of pesticide on target areas and to minimise losses to non-target areas.

Losses must be prevented while the pesticide application function is stopped.

2.4.6. Maintenance

2.4.6.1. Cleaning

The machinery must be designed and constructed to facilitate cleaning, in particular of the tank.

2.4.6.2. Servicing

The machinery must be designed and constructed to facilitate the changing of worn parts. It must be possible to connect the necessary measuring instruments to the machinery to check its correct functioning.

2.4.7. Marking

2.4.7.1. Nozzles

Nozzles must be marked so that their type and size can be identified directly or from information given in the instructions.

2.4.7.2. Filters

Filters and strainers must be marked so that their type and mesh size can be identified directly or from information given in the instructions.

2.4.8. Instructions

The instructions must provide the following information:

(a) precautions to be taken during filling, emptying and cleaning to avoid contamination of the environment;

(b) the conditions of use and the corresponding preparation and adjustments to ensure even distribution and homogeneous deposition of pesticide, avoiding losses;

(c) the type and size of nozzles;

(d) the type and mesh size of strainers and filters;

(e) the frequency of verification and criteria for the replacement of nozzles, strainers and filters;

(f) restrictions on the use of particular pesticides;

(g) the connexion and use of any special equipment or accessories;

(h) the checks to be carried out on the machinery, in accordance with the relevant provisions of Directive [...]”²⁹.”

Article 2

Transposition

1. Member States shall adopt and publish the provisions necessary to comply with this Directive by [DATE...] at the latest. They shall forthwith inform the Commission thereof.

They shall apply those provisions with effect from [DATE...].

When Member States adopt those provisions, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field covered by this Directive, together with a table showing how the provisions of this Directive correspond to the national provisions adopted.

Article 3

Entry into force

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

²⁹ Directive [...] of the European Parliament and of the Council of [...] establishing a framework for Community action to achieve a sustainable use of pesticides - OJ L [...] [...], p.[...].

Article 4
Addressees

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President