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Contents

I Acts whose publication is obligatory

- ★ **Council Directive 2005/25/EC of 14 March 2005 amending Annex VI to Directive 91/414/EEC as regards plant protection products containing micro-organisms ⁽¹⁾** 1

II Acts whose publication is not obligatory

Council

2005/272/EC:

- ★ **Council Decision of 14 March 2005 on the conclusion of the bilateral agreement between the European Community and the Republic of Serbia on trade in textile products** 35
- Agreement between the European Community and the Republic of Serbia on trade in textile products** 36

Price: 18 EUR

⁽¹⁾ Text with EEA relevance.

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Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

I

(Acts whose publication is obligatory)

COUNCIL DIRECTIVE 2005/25/EC**of 14 March 2005****amending Annex VI to Directive 91/414/EEC as regards plant protection products containing micro-organisms****(Text with EEA relevance)**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/414/EC of 15 July 1991 concerning the placing of plant protection products on the market ⁽¹⁾, and in particular Article 18(1) thereof,

Having regard to the proposal from the Commission,

Whereas:

- (1) In accordance with Directive 91/414/EEC, Member States have to ensure that plant protection products are not authorised unless they comply with the requirements provided for in that Directive.
- (2) Directive 91/414/EEC provides for the establishment of Uniform Principles pursuant to which the Member States have to carry out the evaluation of plant protection products with a view to their authorisation.
- (3) Uniform Principles have been laid down for Member States to use in the evaluation and authorisation of chemical plant protection products only. However, there are no equivalent principles for Member States to apply in the evaluation and authorisation of plant protection products containing micro-organisms. It is appropriate to lay down additional Uniform Principles for this type of plant protection product.

- (4) Requirements for the dossiers to be submitted by applicants for the authorisation of plant protection products containing micro-organisms having been included in Directive 91/414/EEC by Commission Directive 2001/36/EEC ⁽²⁾, it is now necessary to lay down Uniform Principles for the evaluation of a dossier concerning plant protection products containing micro-organisms based on such data requirements.

- (5) The provisions of this Directive concerning the protection of water, including the provisions related to monitoring, are without prejudice to Member States' obligations under the Directives concerned, and in particular Council Directives 75/440/EEC of 16 June 1975 concerning the quality required of surface water intended for the abstraction of drinking water in the Member States ⁽³⁾, 80/68/EEC of 17 December 1979 on the protection of groundwater against pollution caused by certain dangerous substances ⁽⁴⁾, 98/83/EC of 3 November 1998 on the quality of water intended for human consumption ⁽⁵⁾ and Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy ⁽⁶⁾.

⁽¹⁾ OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2004/99/EC (OJ L 309, 16.10.2004, p. 6).

⁽²⁾ OJ L 164, 20.6.2001, p. 1.

⁽³⁾ OJ L 194, 25.7.1975, p. 26. Directive to be repealed from 22.12.2007 by Directive 2000/60/EC (OJ L 327, 22.12.2000, p. 1).

⁽⁴⁾ OJ L 20, 26.1.1980, p. 43. Directive to be repealed from 22.12.2013 by Directive 2000/60/EC.

⁽⁵⁾ OJ L 330, 5.12.1998, p. 32. Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

⁽⁶⁾ OJ L 327, 22.12.2000, p. 1. Directive as amended by Decision No 2455/2001/EC (OJ L 331, 15.12.2001, p. 1).

- (6) The provisions of this Directive concerning genetically modified organisms are without prejudice to Member States' obligations under Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms ⁽⁷⁾.
- (7) The Scientific Committee on Plants has provided an opinion on this Directive, and this opinion has been taken into account.
- (8) Directive 91/414/EEC should therefore be amended accordingly,

When Member States adopt those measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

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

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex VI to Directive 91/414/EEC is hereby amended in accordance with the Annex to this Directive.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 28 May 2006. They shall immediately forward to the Commission the text of those measures together with a correlation table between such measures and this Directive.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 14 March 2005.

For the Council
The President
F. BODEN

⁽⁷⁾ OJ L 106, 17.4.2001, p. 1. Directive as last amended by Regulation (EC) No 1830/2003 (OJ L 268, 18.10.2003, p. 24).

ANNEX

Annex VI is hereby amended as follows:

- (1) The title 'Uniform Principles for evaluation and authorisation of plant protection products' shall be replaced by

'PART I

UNIFORM PRINCIPLES FOR EVALUATION AND AUTHORISATION OF CHEMICAL PLANT PROTECTION PRODUCTS';

- (2) The following Part shall be added after Part I

'PART II

UNIFORM PRINCIPLES FOR EVALUATION AND AUTHORISATION OF PLANT PROTECTION PRODUCTS CONTAINING MICRO-ORGANISMS'

CONTENTS

A. **INTRODUCTION**

B. **EVALUATION**

1. **General principles**

2. **Specific principles**

2.1. *Identity*

2.1.1. Identity of the micro-organism in the plant protection product

2.1.2. Identity of the plant protection product

2.2. *Biological, physical, chemical and technical properties*

2.2.1. Biological properties of the micro-organism in the plant protection product

2.2.2. Physical, chemical and technical properties of the plant protection product

2.3. *Further information*

2.3.1. Quality control of the production of the micro-organism in the plant protection product

2.3.2. Quality control of the plant protection product

2.4. *Efficacy*

2.5. *Identification/detection and quantification methods*

2.5.1. Analytical methods for the plant protection product

2.5.2. Analytical methods for the determination of residues

- 2.6. *Impact on human and animal health*
 - 2.6.1. Effects on human or animal health arising from the plant protection product
 - 2.6.2. Effects on human or animal health arising from residues
- 2.7. *Fate and behaviour in the environment*
- 2.8. *Effects on and exposure of non-target organisms*
- 2.9. *Conclusions and proposals*

C. **DECISION-MAKING**

- 1. **General principles**
- 2. **Specific principles**
 - 2.1. *Identity*
 - 2.2. *Biological and technical properties*
 - 2.3. *Further information*
 - 2.4. *Efficacy*
 - 2.5. *Identification/detection and quantification methods*
 - 2.6. *Impact on human and animal health*
 - 2.6.1. Effects on human or animal health arising from the plant protection product
 - 2.6.2. Effects on human or animal health arising from residues
 - 2.7. *Fate and behaviour in the environment*
 - 2.8. *Effects on non-target organisms*

A. **INTRODUCTION**

- 1. The principles developed in Part II of this Annex aim to ensure that evaluations and decisions with regard to authorisation of plant protection products, provided they are microbial plant protection products, result in the implementation of the requirements of Article 4(1)(b), (c), (d) and (e) of this Directive by all Member States at a high level of protection of human and animal health and the environment.
- 2. In evaluating applications for granting authorisations Member States shall:
 - (a) — ensure that dossiers on microbial plant protection products supplied are in accordance with the requirements of Annex IIIB, at the latest at the time of finalisation of the evaluation for the purpose of decision-making, without prejudice, where relevant, to the provisions of Article 13 (1)(a), (4) and (6) of this Directive,
 - ensure that the data submitted are acceptable in terms of quantity, quality, consistency and reliability and sufficient to permit a proper evaluation of the dossier,
 - evaluate, where relevant, justifications submitted by the applicant for not supplying certain data;

- (b) take into account the Annex IIB data concerning the active substance consisting of micro-organisms (including viruses) in the plant protection product, submitted for the purpose of inclusion of the micro-organism concerned in Annex I, and the results of the evaluation of those data, without prejudice, where relevant, to the provisions of Article 13(1)(b), (2), (3) and (6) of this Directive;
 - (c) take into consideration other relevant technical or scientific information they can reasonably possess with regard to the performance of the plant protection product or to the potentially adverse effects of the plant protection product, its components or its metabolites/toxins.
- 3. Where, in the specific principles on evaluation, reference is made to Annex IIB data, this shall be understood as being the data referred to in point 2(b).
 - 4. Where the data and information provided are sufficient to permit completion of the evaluation for one of the proposed uses, applications must be evaluated and a decision made for the proposed use.

Taking account of justifications provided and with the benefit of any subsequent clarifications, Member States shall reject applications for granting authorisations for which the data gaps are such that it is not possible to finalise the evaluation and to make a reliable decision for at least one of the proposed uses.

- 5. During the process of evaluation and decision-making, the Member State shall cooperate with the applicants in order to resolve any questions on the dossier quickly or to identify at an early stage any additional studies necessary for a proper evaluation of the dossier, or to amend any proposed conditions for the use of the plant protection product or to modify its nature or its composition in order to ensure full satisfaction of the requirements of this Annex or of this Directive.

Member States shall normally come to a reasoned decision within 12 months of receiving a technically complete dossier. A technically complete dossier is one that satisfies all the requirements of Annex IIIB.

- 6. The judgements made by the competent authorities of the Member States during the evaluation and decision-making process must be based on scientific principles, preferably recognised at international level, and be made with the benefit of expert advice.
- 7. A microbial plant protection product may contain viable and non-viable micro-organisms (including viruses) and formulation substances. It may also contain relevant metabolites/toxins produced during growth, residues from the growth medium, and microbial contaminants. The micro-organism, relevant metabolites/toxins and the plant protection product with residual growth medium and microbial contaminants present must all be evaluated.
- 8. Member States must take into account those guidance documents taken note of in the Standing Committee on the Food Chain and Animal Health (SCCAH).
- 9. For genetically modified micro-organisms, Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms ⁽¹⁾, must be taken into account. The evaluation completed in the framework of that Directive must be provided and taken into account.
- 10. Definitions and explanations of microbiological terms

Antibiosis: A relationship between two or more species in which one species is actively harmed (as by the production of toxins by the harming species).

⁽¹⁾ OJ L 106, 17.4.2001, p. 1. Directive as last amended by Regulation (EC) No 1830/2003 (OJ L 268, 18.10.2003, p. 24).

Antigenic: Any substance that, as a result of coming in contact with appropriate cells, induces a state of sensitivity and/or immune responsiveness after a latent period (days to weeks) and which reacts in a demonstrable way with antibodies and/or immune cells of the sensitised subject *in vivo* or *in vitro*.

Antimicrobial: Antimicrobial agents or antimicrobial(s) refer to naturally occurring, semi-synthetic or synthetic substances that exhibit antimicrobial activity (kill or inhibit the growth of micro-organisms).

The term 'Antimicrobial(s)' includes:

- antibiotics, which refer to substances produced by or derived from micro-organisms, and
- anticoccidials, which refer to substances that are active against coccidia, single cell protozoan parasites.

CFU: Colony-forming unit; one or more cells that grow to form a single visible colony.

Colonisation: Proliferation and persistence of a micro-organism in an environment, such as on external (skin) or internal body surfaces (intestine, lungs). For colonisation, the micro-organism should at least persist for a longer period than expected in a specific organ. The population of micro-organisms may decline but at a slower rate than normal clearance; it may be a steady population or it may be a growing population. Colonisation can be related to harmless and functional micro-organisms as well as to pathogenic micro-organisms. The possible occurrence of effects is not indicated.

Ecological niche: Unique environmental position occupied by a particular species, perceived in terms of actual physical space occupied and function performed within the community or ecosystem.

Host: An animal (including humans) or plant that harbours or nourishes another organism (parasite).

Host specificity: The range of different host-species that can be colonised by a microbial species or strain. A host-specific micro-organism colonises or has adverse effects on one or only a small number of different host-species. A non-host-specific micro-organism might colonise or might have adverse effects on a broad range of different host-species.

Infection: The introduction or entry of a pathogenic micro-organism into a susceptible host, whether or not it causes pathological effects or disease. The organism must enter the body of the host, usually the cells, and be able to reproduce to form new infective units. Simply ingesting a pathogen does not imply infection.

Infective: Capable of transmitting an infection.

Infectivity: The characteristics of a micro-organism that allow it to infect a susceptible host.

Invasion: The entry of a micro-organism into the host body (e.g. actual penetration of the integument, gut epithelial cells, etc.). 'Primary invasiveness' is a property of pathogenic micro-organisms.

Multiplication: Ability of a micro-organism to reproduce and increase in numbers during an infection.

Mycotoxin: A fungal toxin.

Non-viable micro-organism: A micro-organism that is not capable of replication or of transferring genetic material.

Non-viable residue: A residue that is not capable of replication or of transferring genetic material.

Pathogenicity: The ability of a micro-organism to cause disease and/or inflict damage on the host. Many pathogens cause disease by a combination of (i) toxicity and invasiveness or (ii) toxicity and colonising ability. However, some invasive pathogens cause disease that results from an abnormal reaction of the host's defence system.

Symbiosis: A type of interaction between organisms where one organism lives in intimate association with another, which is favourable for both organisms.

Viable micro-organism: A micro-organism that is capable of replication or of transferring genetic material.

Viable residue: A residue that is capable of replication or of transferring genetic material.

Viroid: Any of a class of infectious agents consisting of a small strand of RNA not associated with any protein. The RNA does not code for proteins and is not translated; it is replicated by host cell enzymes. Viroids are known to cause several plant diseases.

Virulence: Measurement of the degree of disease producing ability of a micro-organism as indicated by the severity of the disease produced. Measure of the dosage (inoculum size) required to cause a specific degree of pathogenicity. It is measured experimentally by the median lethal dose (LD_{50}) or median infective dose (ID_{50}).

B. EVALUATION

The objective of an evaluation is to identify and assess, on a scientific basis and until further experience is reached on a case-by-case basis, potential adverse effects on human and animal health and the environment of the use of a microbial plant protection product. The evaluation shall also be carried out in order to identify the need for risk management measures and to identify and recommend suitable measures.

Due to the ability of micro-organisms to replicate, there is a clear difference between chemicals and micro-organisms used as plant protection products. Hazards arising are not necessarily of the same nature as those presented by chemicals, especially in relation to the capacity of micro-organisms to persist and multiply in different environments. Moreover, micro-organisms consist of a wide range of different organisms, all with their own unique characteristics. These differences between micro-organisms should be taken into account in the evaluation.

The micro-organism in the plant protection product should ideally function as a cell factory working directly on the spot where the target organism is harmful. Thus understanding the mode of action is a crucial step in the evaluation process.

Micro-organisms may produce a range of different metabolites (e.g. bacterial toxins or mycotoxins) many of which may have toxicological significance, and one or more of which may be involved in the mode of action of the plant protection product. The characterisation and identification of relevant metabolites should be assessed and the toxicity of these metabolites should be addressed. Information on production and/or relevance of metabolites may be deduced from:

- (a) toxicity studies,
- (b) biological properties of the micro-organism,
- (c) relationship to known plant, animal or human pathogens,
- (d) mode of action,
- (e) analytical methods.

On the basis of this information, metabolites may be considered as possibly being relevant. Therefore potential exposure to these metabolites should be assessed, in order to decide on their relevance.

1. General principles

1.1. Having regard to current scientific and technical knowledge, Member States shall evaluate the information provided in accordance with the requirements of Annex IIB and IIIB and in particular:

- (a) identify the hazards arising, assess their significance and make a judgement as to the likely risks to humans, animals or the environment; and
- (b) assess the performance in terms of efficacy and phytotoxicity/pathogenicity of the plant protection product for each use for which authorisation is sought.

1.2. The quality/methodology of tests, where there are no standardised test methods, must be evaluated and the following characteristics, when available, of the methods described must be assessed:

relevance; representativeness; sensitivity; specificity; reproducibility; interlaboratory validations; predictiveness.

1.3. In interpreting the results of evaluations, Member States shall take into consideration possible elements of uncertainty in the information obtained during the evaluation, in order to ensure that the chances of failing to detect adverse effects or of underestimating their importance are reduced to a minimum. The decision-making process shall be examined to identify critical decision points or items of data for which uncertainties could lead to a false classification of risk.

The first evaluation made shall be based on the best available data or estimates reflecting the realistic conditions of use of the plant protection product. This must be followed by a repeat evaluation, taking account of potential uncertainties in the critical data and of a range of use conditions that are likely to occur and resulting in a realistic worst-case approach, to determine whether it is possible that the initial evaluation could have been significantly different.

1.4. Member States shall evaluate each microbial plant protection product for which an application for authorisation is made in that Member State — the information evaluated for the micro-organism can be taken into account. Member States must take into account the fact that any co-formulants might have an impact on the characteristics of the plant protection product compared to the micro-organism.

1.5. In evaluating applications and granting authorisations Member States shall consider the proposed practical conditions of use and in particular the purpose of use, the dose, the manner, frequency and timing of applications, and the nature and composition of the plant protection product. Whenever possible Member States shall also take into account the principles of integrated pest control.

1.6. In the evaluation, Member States shall consider the agricultural, plant health or environmental (including climatic) conditions in the areas of use.

1.7. Where specific principles in Section 2 provide for the use of calculation models in the evaluation of a plant protection product, those models shall:

- (a) make a best possible estimation of all relevant processes involved taking into account realistic parameters and assumptions,
- (b) be submitted to an evaluation as referred to in point 1.3.,
- (c) be reliably validated with measurements carried out under circumstances relevant for the use of the model,
- (d) be relevant to the conditions in the area of use,

- (e) be supported with details indicating how the model calculates estimates provided, and explanations of all the inputs to the model and details of how they have been derived.

- 1.8. The data requirements, specified in Annex IIB and IIIB, contain guidance as to when and how certain information must be submitted and as to procedures that must be followed when preparing and evaluating a dossier. That guidance must be respected.

2. **Specific principles**

Member States shall implement the following principles in the evaluation of the data and information submitted in support of applications, without prejudice to the general principles prescribed in Section 1:

2.1. *Identity*

2.1.1. Identity of the micro-organism in the plant protection product

The identity of the micro-organism should be clearly established. It must be ensured that the appropriate data are provided to allow for checking the identity of the micro-organism at strain level in the plant protection product.

The identity of the micro-organism shall be evaluated on the strain level. Where the micro-organism is either a mutant or a genetically modified organism ⁽¹⁾, the specific differences from other strains within the same species must be recorded. Occurrence of resting stages must be recorded.

The deposition of the strain at an internationally recognised culture collection must be checked.

2.1.2. Identity of the plant protection product

Member States shall evaluate the detailed quantitative and qualitative information provided on the composition of the plant protection product, such as that concerning the micro-organism (see above), relevant metabolites/toxins, residual growth medium, co-formulants and microbial contaminants present.

2.2. *Biological, physical, chemical, and technical properties*

2.2.1. Biological properties of the micro-organism in the plant protection product

- 2.2.1.1. The origin of the strain, where relevant, its natural habitat including indications on the natural background level, life cycle and the possibilities for survival, colonisation, reproduction and dispersal must be evaluated. Proliferation of indigenous micro-organisms should after a short growth period level off and continue as for the background micro-organisms.

- 2.2.1.2. The ability of micro-organisms to adapt to the environment must be evaluated. In particular, Member States must take account of the following principles:

- (a) depending on the conditions (e.g. availability of substrates for growth and metabolism) micro-organisms can switch on or off the expression of given phenotypic traits;
- (b) the microbial strains most adapted to the environment can survive and multiply better than the non-adapted strains. Adapted strains have a selective advantage and can form the majority within a population after a number of generations;

⁽¹⁾ See definition of 'genetically modified' in Directive 2001/18/EC.

- (c) the relatively rapid multiplication of micro-organisms leads to a higher frequency of mutations. If a mutation is promoting survival in the environment, the mutant strain can become dominant;
- (d) the properties of viruses, in particular, can change rapidly, including their virulence.

Therefore, where appropriate, information on the genetic stability of the micro-organism under the environmental conditions of proposed use must be evaluated, as well as information on the micro-organism's capacity to transfer genetic material to other organisms and information on the stability of encoded traits.

2.2.1.3. The mode of action of the micro-organism should be evaluated in as much detail as appropriate. The possible role of metabolites/toxins for the mode of action should be evaluated and when identified, the minimal effective concentration for each active metabolite/toxin should be established. Information on mode of action can be a very valuable tool in identifying potential risks. Aspects to be considered in the evaluation, are:

- (a) antibiosis,
- (b) induction of plant resistance,
- (c) interference with the virulence of a pathogenic target organism,
- (d) endophytic growth,
- (e) root colonisation,
- (f) competition of ecological niche (e.g. nutrients, habitats),
- (g) parasitisation,
- (h) invertebrate pathogenicity.

2.2.1.4. In order to evaluate possible effects on non-target organisms, information on the micro-organism's host specificity must be evaluated, taking into account the characteristics and properties described in (a) and (b).

- (a) The ability of a micro-organism to be pathogenic for non-target organisms (humans, animals, and other non-target organisms) must be assessed. Any relationship to known plant, animal or human pathogens that are species of the genus of the active and/or contaminating micro-organisms must be assessed.
- (b) Pathogenicity as well as virulence is strongly related to the host-species (e.g. determined by body temperature, physiological environment) and to the host conditions (e.g. health condition, immune status). For example, multiplication in humans depends upon the ability of the micro-organism to grow at the body temperature of the host. Some micro-organisms can only grow and be metabolically active at temperatures far below or above human body temperature, and therefore can not be pathogenic for humans. However, the route of entry of the micro-organism into the host (oral, inhalation, skin/wound) can also be the critical factor. For example, a microbial species may cause a disease following entry via skin damage, but not via the oral route.

2.2.1.5. Many micro-organisms produce antibiosis substances that cause normal interferences in the microbial community. Resistance to antimicrobial agents of importance for human and veterinary medicine must be assessed. The possibility for transfer of genes that code for resistance to antimicrobial agents must be evaluated.

2.2.2. Physical, chemical and technical properties of the plant protection product

2.2.2.1. Depending on the nature of the micro-organism and the formulation type, the technical properties of the plant protection product must be evaluated.

2.2.2.2. Shelf-life and storage stability of the preparation must be evaluated, taking into account possible changes in composition such as growth of the micro-organism or of contaminating micro-organisms, production of metabolites/toxins, etc.

2.2.2.3. Member States shall evaluate the physical and chemical properties of the plant protection product and the retention of these characteristics after storage and take into consideration:

- (a) where a suitable Food and Agriculture Organisation of the United Nations (FAO) specification exists, the physical and chemical properties addressed in that specification,
- (b) where no suitable FAO specification exists, all relevant physical and chemical properties for the formulation referred to in the Manual on the development and use of FAO and World Health Organisation (WHO) specifications for pesticides.

2.2.2.4. Where the proposed label claims include requirements or recommendations for use of the preparation with other plant protection products or adjuvants as a tank mix, and/or where the proposed label includes indications concerning the compatibility of the preparation with other plant protection products as a tank mix, those plant protection products or adjuvants must be physically and chemically compatible in the tank mix. Biological compatibility must also be demonstrated for tank-mixtures, i.e. it must be shown that each plant protection product in the mixture performs as expected and that no antagonism occurs.

2.3. *Further information*

2.3.1. Quality control of the production of the micro-organism in the plant protection product

The quality assurance criteria proposed for production of the micro-organism must be evaluated. In the evaluation criteria relating to process control, good manufacturing practice, operational practices, process flows, cleaning practices, microbial monitoring and hygiene conditions should be taken into account to ensure good quality of the micro-organism. The quality, stability, purity etc., of the micro-organism must be addressed in the quality control system.

2.3.2. Quality control of the plant protection product

The quality assurance criteria proposed must be evaluated. If the plant protection product contains metabolites/toxins produced during growth and residues from the growth medium this should be evaluated. The possibility of the occurrence of contaminating micro-organisms must be evaluated.

2.4. *Efficacy*

2.4.1. Where the proposed use concerns the control of or protection against an organism, Member States shall evaluate the possibility that this organism could be harmful under the agricultural, plant health and environmental (including climatic) conditions in the area of the proposed use.

2.4.2. Member States shall evaluate whether significant damage, loss or inconvenience could occur under the agricultural, plant health and environmental (including climatic) conditions in the area of proposed use if the plant protection product were not used.

2.4.3. Member States shall evaluate the efficacy data provided for in Annex IIIB on the plant protection product having regard to the degree of control or the extent of the effect desired and having regard to relevant experimental conditions such as:

- (a) the choice of the crop or cultivar,

- (b) the agricultural and environmental (including climatic) conditions (if necessary for acceptable efficacy such data/information should also be given for the time before and after application),
- (c) the presence and density of the harmful organism,
- (d) the development stage of crop and organism,
- (e) the amount of the microbial plant protection product used,
- (f) if required on the label, the amount of adjuvant added,
- (g) the frequency and timing of the applications,
- (h) the type of application equipment,
- (i) the need for any special cleaning measures for the application equipment.

2.4.4. Member States shall evaluate the performance of the plant protection product under the range of agricultural, plant health and environmental (including climatic) conditions likely to be encountered in practice in the area of proposed use. The effect on integrated control must be included in the evaluation. In particular, consideration should be paid to:

- (a) the level, consistency and duration of the effect sought in relation to the dose in comparison with a suitable reference product or products, where they exist, and an untreated control;
- (b) where relevant, the effect on yield or reduction of loss in storage, in terms of quantity and/or quality, in comparison with a suitable reference product or products, where they exist, and an untreated control.

Where no suitable reference product exists, Member States shall evaluate the performance of the plant protection product to determine whether there is a consistent and defined benefit under the agricultural, plant health and environmental (including climatic) conditions likely to be encountered in practice in the area of proposed use.

2.4.5. Member States shall evaluate the degree of adverse effects on the treated crop after use of the plant protection product according to the proposed conditions of use in comparison, where relevant, with a suitable reference product or products, where they exist, and/or an untreated control.

- (a) This evaluation will take into consideration the following information:
 - (i) efficacy data;
 - (ii) other relevant information on the plant protection product such as nature of the plant protection product, dose, method of application, number and timing of applications, incompatibility with other crop treatments;
 - (iii) all relevant information on the micro-organism, including biological properties e.g. mode of action, survival, host specificity.
- (b) This evaluation will include:
 - (i) the nature, frequency, level and duration of observed phytotoxic/phytopathogenic effects and the agricultural, plant health and environmental (including climatic) conditions that affect them;
 - (ii) differences between main cultivars with regard to their sensitivity to phytotoxic/phytopathogenic effects;

- (iii) the part of the treated crop or plant products where phytotoxic/phytopathogenic effects are observed;
- (iv) adverse impact on the yield of the treated crop or plant products in terms of quantity and/or quality;
- (v) adverse impact on treated plants or plant products to be used for propagation, in terms of viability, germination, sprouting, rooting and establishment;
- (vi) where micro-organisms are disseminated, the adverse impact on adjacent crops.

2.4.6. Where the plant protection product label includes requirements for use of the plant protection product with other plant protection products and/or with adjuvants as a tank mix, Member States shall make the evaluations referred to in points 2.4.3 to 2.4.5 in relation to the information supplied for the tank mix.

Where the plant protection product label includes recommendations for use of the plant protection product with other plant protection products and/or with adjuvants as a tank mix, Member States shall evaluate the appropriateness of the mix and of its conditions of use.

- 2.4.7. Where the available data indicate that the micro-organism or significant relevant metabolites/toxins, degradation and reaction products of the formulants persist in soils and/or in or on plant substances in significant quantities after use of the plant protection product according to the proposed conditions of use, Member States shall evaluate the degree of adverse effects on subsequent crops.
- 2.4.8. Where the proposed use of a plant protection product is intended to have an effect on vertebrates, Member States shall evaluate the mechanism by which this effect is obtained and the observed effects on the behaviour and health of the target animals. When the intended effect is to kill the target animal they shall evaluate the time necessary to obtain the death of the animal and the conditions under which death occurs.

This evaluation will take into consideration the following information:

- (a) all relevant information as provided for in Annex IIB and the results of the evaluation thereof, including the toxicological studies;
- (b) all relevant information on the plant protection product as provided for in Annex IIIB, including toxicological studies and efficacy data.

2.5. *Identification/detection and quantification methods*

Member States shall evaluate the analytical methods proposed for post-registration control and monitoring purposes of the viable and non-viable components both in the formulation and as residues in or on treated crops. Sufficient validation is required for pre-authorisation methods and post-authorisation monitoring methods. Methods that are considered suitable for post-authorisation monitoring must be clearly identified.

2.5.1. Analytical methods for the plant protection product

2.5.1.1. Non-viable components

Member States shall evaluate the analytical methods proposed to identify and quantify the toxicologically, ecotoxicologically or environmentally significant non-viable components resulting from the micro-organism and/or present as impurity or co-formulant (including eventually resulting breakdown and/or reaction products thereof).

This evaluation will take into consideration the information on analytical methods provided for in Annex IIB and IIIB and the results of the evaluation thereof. In particular, the following information must be taken into account:

- (a) the specificity and linearity of the proposed methods,

- (b) the precision (repeatability) of the proposed methods,
- (c) the importance of interferences,
- (d) the accuracy of the proposed methods at appropriate concentrations,
- (e) the limit of quantification of the proposed methods.

2.5.1.2. Viable components

Member States shall evaluate the methods proposed to quantify and identify the specific strain concerned and especially methods that discriminate that strain from closely related strains.

This evaluation will take into consideration the information on analytical methods provided for in Annex IIB and IIIB and the results of the evaluation thereof. In particular, the following information must be taken into account:

- (a) the specificity of the proposed methods,
- (b) the precision (repeatability) of the proposed methods,
- (c) the importance of interferences,
- (d) the quantifiability of the proposed methods.

2.5.2. Analytical methods for the determination of residues

2.5.2.1. Non-viable residues

Member States shall evaluate the analytical methods proposed to identify and quantify the toxicologically, ecotoxicologically or environmentally significant non-viable residues resulting from the micro-organism (including eventually resulting breakdown and/or reaction products thereof).

This evaluation will take into consideration the information on analytical methods provided for in Annex IIB and IIIB and the results of the evaluation thereof. In particular, the following information must be taken into account:

- (a) the specificity and linearity of the proposed methods,
- (b) the precision (repeatability) of the proposed methods,
- (c) the reproducibility (independent laboratory validation) of the proposed methods,
- (d) the importance of interferences,
- (e) the accuracy of the proposed methods at appropriate concentrations,
- (f) the limit of quantification of the proposed methods.

2.5.2.2. Viable residues

Member States shall evaluate the methods proposed to identify the specific strain concerned and especially methods that discriminate that strain from closely related strains.

This evaluation will take into consideration the information on analytical methods provided for in Annex IIB and IIIB and the results of the evaluation thereof. In particular, the following information must be taken into account:

- (a) the specificity of the proposed methods,
- (b) the precision (repeatability) of the proposed methods,
- (c) the importance of interferences,
- (d) the quantifiability of the proposed methods.

2.6. *Impact on human or animal health*

The impact on human or animal health must be evaluated. In particular, Member States must take account of the following principles:

- (a) due to the ability of micro-organisms to replicate, there is a clear difference between chemicals and micro-organisms used as plant protection products. Hazards arising are not necessarily of the same nature as those presented by chemicals, especially in relation to the capacity of micro-organisms to persist and multiply in different environments;
- (b) the pathogenicity of the micro-organism to humans and non-target animals, the infectiveness of the micro-organism, the ability of the micro-organism to colonise, the toxicity of metabolites/toxins as well as the toxicity of the residual growth medium, contaminants and co-formulants, are important endpoints in assessing adverse effects arising from the plant protection product;
- (c) colonisation, infectiveness and toxicity comprise a complex set of interactions between micro-organisms and hosts and these endpoints may not be resolved easily as independent endpoints;
- (d) in combining these endpoints, the most important aspects of the micro-organism that must be assessed are:
 - ability to persist and multiply in a host (indicative of colonisation or infectivity),
 - ability to produce non-adverse or adverse effects in a host, indicative of infectivity, pathogenicity, and/or toxicity;
- (e) moreover, the complexity of the biological issues should be taken into account in evaluating the hazards and risks presented by use of these plant protection products for human and animals. An assessment of pathogenicity and infectiveness is necessary even if the potential of exposure is deemed low;
- (f) for risk assessment purposes the acute toxicity studies used should, where available, include at least two doses (e.g. one very high dose and one corresponding to the expected exposure under practical conditions).

2.6.1. Effects on human or animal health arising from the plant protection product

- 2.6.1.1. Member States shall evaluate operator exposure to the micro-organism, and/or to toxicologically relevant compounds in the plant protection product (e.g. their metabolites/toxins, residual growth medium, contaminants and co-formulants), likely to occur under the proposed conditions of use (including in particular dose, application method and climatic conditions). Realistic data on exposure levels must be used and, if such data are not available, a suitable, validated calculation model. When available, a European harmonised generic exposure database for plant protection products should be used.

(a) This evaluation will take into consideration the following information:

- (i) the medical data and the toxicity, infectivity and pathogenicity studies as provided for in Annex IIB, and the results of the evaluation thereof. Tier 1 tests should permit an evaluation to be made of a micro-organism with respect to its ability to persist or grow in the host and its ability to cause effects/reactions in the host. Parameters that indicate the absence of ability to persist and multiply in the host, and the absence of ability to produce non-adverse or adverse effects in a host, include fast and complete clearance from the body, no activation of the immune system, no histopathological changes, and for replication temperatures far below or far above mammalian body temperatures. These parameters can in some cases be assessed using acute studies and existing human data, and sometimes can only be assessed using repeated dose studies.

Evaluation based on relevant parameters of Tier 1 tests should lead to an assessment of the possible effects of occupational exposure, taking into account the intensity and duration of exposure including exposure due to repeated use during practical use.

The toxicity of certain metabolites/toxins can only be assessed, if it has been demonstrated that the test animals are actually exposed to these metabolites/toxins;

- (ii) other relevant information on the micro-organism, the metabolites/toxins, residual growth medium, contaminants and co-formulants in the plant protection product, such as their biological, physical and chemical properties (e.g. survival of the micro-organism at the body temperature of humans and animals, ecological niche, behaviour of the micro-organism and/or metabolites/toxins during application);

- (iii) the toxicological studies provided for in Annex IIIB;

- (iv) other relevant information provided for in Annex IIIB such as:

- composition of the preparation,
- nature of the preparation,
- size, design and type of packaging,
- field of use and nature of the crop or target,
- method of application including handling, loading and mixing of the plant protection product,
- exposure reduction measures recommended,
- protective clothing recommendations,
- maximum application rate,
- minimum spray application volume stated on the label,
- number and timing of applications.

- (b) On the basis of the information mentioned in (a) the following overall end-points should be established for single or repeated operator exposure following the intended use:
- persistence or growth of the micro-organism in the host,
 - adverse effects observed,
 - observed or expected effects of contaminants (including contaminating micro-organisms),
 - observed or expected effects of relevant metabolites/toxins.

If there are indications of colonisation in the host and/or if any adverse effects, indicative of toxicity/infectivity are observed, taking into account the exposure scenario (i.e. acute or repeated exposure), further testing is indicated.

- (c) This evaluation shall be made for each type of application method and application equipment proposed for use of the plant protection product as well as for the different types and sizes of containers to be used, taking into account mixing, loading operations, application of the plant protection product and cleaning and routine maintenance of application equipment. Where relevant, other authorised uses of the plant protection product in the area of envisaged use containing the same active substance or which give rise to the same residues may also be taken into account. It should be taken into account that if replication of the micro-organism is expected, exposure assessment could be highly speculative.
- (d) The absence or presence of the potential for colonisation or the possibility of effects in operators at the tested dose levels as provided for in Annex IIB and IIIB should be assessed with regard to measured or estimated levels of human exposure. This risk assessment, preferably quantitative, should include consideration of e.g. mode of action, biological, physical and chemical properties of the micro-organism and other substances in the formulation.

2.6.1.2. Member States shall examine information relating to the nature and characteristics of the packaging proposed with particular reference to the following aspects:

- (a) the type of packaging,
- (b) its dimensions and capacity,
- (c) the size of the opening,
- (d) the type of closure,
- (e) its strength, leakproofness and resistance to normal transport and handling,
- (f) its resistance to and compatibility with the contents.

2.6.1.3. Member States shall examine the nature and characteristics of the protective clothing and equipment proposed with particular reference to the following aspects:

- (a) obtainability and suitability,
- (b) effectiveness,
- (c) ease of wearing taking into account physical stress and climatic conditions,
- (d) resistance to and compatibility with the plant protection product.

2.6.1.4. Member States shall evaluate the possibility of exposure of other humans (workers exposed after the application of the plant protection product, such as re-entering workers, or bystanders) or animals to the micro-organism and/or to other toxicologically relevant compounds in the plant protection product under the proposed conditions of use. This evaluation will take into consideration the following information:

- (a) the medical data and the toxicity, infectivity and pathogenicity studies provided for in Annex IIB, and the results of the evaluation thereof. Tier 1 tests should permit an evaluation to be made of a micro-organism with respect to its ability to persist or grow in the host and its ability to cause effects/reactions in the host. Parameters that indicate the absence of ability to persist and multiply in the host, and the absence of ability to produce non-adverse or adverse effects in a host, include rapid and complete clearance from the body, no activation of the immune system, no histopathological changes, and inability to replicate at mammalian body temperatures. These parameters can in some cases be assessed using acute studies and existing human data, and sometimes can only be assessed using repeated dose studies.

Evaluation based on relevant parameters of Tier 1 tests should lead to an assessment of the possible effects of occupational exposure, taking into account the intensity and duration of exposure, including exposure due to repeated use during practical use.

The toxicity of certain metabolites/toxins can only be assessed, if it has been demonstrated that the test animals are actually exposed to these metabolites/toxins;

- (b) other relevant information on the micro-organism, the metabolites/toxins, residual growth medium, contaminants and co-formulants in the plant protection product, such as their biological, physical and chemical properties (e.g. survival of the micro-organism at the body temperature of humans and animals, ecological niche, behaviour of the micro-organism and/or metabolites/toxins during application);
- (c) the toxicological studies provided for in Annex IIIB;
- (d) other relevant information on the plant protection product as provided for in Annex IIIB such as:
 - re-entry periods, necessary waiting periods or other precautions to protect humans and animals,
 - method of application, in particular spraying,
 - maximum application rate,
 - minimum spray application volume,
 - composition of the preparation,
 - excess remaining on plants and plant products after treatment, taking into account the influence of factors such as temperature, UV light, pH and the presence of certain substances,
 - further activities whereby workers are exposed.

2.6.2. Effects on human or animal health arising from residues

In the evaluation, non-viable and viable residues must be addressed separately. Viruses and viroids should be considered as viable residues since they are capable of transferring genetic material, although strictly speaking they are not living.

2.6.2.1. Non-viable residues

- (a) Member States shall evaluate the possibility of exposure of humans or animals to non-viable residues and their degradation products via the food chain due to the possible occurrence of such residues in or on edible parts of treated crops. In particular, the following information should be taken into account:
- the stage of development of the micro-organism at which non-viable residues are produced,
 - the development stages/life cycle of the micro-organism under typical environmental conditions; in particular, attention shall be paid to the assessment of the likelihood of survival and multiplication of the micro-organism in or on crops, food or feed, and, as a consequence, the likelihood of the production of non-viable residues,
 - the stability of relevant non-viable residues (including the effects of factors such as temperature, UV light, pH and the presence of certain substances),
 - any experimental study showing whether or not relevant non-viable residues are translocated in plants,
 - data concerning the proposed good agricultural practice (including number and timing of applications, maximum application rate and minimum spray application volume, proposed pre-harvest intervals for envisaged uses, or withholding periods or storage periods, in the case of post-harvest uses) and additional data on application as provided for in Annex IIIB,
 - where relevant, other authorised uses of plant protection products in the area of envisaged use, i.e. containing the same residues, and
 - the natural occurrence of non-viable residues on edible plant parts as a consequence of naturally occurring micro-organisms.
- (b) Member States shall evaluate the toxicity of non-viable residues and their degradation products having regard in particular to the specific information provided in accordance with Annex IIB and IIIB.
- (c) Where non-viable residues or their degradation products are considered toxicologically relevant for humans and/or animals and when exposure is not considered negligible, the actual levels in or on the edible parts of treated crops should be determined, taking into consideration:
- analytical methods for the non-viable residues,
 - the growth curves of the micro-organism under optimal conditions,
 - the production/formation of non-viable residues at relevant moments (e.g. at the anticipated harvest time).

2.6.2.2. Viable residues

- (a) Member States shall evaluate the possibility of exposure of humans or animals to viable residues via the food chain due to the possible occurrence of such residues in or on edible parts of treated crops. In particular, the following information should be taken into account:
- the likelihood of survival, the persistence and multiplication of the micro-organism in or on crops, food or feed. The various development stages/life cycle of the micro-organism should be addressed,
 - information concerning its ecological niche,

- information on fate and behaviour in the various parts of the environment,
 - the natural occurrence of the micro-organism (and/or a related micro-organism),
 - data concerning the proposed good agricultural practice (including number and timing of applications, maximum application rate and minimum spray application volume, proposed pre-harvest intervals for envisaged uses, or withholding periods or storage periods in the case of post-harvest uses) and additional data on application as provided for in Annex IIB,
 - where relevant, other authorised uses of plant protection products in the area of envisaged use, i.e. containing the same micro-organism or which result in the same residues.
- (b) Member States shall evaluate the specific information concerning the ability of viable residues to persist or grow in the host and the ability of such residues to cause effects/reactions in the host. In particular, the following information should be taken into account:
- the medical data and toxicity, infectivity and pathogenicity studies provided for in Annex IIB, and the results of the evaluation thereof,
 - the development stages/life cycle of the micro-organism under typical environmental conditions (e.g. in or on the treated crop),
 - the mode of action of the micro-organism,
 - the biological properties of the micro-organism (e.g. host specificity).

The various development stages/life cycle of the micro-organism should be addressed.

- (c) In the event that viable residues are considered to be toxicologically relevant for humans and/or animals and if exposure is not considered negligible, the actual levels in or on the edible parts of treated crops should be determined, taking into consideration:
- analytical methods for the viable residues,
 - the growth curves of the micro-organism under optimal conditions,
 - the possibilities of extrapolating data from one crop to another.

2.7. *Fate and behaviour in the environment*

The biocomplexity of the ecosystems and interactions in the microbial communities concerned must be taken into account.

Information on the origin and properties (e.g. specificity) of the micro-organism/its residual metabolites/toxins and its intended use forms the basis for an assessment of environmental fate and behaviour. The mode of action of the micro-organism should be taken into consideration.

An assessment shall be made of the fate and behaviour of any known relevant metabolite that is produced by the micro-organism. The assessment shall be made for each environmental compartment, and shall be triggered on the basis of the criteria specified in section 7 (iv) of Annex IIB.

In the assessment of the environmental fate and behaviour of plant protection products, Member States shall have regard to all aspects of the environment, including biota. The potential for persistence and multiplication of micro-organisms has to be assessed in all environmental compartments unless it can be justified that particular micro-organisms will not reach a specific compartment. The mobility of micro-organisms and their residual metabolites/toxins must be considered.

- 2.7.1. Member States shall evaluate the possibility of contamination of ground water, surface water and drinking water under the proposed conditions of use of the plant protection product.

In the overall assessment, Member States should pay particular attention to potential adverse effects on humans through groundwater contamination, when the active substance is applied in regions with vulnerable conditions, such as drinking water abstraction areas.

- 2.7.2. Member States shall evaluate the risk for the aquatic compartment where the possibility of the exposure of aquatic organisms has been established. A micro-organism may give rise to risks because of its potential through multiplication to establish itself in the environment and can therefore have a long-lasting or permanent impact on microbial communities or their predators.

This evaluation will take into consideration the following information:

- (a) the biological properties of the micro-organism,
 - (b) the survival of the micro-organism in the environment,
 - (c) its ecological niche,
 - (d) the natural background level of the micro-organism, where it is indigenous,
 - (e) information on fate and behaviour in the various parts of the environment,
 - (f) where relevant, information on potential interference with analytical systems used for the control of the quality of drinking water as provided for in Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption ⁽¹⁾,
 - (g) where relevant, other authorised uses of plant protection products in the area of envisaged use, e. g. containing the same active substance or which gives rise to the same residues.
- 2.7.3. Member States shall evaluate the possibility of exposure of organisms in the atmosphere to the plant protection product under the proposed conditions of use; if this possibility exists they shall evaluate the risk for the atmosphere. The transport, short-range and long-range, of the micro-organism in the atmosphere should be taken into account.
- 2.7.4. Member States shall evaluate the possibility of exposure of organisms in the terrestrial compartment to the plant protection product under the proposed conditions of use; if this possibility exists they shall evaluate the risks arising for the terrestrial compartment. A micro-organism may give rise to risks because of its potential through multiplication to establish itself in the environment and can therefore have a long-lasting or permanent impact on microbial communities or their predators.

This evaluation will take into consideration the following information:

- (a) the biological properties of the micro-organism,
- (b) the survival of the micro-organism in the environment,
- (c) its ecological niche,
- (d) the natural background level of the micro-organism, where it is indigenous,
- (e) information on fate and behaviour in the various parts of the environment,

⁽¹⁾ OJ L 330, 5.12.1998, p. 32. Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

- (f) where relevant, other authorised uses of plant protection products in the area of envisaged use, e. g. containing the same active substance or which gives rise to the same residues.

2.8. *Effects on and exposure of non-target organisms*

Information on the ecology of the micro-organism and effects on the environment should be assessed as well as possible exposure levels and the effects of its relevant metabolites/toxins. An overall assessment of the environmental risks that the plant protection product may cause, taking into account the normal levels of exposure to micro-organisms both in the environment as well as in the body of organisms, is necessary.

Member States shall evaluate the possibility of exposure of non-target organisms under the proposed conditions of use and if this possibility exists they shall evaluate the risks arising for the non-target organisms concerned.

Where applicable, an assessment of infectivity and pathogenicity is necessary, unless it can be justified that non-target organisms will not be exposed.

To assess the possibility of exposure the following information should also be taken into consideration:

- (a) the survival of the micro-organism in the respective compartment,
- (b) its ecological niche,
- (c) the natural background level of the micro-organism, where it is indigenous,
- (d) information on fate and behaviour in the various parts of the environment,
- (e) where relevant, other authorised uses of the plant protection product in the area of envisaged use containing the same active substance or which give rise to the same residues.

2.8.1. Member States shall evaluate the possibility of exposure of and effects on terrestrial wildlife (non-domestic birds, mammals and other terrestrial vertebrates).

2.8.1.1. A micro-organism may give rise to risks because of its potential to infect and multiply in avian and mammalian host systems. Whether or not identified risks could be changed due to the formulation of the plant protection product shall be assessed, taking into account the following information on the micro-organism:

- (a) its mode of action,
- (b) other biological properties,
- (c) studies on mammalian toxicity, pathogenicity and infectivity,
- (d) studies on avian toxicity, pathogenicity and infectivity.

2.8.1.2. A plant protection product may give rise to toxic effects due to the action of toxins or co-formulants. For the assessment of such effects, the following information should be taken into consideration:

- (a) studies on mammalian toxicity,
- (b) studies on avian toxicity,
- (c) information on fate and behaviour in the various parts of the environment.

If mortality or signs of intoxication are observed in the tests the evaluation must include a calculation of toxicity/exposure ratios based on the quotient of the LD_{50} value and the estimated exposure expressed in mg/kg body weight.

2.8.2. Member States shall evaluate the possibility of exposure of and effects on aquatic organisms.

2.8.2.1. A micro-organism may give rise to risks because of its potential to infect and multiply in aquatic organisms. Whether or not identified risks could be changed due to the formulation of the plant protection product shall be assessed, taking into account the following information on the micro-organism:

- (a) its mode of action,
- (b) other biological properties,
- (c) studies on toxicity, pathogenicity and infectivity.

2.8.2.2. A plant protection product may give rise to toxic effects due to the action of toxins or co-formulants. For the assessment of such effects the following information should be taken into consideration:

- (a) studies on toxicity to aquatic organisms,
- (b) information on fate and behaviour in the various parts of the environment.

If mortality or signs of intoxication are observed in the tests the evaluation must include a calculation of toxicity/exposure ratios based on the quotient of the EC_{50} value and/or the NOEC value and the estimated exposure.

2.8.3. Member States shall evaluate the possibility of exposure of and effects on bees.

2.8.3.1. A micro-organism may give rise to risks because of its potential to infect and multiply in bees. Whether or not identified risks could be changed due to the formulation of the plant protection product shall be assessed, taking into account the following information on the micro-organism:

- (a) its mode of action,
- (b) other biological properties,
- (c) studies on toxicity, pathogenicity and infectivity.

2.8.3.2. A plant protection product may give rise to toxic effects due to the action of toxins or co-formulants. For the assessment of such effects the following information should be taken into consideration:

- (a) studies on toxicity to bees,
- (b) information on fate and behaviour in the various parts of the environment.

If mortality or signs of intoxication are observed in the tests the evaluation must include a calculation of the hazard quotient, based on the quotient of the dose in g/ha and the LD_{50} value in $\mu\text{g}/\text{bee}$.

2.8.4. Member States shall evaluate the possibility of exposure of and effects on arthropods other than bees.

2.8.4.1. A micro-organism may give rise to risks because of its potential to infect and multiply in arthropods other than bees. Whether or not identified risks could be changed due to the formulation of the plant protection product shall be assessed, taking into account the following information on the micro-organism:

- (a) its mode of action,
- (b) other biological properties,

- (c) studies on toxicity, pathogenicity and infectivity to honeybees and other arthropods.

2.8.4.2. A plant protection product may give rise to toxic effects due to the action of toxins or co-formulants. For the assessment of such effects the following information should be taken into consideration:

- (a) studies on toxicity to arthropods,
- (b) information on fate and behaviour in the various parts of the environment,
- (c) available data from biological primary screening.

If mortality or signs of intoxication are observed in the tests the evaluation must include a calculation of toxicity/exposure ratios based on the quotient of the ER_{50} value (effective rate) and the estimated exposure.

2.8.5. Member States shall evaluate the possibility of exposure of and effects on earthworms.

2.8.5.1. A micro-organism may give rise to risks because of its potential to infect and multiply in earthworms. Whether or not identified risks could be changed due to the formulation of the plant protection product shall be assessed, taking into account the following information on the micro-organism:

- (a) its mode of action,
- (b) other biological properties,
- (c) studies on earthworm toxicity, pathogenicity and infectivity.

2.8.5.2. A plant protection product may give rise to toxic effects due to the action of toxins or co-formulants. For the assessment of such effects the following information should be taken into consideration:

- (a) studies on earthworm toxicity,
- (b) information on fate and behaviour in the various parts of the environment.

If mortality or signs of intoxication are observed in the tests the evaluation must include a calculation of toxicity/exposure ratios based on the quotient of the LC_{50} value and the estimated exposure expressed in mg/kg dry weight soil.

2.8.6. Member States shall evaluate the possibility of exposure of and effects on soil micro-organisms.

2.8.6.1. A micro-organism may give rise to risks because of its potential to interfere with nitrogen and carbon mineralisation in the soil. Whether or not identified risks could be changed due to the formulation of the plant protection product shall be assessed, taking into account the following information on the micro-organism:

- (a) its mode of action,
- (b) other biological properties.

Experimental data are not normally required, i.e. where it can be justified that a proper risk assessment can be performed with the available information.

2.8.6.2. Member States shall evaluate the impact of exotic/non-indigenous micro-organisms on non-target micro-organisms and on their predators following use of the plant protection product according to the proposed conditions of use. Experimental data are not normally required, i.e. where it can be justified that a proper risk assessment can be performed with the available information.

2.8.6.3. A plant protection product may give rise to toxic effects due to the action of toxins or co-formulants. For the assessment of such effects the following information should be taken into consideration:

- (a) information on fate and behaviour in the various parts of the environment,
- (b) all available information from biological primary screening.

2.9. *Conclusions and proposals*

Member States shall draw conclusions on the need for further information and/or testing and the need for measures to limit the risks arising. Member States shall justify proposals for the classification and labelling of plant protection products.

C. **DECISION-MAKING**

1. **General principles**

- 1.1. Where appropriate, Member States shall impose conditions or restrictions on the authorisations they grant. The nature and severity of these conditions or restrictions must be selected on the basis of, and be appropriate to, the nature and extent of the expected advantages and the risks likely to arise.
- 1.2. Member States shall ensure that decisions taken to grant authorisations, take account of the agricultural, plant health or environmental (including climatic) conditions in the areas of envisaged use. Such considerations may result in specific conditions and restrictions on use, and, in authorisation being granted for some but not other areas within the Member State in question.
- 1.3. Member States shall ensure that the authorised amounts, in terms of rates and number of applications, are the minimum necessary to achieve the desired effect even where higher amounts would not result in unacceptable risks to human or animal health or to the environment. The authorised amounts must be differentiated according to, and be appropriate to, the agricultural, plant health or environmental (including climatic) conditions in the various areas for which an authorisation is granted. However, the rates and the number of applications may not give rise to undesirable effects such as the development of resistance.
- 1.4. Member States shall ensure that decisions respect the principles of integrated pest control if the plant protection product is intended for use in conditions where these principles are relied on.
- 1.5. Since the evaluation is to be based on data concerning a limited number of representative species, Member States shall ensure that use of plant protection products does not have any long-term repercussions for the abundance and diversity of non-target species.
- 1.6. Before issuing an authorisation, Member States shall ensure that the label of the plant protection product:
 - (a) fulfils the requirements of Article 16 of this Directive,
 - (b) also contains the information on protection of users required by Community legislation on worker protection,
 - (c) specifies in particular the conditions or restrictions under which the plant protection product may or may not be used as referred to in points 1.1 to 1.5,

- (d) The authorisation shall mention the particulars indicated in Article 16(1)(g) and (h) of this Directive and Article 10(1.2), (2.4), (2.5) and (2.6) of Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations ⁽¹⁾.

1.7. Before issuing authorisations, Member States shall:

- (a) ensure that the proposed packaging is in accordance with the provisions of Directive 1999/45/EC;
- (b) ensure that:
 - the procedures for destruction of the plant protection product,
 - the procedures for neutralisation of any adverse effects of the plant protection product if it is accidentally dispersed, and
 - the procedures for the decontamination and destruction of the packaging,

are in accordance with the relevant regulatory provisions.

1.8. No authorisation shall be granted unless all the requirements referred to in point 2 are satisfied. However, when one or more of the specific decision-making requirements referred to in point 2.4 are not fully satisfied, authorisations shall be granted only where the advantages of the use of the plant protection product under the proposed conditions of use outweigh the possible adverse effects of its use. Any restrictions on use of the plant protection product relating to non-compliance with some of the requirements referred to in point 2.4 must be mentioned on the label. These advantages can be in terms of:

- (a) advantages for and compatibility with integrated control measures or organic farming,
- (b) facilitating strategies to minimise the risk of development of resistance,
- (c) reduced risk for operators and consumers,
- (d) reduced contamination of the environment and reduced impact on non-target species.

1.9. Where an authorisation has been granted according to the requirements provided for in this Annex, Member States may, by virtue of Article 4(6):

- (a) define, where possible, preferably in close cooperation with the applicant, measures to improve the performance of the plant protection product, and/or
- (b) define, where possible, in close cooperation with the applicant, measures to reduce further the exposure that could occur during and after use of the plant protection product.

Member States shall inform applicants of any measures identified under (a) or (b) and shall invite applicants to provide any supplementary data and information necessary to demonstrate performance or potential risks arising under the changed conditions.

⁽¹⁾ OJ L 200, 30.7.1999, p. 1. Directive as last amended by Directive 2004/66/EC (OJ L 168, 1.5.2004, p. 35).

- 1.10. Member States shall ensure, as far as is practically possible, that for all micro-organisms that are considered for an authorisation, the applicant has taken into account all available relevant knowledge and information in literature at the time of submission.
- 1.11. Where the micro-organism has been genetically modified, as defined in Directive 2001/18/EC, no authorisation shall be granted unless the evaluation conducted in accordance with Directive 2001/18/EC has been submitted, as required under Article 1(3) of that Directive. The relevant decision taken by the competent authorities in accordance with Directive 2001/18/EC must be provided.
- 1.12. In accordance with Article 1(3) of this Directive, no authorisation shall be granted for a plant protection product containing a genetically modified organism unless authorisation is granted according to the provisions in Directive 2001/18/EC, part C, under which that organism can be released into the environment.
- 1.13. No authorisation shall be granted if relevant metabolites/toxins (i.e. those expected to be of concern for human health and/or the environment) known to be formed by the micro-organism, and/or by microbial contaminants are present in the plant protection product, unless it can be shown that the amount present is at an acceptable level before and after its proposed use.
- 1.14. Member States shall ensure that adequate quality control measures are applied to ensure the identity of the micro-organism and contents of the plant protection product. Such measures must include a Hazard Analysis Critical Control Point (HACCP) system or equivalent system.

2. **Specific principles**

The specific principles shall apply without prejudice to the general principles referred to in Section 1.

2.1. *Identity*

For each authorisation granted the Member States shall ensure that the micro-organism concerned is deposited at an internationally recognised culture collection and has an accession number. Each micro-organism must be identified and named at the species level and characterised at the strain level. There must also be information as to whether or not the micro-organism is a wild type or a spontaneous or induced mutant, or a genetically modified organism.

2.2. *Biological and technical properties*

- 2.2.1. There must be sufficient information to permit assessment of the minimum and maximum content of the micro-organism in the material used for the manufacturing of plant protection products, as well as in the plant protection product. The content of other components and formulants in the plant protection product and contaminating micro-organisms derived from the production process must to the extent possible be defined. Member States shall ensure that the level of contaminating organisms is controlled to an acceptable level. In addition: the physical nature and state of the plant protection product must be specified, preferably according to the 'Catalogue of pesticide formulation types and international coding system (CropLife International Technical Monograph No 2, 5th Edition, 2002)'.
- 2.2.2. No authorisation shall be granted if, at any stage in the development of a microbial plant protection product, it becomes apparent, on the basis of a build-up of resistance, or transfer of resistance, or other mechanism, that there may be interference with the effectiveness of an anti-microbial agent used in human or animal medicine.

2.3. *Further information*

No authorisation shall be granted unless full information is provided on the continuous quality control of the production method, production process and plant protection product. In particular, the occurrence of spontaneous changes in major characteristics of the micro-organism and the absence/presence of contaminating organisms shall be considered. The quality assurance criteria for production and the techniques used to ensure a uniform plant protection product must to the extent possible be described and specified.

2.4. *Efficacy*

2.4.1. Performance

2.4.1.1. No authorisation shall be granted where the proposed uses include recommendations for the control of or protection against organisms which are not considered to be harmful on the basis of experience acquired or scientific evidence under normal agricultural, plant health and environmental (including climatic) conditions in the areas of proposed use or where the other intended effects are not considered to be beneficial under those conditions.

2.4.1.2. The level, consistency and duration of control or protection or other intended effects must be similar to those resulting from the use of suitable reference products. If no suitable reference product exists, the plant protection product must be shown to give a defined benefit in terms of the level, consistency and duration of control or protection or other intended effects under the agricultural, plant health and environmental (including climatic) conditions in the area of proposed use.

2.4.1.3. Where relevant, yield response when the plant protection product is used and reduction of loss in storage must be quantitatively and/or qualitatively similar to those resulting from the use of suitable reference products. If no suitable reference product exists, the plant protection product must be shown to give a consistent and defined quantitative and/or qualitative benefit in terms of yield response and reduction of loss in storage under the agricultural, plant health and environmental (including climatic) conditions in the area of proposed use.

2.4.1.4. Conclusions as to the performance of the preparation must be valid for all areas of the Member State in which it is to be authorised, and for all conditions under which its use is proposed, except where the proposed label specifies that the preparation is intended for use in certain specified circumstances (e.g. light infestations, particular soil types or particular growing conditions).

2.4.1.5. Where proposed label claims include requirements for use of the preparation with other specified plant protection products or adjuvants as a tank mix, the mixture must achieve the desired effect and comply with the principles referred to in points 2.4.1.1 to 2.4.1.4.

Where proposed label claims include recommendations for use of the preparation with specified plant protection products or adjuvants as a tank mix, Member States shall not accept the recommendations unless they are justified.

2.4.1.6. If there is evidence of a development of resistance of pathogens towards the plant protection product, the Member State shall decide if the submitted resistance management strategy addresses this adequately and sufficiently.

2.4.1.7. Only plant protection products containing non-viable micro-organisms may be authorised for use to control vertebrate species. The intended effect on vertebrates to be controlled shall be obtained without unnecessary suffering and unnecessary pain for these animals.

2.4.2. Absence of unacceptable effects on plants and plant products

- 2.4.2.1. There must be no relevant phytotoxic effects on treated plants or plant products except where the proposed label indicates appropriate limitations of use.
- 2.4.2.2. There must be no reduction of yield at harvest due to phytotoxic effects below that which could be obtained without the use of the plant protection product, unless this reduction is compensated for by other advantages such as an enhancement of the quality of the treated plants or plant products.
- 2.4.2.3. There must be no unacceptable adverse effects on the quality of treated plants or plant products, except in the case of adverse effects on processing where proposed label claims specify that the preparation should not be applied to crops to be used for processing purposes.
- 2.4.2.4. There must be no unacceptable adverse effects on treated plants or plant products used for propagation or reproduction, such as effects on viability, germination, sprouting, rooting and establishment, except where proposed label claims specify that the preparation should not be applied to plants or plant products to be used for propagation or reproduction.
- 2.4.2.5. There must be no unacceptable impact on succeeding crops, except where proposed label claims specify that particular crops, which would be affected, should not be grown following the treated crop.
- 2.4.2.6. There must be no unacceptable impact on adjacent crops, except where proposed label claims specify that the preparation should not be applied when particular sensitive adjacent crops are present.
- 2.4.2.7. Where proposed label claims include requirements for use of the preparation with other plant protection products or adjuvants, as a tank mix, the mixture must comply with the principles referred to in points 2.4.2.1 to 2.4.2.6.
- 2.4.2.8. The proposed instructions for cleaning the application equipment must be both practical and effective so that they can be applied with ease so as to ensure the removal of residual traces of the plant protection product which could subsequently cause damage.

2.5. *Identification/detection and quantification methods*

The methods proposed must reflect the latest techniques. Methods for post-authorisation monitoring should involve the use of commonly available reagents and equipment.

- 2.5.1. No authorisation shall be granted unless there is an adequate method of sufficient quality to identify and quantify the micro-organism and non-viable components (e.g. toxins, impurities and co-formulants) in the plant protection product. In the case of a plant protection product containing more than one micro-organism, the recommended methods should be capable of identifying and determining the content of each one.
- 2.5.2. No authorisation shall be granted unless there are adequate methods for post-registration control and monitoring of viable and/or non-viable residues. Methods must be available for analysis of:
 - (a) plants, plant products, foodstuffs of plant and animal origin and feedingstuffs if toxicologically relevant residues occur. Residues are considered relevant if a maximum residue level (MRL) or a waiting or re-entry safety period or other such precaution is required,
 - (b) soil, water, air and/or body tissues if toxicologically, ecotoxicologically or environmentally relevant residues occur.

2.6. *Impact on human and animal health*

2.6.1. Effects on human and animal health arising from the plant protection product

2.6.1.1. No authorisation shall be granted if on the basis of the information provided in the dossier it appears that the micro-organism is pathogenic to humans or non-target animals under the proposed conditions of use.

2.6.1.2. No authorisation shall be granted if the micro-organism and/or the plant protection product containing the micro-organism might, under the recommended conditions of use, including a realistic worst case scenario, colonise or cause adverse effects in humans or animals.

When making a decision on the authorisation of the microbial plant protection product, Member States shall consider possible effects on all human populations, namely professional users, non-professional users and humans exposed directly or indirectly through the environment and at work, and animals.

2.6.1.3. All micro-organisms should be regarded as potential sensitisers, unless it is established by means of relevant information that there is no risk of sensitisation, taking into account immuno-compromised and other sensitive individuals. Authorisations granted shall therefore specify that protective clothing and suitable gloves be worn and that the plant protection product containing the micro-organism should not be inhaled. Moreover, the proposed conditions of use may require use of additional items of protective clothing and equipment.

Where the proposed conditions of use require use of items of protective clothing, no authorisation shall be granted unless those items are effective and in accordance with relevant Community provisions, and are readily obtainable by the user and unless it is feasible to use them under the conditions of use of the plant protection product, taking into account climatic conditions in particular.

2.6.1.4. No authorisation shall be granted if it is known that transfer of genetic material from the micro-organism to other organisms may lead to adverse effects on human and animal health, including resistance to known therapeutic substances.

2.6.1.5. Plant protection products which, because of particular properties, or which, if mishandled or misused, could lead to a high degree of risk must be subject to particular restrictions such as restrictions on the size of packaging, formulation type, distribution, use or manner of use. Moreover, plant protection products which are classified as very toxic may not be authorised for use by non-professional users.

2.6.1.6. Waiting and re-entry safety periods or other precautions must be established in such a way that no colonisation of or adverse effects on bystanders or workers exposed after application of the plant protection product are expected.

2.6.1.7. Waiting and re-entry safety periods or other precautions must be established in such a way that no colonisation of or adverse effects on animals are expected.

2.6.1.8. Waiting and re-entry periods or other precautions to ensure that no colonisation or adverse effects are expected must be realistic; if necessary, special precautionary measures must be prescribed.

2.6.1.9. The conditions of authorisation shall be in compliance with Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work ⁽¹⁾, and Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work ⁽²⁾. The experimental data and information relevant to the recognition of the symptoms of infection or pathogenicity and on the effectiveness of first aid and therapeutic measures provided shall be considered. The conditions of authorisation shall also be in compliance with Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work ⁽³⁾. The conditions of authorisation shall also be in compliance with Council Directive 89/656/EEC of 30 November 1989 on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace ⁽⁴⁾.

2.6.2. Effects on human and animal health arising from residues

2.6.2.1. No authorisation shall be granted unless there is sufficient information for plant protection products containing the micro-organism, to decide that there is no harmful effect on human or animal health arising from exposure to the micro-organism, its residual traces and metabolites/toxins remaining in or on plants or plant products.

2.6.2.2. No authorisation shall be granted unless viable residues and/or non-viable residues occurring reflect the minimum quantities of the plant protection product necessary to achieve adequate control corresponding to good agricultural practice, applied in such a manner (including pre-harvest intervals or withholding periods or storage periods) that the viable residues and/or toxins at harvest, slaughter or after storage are reduced to a minimum.

2.7. *Fate and behaviour in the environment*

2.7.1. No authorisation shall be granted if the available information indicates that there may be unacceptable adverse environmental effects due to the fate and behaviour of the plant protection product in the environment.

2.7.2. No authorisation shall be granted if contamination of ground water, surface water or drinking water expected as a result of the use of a plant protection product under the proposed conditions of use, may cause interference with the analytical systems for the control of the quality of drinking water provided for in Directive 98/83/EC.

2.7.3. No authorisation shall be granted if the contamination of groundwater expected as a result of the use of a plant protection product under the proposed conditions of use contravenes or exceeds whichever of the following is the lower:

(a) the parameters or maximum permissible concentrations laid down by Directive 98/83/EC, or

(b) the parameters or maximum permissible concentrations laid down for components in the plant protection product such as relevant metabolites/toxins in accordance with Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy ⁽⁵⁾, or

⁽¹⁾ OJ L 131, 5.5.1998, p. 11.

⁽²⁾ OJ L 262, 17.10.2000, p. 21.

⁽³⁾ OJ L 158, 30.4.2004 p. 50.

⁽⁴⁾ OJ L 393, 30.12.1989, p. 18.

⁽⁵⁾ OJ L 327, 22.12.2000, p. 1. Directive as amended by Decision No 2455/2001/EC.

- (c) the parameters for the micro-organism or the maximum concentration laid down by the Commission for components in the plant protection product such as relevant metabolites/toxins when including the micro-organism in Annex I, on the basis of appropriate data, in particular, toxicological data, or, where that concentration has not been laid down, the concentration corresponding to 1/10 of the acceptable daily intake (ADI) laid down when the micro-organism was included in Annex I,

unless it is scientifically demonstrated that under relevant field conditions the lower of the parameters or concentrations is not contravened or exceeded.

- 2.7.4. No authorisation shall be granted if the contamination of surface water expected as a result of the use of a plant protection product under the proposed conditions of use:

- (a) exceeds, where the surface water in or from the area of envisaged use is intended for the extraction of drinking water, the parameters or values established in accordance with Council Directive 75/440/EEC of 16 June 1975 concerning the quality required of surface water intended for the abstraction of drinking water in the Member States ⁽¹⁾, or
- (b) exceeds the parameters or values for components in the plant protection product, such as relevant metabolites/toxins, established in accordance with Directive 2000/60/EC or
- (c) has an impact deemed unacceptable on non-target species, including animals, according to the relevant requirements provided for in point 2.8.

The proposed instruction for use of the plant protection product, including procedures for cleaning application equipment, must be such that the likelihood of accidental contamination of surface water is reduced to a minimum.

- 2.7.5. No authorisation shall be granted if it is known that transfer of genetic material from the micro-organism to other organisms, may lead to unacceptable effects on the environment.
- 2.7.6. No authorisation shall be granted unless there is sufficient information on the possible persistence/competitiveness of the micro-organism and relevant secondary metabolites/toxins in or on the crop under the environmental conditions prevailing at and following the intended use.
- 2.7.7. No authorisation shall be granted if it can be expected that the micro-organism and/or its possible relevant metabolites/toxins will persist in the environment in concentrations considerably higher than the natural background levels, taking into account repeated applications over the years, unless a robust risk assessment indicates that the risks from accumulated plateau concentrations are acceptable.

2.8. *Effects on non-target organisms*

Member States shall ensure that the available information is sufficient to permit a decision to be taken as to whether or not there may be unacceptable effects on non-target species (flora and fauna), due to exposure to the plant protection product containing the micro-organism following its intended use.

Member States shall pay special attention to possible effects on beneficial organisms used for biological control and organisms playing an important role in integrated control.

⁽¹⁾ OJ L 194, 25.7.1975, p. 26. Directive to be repealed from 22.12.2007 by Directive 2000/60/EC (OJ L 327, 22.12. 2000, p. 1).

2.8.1. Where there is a possibility of birds and other non-target terrestrial vertebrates being exposed, no authorisation shall be granted if:

- (a) the micro-organism is pathogenic to birds and other non-target terrestrial vertebrates,
- (b) in case of toxic effects due to components in the plant protection product, such as relevant metabolites/toxins, the toxicity/exposure ratio is less than 10 on the basis of the acute LD₅₀ value or the long-term toxicity/exposure ratio is less than 5, unless it is clearly established through an appropriate risk assessment that under field conditions no unacceptable effects occur — directly or indirectly — after use of the plant protection product according to the proposed conditions of use.

2.8.2. Where there is a possibility of aquatic organisms being exposed, no authorisation shall be granted if:

- (a) the micro-organism is pathogenic to aquatic organisms,
- (b) in case of toxic effects due to components in the plant protection product such as relevant metabolites/toxins, the toxicity/exposure ratio is less than 100 in case of acute toxicity (EC₅₀) to daphnia and fish and 10 for long-term/chronic toxicity to algae (EC₅₀), daphnia (NOEC) and fish (NOEC), unless it is clearly established through an appropriate risk assessment that under field conditions no unacceptable impact on the viability of exposed species occurs — directly or indirectly — after use of the plant protection product according to the proposed conditions of use.

2.8.3. Where there is a possibility of bees being exposed, no authorisation shall be granted:

- (a) if the micro-organism is pathogenic to bees,
- (b) in case of toxic effects due to components in the plant protection product such as relevant metabolites/toxins, the hazard quotients for oral or contact exposure of honeybees are greater than 50, unless it is clearly established through an appropriate risk assessment that under field conditions there are no unacceptable effects on honeybee larvae, honeybee behaviour, or colony survival and development after use of the plant protection product according to the proposed conditions of use.

2.8.4. Where there is a possibility of arthropods other than bees being exposed, no authorisation shall be granted if:

- (a) the micro-organism is pathogenic to arthropods other than bees,
- (b) in case of toxic effects due to components in the plant protection product such as relevant metabolites/toxins, unless it is clearly established through an appropriate risk assessment that under field conditions there is no unacceptable impact on those organisms after use of the plant protection product according to the proposed conditions of use. Any claims for selectivity and proposals for use in integrated pest management systems shall be substantiated by appropriate data.

2.8.5. Where there is a possibility of earthworms being exposed, no authorisation shall be granted if the micro-organism is pathogenic to earthworms or in the case of toxic effects due to components in the plant protection product such as relevant metabolites/toxins, the acute toxicity/exposure ratio is less than 10, or the long-term toxicity/exposure ratio is less than 5, unless it is clearly established through an appropriate risk assessment that under field conditions earthworm populations are not at risk after use of the plant protection product according to the proposed conditions of use.

- 2.8.6. Where there is a possibility of non-target soil micro-organisms being exposed, no authorisation shall be granted if the nitrogen or carbon mineralisation processes in laboratory studies are affected by more than 25 % after 100 days, unless it is clearly established through an appropriate risk assessment that under field conditions there is no unacceptable impact on the microbial community after use of the plant protection product according to the proposed conditions of use, taking account of the ability of micro-organisms to multiply.
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II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DECISION

of 14 March 2005

on the conclusion of the bilateral agreement between the European Community and the Republic of Serbia on trade in textile products

(2005/272/EC)

THE COUNCIL OF THE EUROPEAN UNION,

HAS DECIDED AS FOLLOWS:

Article 1

Having regard to the Treaty establishing the European Community, and in particular Article 133 in conjunction with the first sentence of the first subparagraph of Article 300 (2) thereof,

The Agreement between the European Community and the Republic of Serbia on trade in textile products is hereby approved on behalf of the Community.

The text of the Agreement is attached to this Decision.

Having regard to the proposal from the Commission,

Article 2

Whereas:

The President of the Council is hereby authorised to designate the person(s) empowered to sign, on behalf of the Community, the Agreement in order to bind the Community.

- (1) The Commission has negotiated on behalf of the Community a bilateral agreement on trade in textile products with the Republic of Serbia.

Done at Brussels, 14 March 2005.

- (2) The Agreement should be approved on behalf of the Community,

For the Council
The President
F. BODEN

AGREEMENT**between the European Community and the Republic of Serbia on trade in textile products**

THE EUROPEAN COMMUNITY, hereinafter referred to as 'the Community',

of the one part,

and

THE REPUBLIC OF SERBIA, hereinafter referred to as 'Serbia',

of the other part,

DESIRING to promote, with a view to permanent cooperation and in conditions providing every security for trade, the orderly and equitable development of trade in textile products between the Community and Serbia (hereinafter referred to together as Parties), as a further step towards deeper trade and political relations including substantial trade liberalisation between the two Parties in the framework of the Stabilisation and Association process;

CONSIDERING that United Nations Security Council Resolution 1244 (1999) established an international civil presence in order to provide an interim administration for Kosovo (United Nations Interim Administration Mission in Kosovo), and it is not possible at this time to apply the obligations undertaken in this Agreement in Kosovo,

HAVE AGREED AS FOLLOWS:

Article 1

This Agreement establishes the regime applicable to trade of textile products originating in the Community and in Serbia listed in Annex I.

TITLE I**BASIC PROVISIONS***Article 2*

The Parties agree that:

1. the rates of customs duties applicable in Serbia to textile products originating in the Community shall be dismantled according to the schedule in Annex II;

2. the Community will continue to grant duty free treatment to textile products originating in Serbia in accordance with the applicable Community legislation.

Article 3

1. Quantitative restrictions on imports of textile products listed in Annex I into Serbia of goods originating in the Community and measures having equivalent effect, including non-tariff barriers as specified, in particular, in Annex III, shall not be maintained nor introduced from the date of application of this Agreement except as provided under Articles 5 and 7.

2. Without prejudice to Article 4(1), quantitative restrictions on imports of textile products listed in Annex I into the Community of goods originating in Serbia shall be suspended. Measures having equivalent effect, including non-tariff barriers as specified, in particular, in Annex III, shall not be maintained nor introduced from the date of application of this Agreement, except as provided for under Articles 5, 6 and 7.

Article 4

1. The Community will suspend the quantitative restrictions currently in force for categories listed in Annex IV, as soon as Serbia notifies to the Community that it has implemented its commitments under Article 2(1).

2. Title II lays down the arrangements applicable to quantitative restrictions and the surveillance regime.

Article 5

1. Either Party retains the right to suspend its obligations in Articles 2, 3 and in Article 4(1) should the other Party fail to fulfil its obligations.

2. If the Community re-introduces quantitative restrictions, they shall be established at the year 2004 levels, increased by annual growth rates as last applied for that year.

3. The Parties agree to consult with each other before exercising their rights, in accordance with Article 8.

Article 6

1. With a view to ensuring the effective functioning of this Agreement, the Parties agree to cooperate fully in order to prevent, to investigate and to take any necessary legal and/or administrative action against circumvention by transshipment, re-routing, false declaration concerning the country or place of origin, falsification of documents, false declaration concerning fibre content, quantities, description or classification of merchandise and by whatever other means. Accordingly, the Parties agree to establish the necessary legal provisions and administrative procedures permitting effective action to be taken against such circumvention, which shall include the adoption of legally binding corrective measures against exporters and/or importers involved.

2. If it appears on the basis of available information that this Agreement is circumvented, the Community will consult with Serbia in accordance with Article 8.

3. If the Parties fail to reach a mutually satisfactory solution, the Community shall have the right:

- (a) to introduce quantitative restrictions against the same products originating in Serbia as those involved in circumvention or to take any other appropriate measures;
- (b) to set off the relevant quantities against the quantitative restrictions that are established under this Agreement.

4. Where available information shows that false declaration concerning fibre content, quantities, description or classification of products originating in Community or in Serbia has occurred, both Parties shall have the right to refuse to import the products in question.

5. The Parties agree to establish a system of administrative cooperation to prevent and to address effectively all problems arising from circumvention in accordance with Annex V.

Article 7

1. Where as a direct consequence of the application of the liberalisation measures provided for in this Agreement any product is being imported in such increased quantities and under such conditions as to cause or threaten to cause:

- (a) serious injury to domestic producers of like or directly competitive products in the territory of the importing Party, or
- (b) serious disturbances in any related sector of the economy or difficulties which could bring about deterioration in the economic situation of a region,

the Party concerned may take appropriate measures after consultations are held in accordance with Article 8. In

case the other Party considers the measure adopted is not justified, it shall be free to suspend the application of substantially equivalent concessions granted under this Agreement after consultations are held in accordance with Article 8.

2. The Parties may request consultations in accordance with Article 8 when either of them ascertains that during a particular year of application of this Agreement difficulties arise in the Community or in Serbia due to a sharp and substantial increase, by comparison to the preceding year, in imports of a given category of Group I.

Article 8

1. The consultation procedures referred to in this Agreement shall be governed by the following provisions:

- (a) any request for consultations shall be notified in writing to the other Party;
- (b) the request for consultations shall be followed, within a reasonable period of time and in any case not later than 15 days following the notification, by a report setting out the circumstances which, in the opinion of the requesting Party, justify the submission of such a request;
- (c) the Parties shall enter into consultations within 30 days of notification of the request at the latest, with a view to reaching a mutually acceptable solution within a further 30-day period at the latest, unless this period is extended by common accord.

2. At the request of either of the Parties, consultations shall be held on any problems arising from the application of this Agreement. Any consultations held under this Article shall take place in a spirit of cooperation and with a desire to reconcile the differences between the Parties.

TITLE II

**QUANTITATIVE RESTRICTIONS AND SURVEILLANCE
REGIME**

Article 9

1. The classification of the products covered by this Agreement is based on the tariff and statistical nomenclature of the Community (hereinafter referred to as the Combined Nomenclature or, in abbreviated form, CN) and any amendments thereof.

Where any decision on classification results in a change of classification practice or a change of category of any product subject to this Agreement the affected products shall follow the trade regime applicable to the practice or category they fall into after such changes.

Any amendment to the Combined Nomenclature made in accordance with the procedures in force in the Community concerning categories of products covered by this Agreement or any decision relating to the classification of goods shall not have the effect of reducing quantitative restrictions introduced pursuant to this Agreement.

2. The origin of the products covered by this Agreement shall be determined in accordance with the non-preferential rules of origin in force in the Community.

The origin of the products subject to the tariff dismantling schedule provided for in Article 2(1), shall be determined in accordance with Community rules that apply to autonomous preferential tariff measures for certain countries or territories. Any amendment to these rules of origin shall be communicated to Serbia.

The procedures for control of the origin of the products referred to above are laid down in Annex V.

Article 10

1. If quantitative restrictions are re-introduced in accordance with Articles 5, 6 and 7, exports of the textile products under quantitative restrictions shall be subject to a double-checking system as specified in Annex V.

2. Following consultations in accordance with the procedures set out in Article 8, exports of products in Annex I not subject to quantitative restrictions may be subject to the double-checking system referred to in Annex V or to a prior surveillance introduced by the Community.

Article 11

1. The Parties recognise that re-imports of textile products into the Community after processing in Serbia are a specific form of industrial and trade cooperation.

2. Should quantitative restrictions be established under the conditions specified in this Agreement, these re-imports shall not be subject to these quantitative restrictions if they are subject to the specific arrangements laid down in Title III.

Article 12

Exports from Serbia of cottage-industry fabrics woven on hand- or foot-operated looms, garments or other made-up articles obtained manually from such fabrics and of traditional folklore handicraft products shall not be subject to the quantitative restrictions established under this Agreement, provided that these products originating in Serbia meet the conditions laid down in Annex VI.

Article 13

1. Imports into the Community of textile products covered by this Agreement shall not be subject to any quantitative restrictions that may be established under this Agreement, provided that they are declared to be for re-export outside the Community in the same state or after processing, within the framework of the administrative system of control which exists within the Community.

However, the release into free circulation of products into the Community under the conditions referred to above shall be subject to the production of an export licence issued by the Ministry of International Economic Relations of Serbia, and to the production of a proof of origin in accordance with Annex V.

2. Where the Community authorities ascertain that imports of textile products have been set off against quantitative restrictions that may have been established under this Agreement, but that the products have subsequently been re-exported outside the Community, the authorities shall inform the Ministry of International Economic Relations of Serbia within four weeks of the quantities involved and authorise imports of identical quantities of the same products, which shall not be set off against the quantitative restriction established under this Agreement for the current or the following year, as appropriate.

Article 14

Should quantitative restrictions be introduced under this Agreement, the following provisions shall apply:

1. in any year advance use of a portion of the quantitative restriction established for the following year is authorised for each category of products up to 5 % of the quantitative restriction for the current year.

Amounts delivered in advance shall be deducted from the corresponding quantitative restrictions established for the following year;

2. carryover to the corresponding quantitative restriction for the following year of the amounts not used during any year is authorised for each category of products up to 10 % of the quantitative restriction for the current year;

3. transfers in respect of categories in group I shall not be made from any category except as follows:

— transfers between categories 1, 2 and 3 may be made up to 12 % of the quantitative restriction for the category to which the transfer is made,

— transfers between categories 4, 5, 6, 7 and 8 may be made up to 12 % of the quantitative restriction for the category to which the transfer is made.

Transfers into any category in groups II and III may be made from any category or categories in groups I, II and III up to 12 % of the quantitative restriction for the category to which the transfer is made;

4. the table of equivalence applicable to the transfers referred to is given in Annex I;
5. the increase in any category of products resulting from the cumulative application of the provisions in paragraphs 1, 2 and 3 during a year shall not exceed 17 %;
6. prior notification shall be given by the Ministry of International Economic Relations of Serbia in the event of recourse to the provisions of paragraphs 1, 2 and 3, at least 15 days in advance.

Article 15

The annual growth rate for the quantitative restrictions which may be introduced as provided for by this Agreement for the products covered by it shall be fixed by agreement between the Parties in accordance with the consultation procedures established in Article 8.

Article 16

1. The Ministry of International Economic Relations of Serbia shall supply the Commission of the European Communities with precise statistical information on all export licences issued for categories of textile products subject to the quantitative restrictions established under this Agreement or to a double-checking system, expressed in quantities and in terms of value and broken down by Member States of the Community, as well as on all certificates issued by the Customs Administration of Serbia for products referred to in Article 12 and subject to Annex VI.

2. The Community shall likewise transmit to the Ministry of International Economic Relations of Serbia precise statistical information on import authorisations issued by the Community authorities and import statistics for textile products.

3. The information referred to above shall, for all categories of products, be forwarded before the end of the month following the month to which the statistics relate.

4. Upon request by the Community, the Ministry of International Economic Relations of Serbia shall supply import statistics for all products covered by Annex I.

5. If on the basis of the information exchanged it appears that there are significant discrepancies between the returns for exports and those for imports, consultations may be initiated in accordance with the procedure specified in Article 8.

6. For the purpose of applying the provisions of this Agreement, the Community undertakes to provide the Ministry of International Economic Relations of Serbia before 15 April of each year with the preceding year's statistics on imports of all textile products covered by this Agreement, broken down by supplying country and Member State.

Article 17

1. Serbia shall monitor its exports of products under restraint or surveillance into the Community. Should a sudden and prejudicial change in traditional trade flows arise, the Community will be entitled to request consultations in order to find a satisfactory solution to those problems. Such consultations shall be held within 15 working days of their being requested by the Community.

2. Serbia shall endeavour to ensure that exports of textile products subject to quantitative restrictions, which may be established under this Agreement into the Community are spaced out as evenly as possible over the year, due account being taken in particular of seasonal factors.

Article 18

In the event of denunciation of this Agreement, the quantitative restrictions that may be established pursuant to it shall be reduced on a *pro rata temporis* basis unless the Parties decide otherwise by common agreement.

Article 19

The Parties undertake to refrain from discrimination in the allocation of export licences and import authorisations or documents referred to in Annexes V and VI.

TITLE III

OUTWARD PROCESS TRAFFIC (OPT)

Article 20

Re-imports into the Community, within the meaning of Article 11, shall be subject to this Agreement, unless the following special provisions provide otherwise.

1. Re-imports into the Community referred to in Article 11 may be made subject to specific quantitative restrictions following consultations in accordance with the procedures set out in Article 8, provided the products concerned are subject to quantitative restrictions pursuant to this Agreement, to a double-checking system or to surveillance measures.

2. Having regard to the interests of both Parties, the Community may at its discretion, or in response to a request under Article 8:

TITLE IV

FINAL PROVISIONS

- (a) examine the possibility of transferring from one category to another, using in advance or carrying over from one year to the next, portions of specific quantitative restrictions;
- (b) consider the possibility of increasing specific quantitative restrictions.

Article 21

The operation of this Agreement shall be reviewed prior to the accession of Serbia to the World Trade Organisation (WTO). Should Serbia become a Member of the WTO before the expiry of this Agreement, the Agreements and rules of the WTO shall be applied from the date of Serbia's accession to the WTO.

3. However, the Community may apply automatically the flexibility rules set out in paragraph 2 within the following restrictions:

Article 22

- (a) transfers between categories may not exceed 25 % of the quantity set for the category to which the transfer is made;
- (b) carry-over of a specific quantitative restriction from one year to the next may not exceed 13,5 % of the quantity set for the year of actual utilisation;
- (c) advance use of specific quantitative restrictions from one year to another may not exceed 7,5 % of the quantity set for the year of actual utilisation.

1. This Agreement shall apply, on the one hand, to the territories in which the Treaty establishing the Community is applied and under the conditions laid down in that Treaty and, on the other hand, to the territory of Serbia. As regards Serbia, this Agreement shall be binding and directly applicable for all its authorities.

2. This Agreement shall not apply in Kosovo which is at present under international administration pursuant to United Nations Security Council Resolution 1244 of 10 June 1999. This is without prejudice to the current status of Kosovo or the determination of its final status under the same Resolution.

Article 23

4. The Community shall inform Serbia of any measures taken pursuant to the preceding paragraphs.
5. The competent authorities in the Community shall debit the specific quantitative restrictions referred to in paragraph 1 at the time of issue of the prior authorisation required by the relevant Community legislation which governs economic outward processing arrangements. A specific quantitative restriction shall be debited for the year in which a prior authorisation is issued.
6. A certificate of origin made out by the organisations authorised to do so under the law of Serbia shall be issued, in accordance with Annex V, for all products covered by this Title. This certificate shall bear a reference to the prior authorisation mentioned in paragraph 5 as evidence that the processing operation it describes has been carried out in Serbia.

1. This Agreement shall enter into force on the first day of the second month following the date on which the Parties notify each other of the completion of the procedures necessary for that purpose. The Parties agree to review this Agreement in the light of possible negotiations on a Stabilisation and Association Agreement.

2. Either Party may at any time propose modifications to this Agreement.

3. Either Party may at any time denounce this Agreement provided that at least 60 days' notice is given. In that event, this Agreement shall come to an end on the expiry of the period of notice.

4. The Annexes attached to this Agreement shall form an integral part thereof.

Article 24

7. The Community shall provide Serbia with the names and addresses of, and specimens of the stamps used by, the competent authorities of the Community, which issue the prior authorisations referred to in paragraph 5.

This Agreement shall be drawn up in duplicate in the Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Slovakian, Slovenian, Spanish, Swedish and Serbian languages, each of these texts being equally authentic.

Hecho en Bruselas, el treinta y uno de marzo del dos mil cinco.

V Bruselu dne třicátého prvního března dva tisíce pět.

Udfærdiget i Bruxelles den enogtredivte marts to tusind og fire.

Geschehen zu Brüssel am einunddreißigsten März zweitausendfünf.

Kahe tuhande viienda aasta märtsikuu kolmekümne esimesel päeval Brüsselis.

Έγινε στις Βρυξέλλες, στις τριάντα μία Μαρτίου δύο χιλιάδες πέντε.

Done at Brussels on the thirty-first day of March in the year two thousand and five.

Fait à Bruxelles, le trente-et-un mars deux mille cinq.

Fatto a Bruxelles, addì trentuno marzo duemilacinque.

Briselē, divtūkstoš piektā gada trīsdesmit pirmajā martā.

Priimta du tūkstančiai penktų metų kovo trisdešimt pirmą dieną Briuselyje.

Kelt Brüsszelben, a kettőezer ötödik év március harmincegyedik napján.

Magħmul fi Brussel, fil-wiehed u tletin jum ta' Marzu tas-sena elfejn u hamsa.

Gedaan te Brussel, de eenendertigste maart tweeduizend vijf.

Sporządzono w Brukseli dnia trzydziestego pierwszego marca roku dwutysięcznego piątego.

Feito em Bruxelas, em trinta e um de Março de dois mil e cinco.

V Bruselju, enaintridesetega marca leta dva tisoč pet.

V Bruseli dňa tridsiateho prvého marca dvetisícpäť.

Tehty Brysselissä kolmantenakymmenentenäensimmäisenä päivänä maaliskuuta vuonna kaksituhattaviisi.

Som skedde i Bryssel den trettioförsta mars tjugohundrafem.

Сачињено у Бриселу тридесет првог марта две хиљаде и пете године.

Por la Comunidad Europea
Za Evropské společenství
For Det Europæiske Fællesskab
Für die Europäische Gemeinschaft
Euroopa Ühenduse nimel
Για την Ευρωπαϊκή Κοινότητα
For the European Community
Pour la Communauté européenne
Per la Comunità europea
Eiropas Kopienas vārdā
Europas bendrijos vardu
az Európai Közösség részéről
Għall-Komunità Ewropea
Voor de Europese Gemeenschap
W imieniu Wspólnoty Europejskiej
Pela Comunidade Europeia
Za Európske spoločenstvo
za Evropsko skupnost
Euroopan yhteisön puolesta
På Europeiska gemenskapens vägnar
За Европску заједницу

M. Schuman

Por la República de Serbia
Za Srbskou republiku
For Republikken Serbien
Für die Republik Serbien
Serbia Vabariigi nimel
Για τη Δημοκρατία της Σερβίας
For the Republic of Serbia
Pour la République de Serbie
Per la Repubblica di Serbia
Serbijas Republikas vārdā
Serbijos Respublikos vardu
a Szerb Köztársaság részéről
Ghar-Repubblika tas-Serbja
Voor de Republiek Servië
W imieniu Republiki Serbii
Pela República da Sérvia
Za Srbskú republiku
Za Republiko Srbijo
Serbian tasavallan puolesta
För Republiken Serbien
За Республику Србију

Milan P. Pavlovic

ANNEX I

TEXTILE PRODUCTS REFERRED TO IN ARTICLE 1

1. Without prejudice to the rules for the interpretation of the combined nomenclature, the wording of the description of goods is considered to be of indicative value only, since the products covered by each category are determined, within this Annex, by CN codes. Where there is an 'ex' symbol in front of a CN code, the products covered in each category are determined by the scope of the CN code and by that of the corresponding description.
2. When the constitutive material of the products of categories 1 to 114 is not specifically mentioned, these products are to be taken to be made exclusively of wool or of fine hair, of cotton or of man-made fibres.
3. Garments which are not recognisable as being garments for men or boys or as being garments for women or girls are classified with the latter.
4. Where the expression 'babies' garments' is used, this is meant to cover garments up to and including commercial size 86.

Category	Description CN code 2005	Table of equivalence	
		pieces/kg	g/piece
(1)	(2)	(3)	(4)

GROUP I A

1	Cotton yarn, not put up for retail sale		
	5204 11 00 5204 19 00 5205 11 00 5205 12 00 5205 13 00 5205 14 00 5205 15 10 5205 15 90 5205 21 00 5205 22 00 5205 23 00 5205 24 00 5205 26 00 5205 27 00 5205 28 00 5205 31 00 5205 32 00 5205 33 00 5205 34 00 5205 35 00 5205 41 00 5205 42 00 5205 43 00 5205 44 00 5205 46 00 5205 47 00 5205 48 00 5206 11 00 5206 12 00 5206 13 00 5206 14 00 5206 15 00 5206 21 00 5206 22 00 5206 23 00 5206 24 00 5206 25 00 5206 31 00 5206 32 00 5206 33 00 5206 34 00 5206 35 00 5206 41 00 5206 42 00 5206 43 00 5206 44 00 5206 45 00 ex 5604 90 00		
2	Woven fabrics of cotton, other than gauze, terry fabrics, pile fabrics, chenille fabrics, tulle and other net fabrics		
	5208 11 10 5208 11 90 5208 12 16 5208 12 19 5208 12 96 5208 12 99 5208 13 00 5208 19 00 5208 21 10 5208 21 90 5208 22 16 5208 22 19 5208 22 96 5208 22 99 5208 23 00 5208 29 00 5208 31 00 5208 32 16 5208 32 19 5208 32 96 5208 32 99 5208 33 00 5208 39 00 5208 41 00 5208 42 00 5208 43 00 5208 49 00 5208 51 00 5208 52 10 5208 52 90 5208 53 00 5208 59 00 5209 11 00 5209 12 00 5209 19 00 5209 21 00 5209 22 00 5209 29 00 5209 31 00 5209 32 00 5209 39 00 5209 41 00 5209 42 00 5209 43 00 5209 49 00 5209 51 00 5209 52 00 5209 59 00 5210 11 00 5210 12 00 5210 19 00 5210 21 00 5210 22 00 5210 29 00 5210 31 00 5210 32 00 5210 39 00 5210 41 00 5210 42 00 5210 49 00 5210 51 00 5210 52 00 5210 59 00 5211 11 00 5211 12 00 5211 19 00 5211 21 00 5211 22 00 5211 29 00 5211 31 00 5211 32 00 5211 39 00 5211 41 00 5211 42 00 5211 43 00 5211 49 10 5211 49 90 5211 51 00 5211 52 00 5211 59 00 5212 11 10 5212 11 90 5212 12 10 5212 12 90 5212 13 10 5212 13 90 5212 14 10 5212 14 90 5212 15 10 5212 15 90 5212 21 10 5212 21 90 5212 22 10 5212 22 90 5212 23 10 5212 23 90 5212 24 10 5212 24 90 5212 25 10 5212 25 90 ex 5811 00 00 ex 6308 00 00		

Category	Description CN code 2005	Table of equivalence	
		pieces/kg	g/piece
(1)	(2)	(3)	(4)
2 (a)	Of which: Other than unbleached or bleached		
	5208 31 00 5208 32 16 5208 32 19 5208 32 96 5208 32 99 5208 33 00 5208 39 00 5208 41 00 5208 42 00 5208 43 00 5208 49 00 5208 51 00 5208 52 10 5208 52 90 5208 53 00 5208 59 00 5209 31 00 5209 32 00 5209 39 00 5209 41 00 5209 42 00 5209 43 00 5209 49 00 5209 51 00 5209 52 00 5209 59 00 5210 31 00 5210 32 00 5210 39 00 5210 41 00 5210 42 00 5210 49 00 5210 51 00 5210 52 00 5210 59 00 5211 31 00 5211 32 00 5211 39 00 5211 41 00 5211 42 00 5211 43 00 5211 49 10 5211 49 90 5211 51 00 5211 52 00 5211 59 00 5212 13 10 5212 13 90 5212 14 10 5212 14 90 5212 15 10 5212 15 90 5212 23 10 5212 23 90 5212 24 10 5212 24 90 5212 25 10 5212 25 90 ex 5811 00 00 ex 6308 00 00		
3	Woven fabrics of synthetic fibres (discontinuous or waste) other than narrow woven fabrics, pile fabrics (including terry fabrics) and chenille fabrics		
	5512 11 00 5512 19 10 5512 19 90 5512 21 00 5512 29 10 5512 29 90 5512 91 00 5512 99 10 5512 99 90 5513 11 20 5513 11 90 5513 12 00 5513 13 00 5513 19 00 5513 21 10 5513 21 30 5513 21 90 5513 22 00 5513 23 00 5513 29 00 5513 31 00 5513 32 00 5513 33 00 5513 39 00 5513 41 00 5513 42 00 5513 43 00 5513 49 00 5514 11 00 5514 12 00 5514 13 00 5514 19 00 5514 21 00 5514 22 00 5514 23 00 5514 29 00 5514 31 00 5514 32 00 5514 33 00 5514 39 00 5514 41 00 5514 42 00 5514 43 00 5514 49 00 5515 11 10 5515 11 30 5515 11 90 5515 12 10 5515 12 30 5515 12 90 5515 13 11 5515 13 19 5515 13 91 5515 13 99 5515 19 10 5515 19 30 5515 19 90 5515 21 10 5515 21 30 5515 21 90 5515 22 11 5515 22 19 5515 22 91 5515 22 99 5515 29 00 5515 91 10 5515 91 30 5515 91 90 5515 92 10 5515 92 90 5515 99 10 5515 99 30 5515 99 90 ex 5803 90 40 ex 5905 00 70 ex 6308 00 00		
3 (a)	Of which: Other than unbleached or bleached		
	5512 19 10 5512 19 90 5512 29 10 5512 29 90 5512 99 10 5512 99 90 5513 21 10 5513 21 30 5513 21 90 5513 22 00 5513 23 00 5513 29 00 5513 31 00 5513 32 00 5513 33 00 5513 39 00 5513 41 00 5513 42 00 5513 43 00 5513 49 00 5514 21 00 5514 22 00 5514 23 00 5514 29 00 5514 31 00 5514 32 00 5514 33 00 5514 39 00 5514 41 00 5514 42 00 5514 43 00 5514 49 00 5515 11 30 5515 11 90 5515 12 30 5515 12 90 5515 13 19 5515 13 99 5515 19 30 5515 19 90 5515 21 30 5515 21 90 5515 22 19 5515 22 99 ex 5515 29 00 5515 91 30 5515 91 90 ex 5515 92 10 ex 5515 92 90 5515 99 30 5515 99 90 ex 5803 90 40 ex 5905 00 70 ex 6308 00 00		
GROUP I B			
4	Shirts, T-shirts, lightweight fine knit roll, polo or turtle necked jumpers and pullovers (other than of wool or fine animal hair), undervests and the like, knitted or crocheted	6,48	154
	6105 10 00 6105 20 10 6105 20 90 6105 90 10 6109 10 00 6109 90 10 6109 90 30 6110 20 10 6110 30 10		

Category	Description CN code 2005	Table of equivalence	
		pieces/kg	g/piece
(1)	(2)	(3)	(4)
5	Jerseys, pullovers, slip-overs, waistcoats, twinsets, cardigans, bed-jackets and jumpers (others than jackets and blazers), anoraks, wind-cheaters, waister jackets and the like, knitted or crocheted	4,53	221
	6101 10 90 6101 20 90 6101 30 90 6102 10 90 6102 20 90 6102 30 90 6110 11 10 6110 11 30 6110 11 90 6110 12 10 6110 12 90 6110 19 10 6110 20 90 6110 20 91 6110 20 99 6110 30 91 6110 30 99		
6	Men's or boys' woven breeches, shorts other than swimwear and trousers (including slacks); women's or girls' woven trousers and slacks, of wool, of cotton or of man made fibres; lower parts of track suits with lining, others than category 16 or 29, of cotton or of man-made fibres	1,76	568
	6203 41 10 6203 41 90 6203 42 31 6203 42 33 6203 42 35 6203 42 90 6203 43 19 6203 43 90 6203 49 19 6203 49 50 6204 61 10 6204 62 31 6204 62 33 6204 62 39 6204 63 18 6204 69 18 6211 32 42 6211 33 42 6211 42 42 6211 43 42		
7	Women's or girls' blouses, shirts and shirt-blouses, whether or not knitted or crocheted, of wool, of cotton or man-made fibres	5,55	180
	6106 10 00 6106 20 00 6106 90 10 6206 20 00 6206 30 00 6206 40 00		
8	Men's or boys' shirts, other than knitted or crocheted, of wool, cotton or man-made fibres	4,60	217
	6205 10 00 6205 20 00 6205 30 00		

GROUP II A

9	Terry towelling and similar woven terry fabrics of cotton; toilet linen and kitchen linen, other than knitted or crocheted, of terry towelling and woven terry fabrics, of cotton		
	5802 11 00 5802 19 00 ex 6302 60 00		
20	Bed linen, other than knitted or crocheted		
	6302 21 00 6302 22 90 6302 29 90 6302 31 00 6302 32 90 6302 39 90		
22	Yarn of staple or waste synthetic fibres, not put up for retail sale		
	5508 10 10 5509 11 00 5509 12 00 5509 21 00 5509 22 00 5509 31 00 5509 32 00 5509 41 00 5509 42 00 5509 51 00 5509 52 00 5509 53 00 5509 59 00 5509 61 00 5509 62 00 5509 69 00 5509 91 00 5509 92 00 5509 99 00		
22 (a)	Of which acrylic		
	ex 5508 10 10 5509 31 00 5509 32 00 5509 61 00 5509 62 00 5509 69 00		

Category	Description CN code 2005	Table of equivalence	
		pieces/kg	g/piece
(1)	(2)	(3)	(4)
23	Yarn of staple or waste artificial fibres, not put up for retail sale		
	5508 20 10 5510 11 00 5510 12 00 5510 20 00 5510 30 00 5510 90 00		
32	Woven pile fabrics and chenille fabrics (other than terry towelling or terry fabrics of cotton and narrow woven fabrics) and tufted textile surfaces, of wool, of cotton or of man-made textile fibres		
	5801 10 00 5801 21 00 5801 22 00 5801 23 00 5801 24 00 5801 25 00 5801 26 00 5801 31 00 5801 32 00 5801 33 00 5801 34 00 5801 35 00 5801 36 00 5802 20 00 5802 30 00		
32 (a)	Of which: Cotton corduroy		
	5801 22 00		
39	Table linen, toilet linen and kitchen linen, other than knitted or crocheted, other than of terry towelling or a similar terry fabrics of cotton		
	6302 51 00 6302 53 90 ex 6302 59 00 6302 91 00 6302 93 90 ex 6302 99 00		
GROUP II B			
12	Panty-hose and tights, stockings, understockings, socks, ankle-socks, sockettes and the like, knitted or crocheted, other than for babies, including stockings for varicose veins, other than products of category 70	24,3 pairs	41
	6115 12 00 6115 19 00 6115 20 11 6115 20 90 6115 91 00 6115 92 00 6115 93 10 6115 93 30 6115 93 99 6115 99 00		
13	Men's or boys' underpants and briefs, women's or girls' knickers and briefs, knitted or crocheted, of wool, of cotton or of man-made fibres	17	59
	6107 11 00 6107 12 00 6107 19 00 6108 21 00 6108 22 00 6108 29 00 ex 6212 10 10		
14	Men's or boys' woven overcoats, raincoats and other coats, cloaks and capes, of wool, of cotton or of man-made textile fibres (other than parkas) (of category 21)	0,72	1 389
	6201 11 00 ex 6201 12 10 ex 6201 12 90 ex 6201 13 10 ex 6201 13 90 6210 20 00		
15	Women's or girls' woven overcoats, raincoats and other coats, cloaks and capes; jackets and blazers, of wool, of cotton or of man-made textile fibres (other than parkas) (of category 21)	0,84	1 190
	6202 11 00 ex 6202 12 10 ex 6202 12 90 ex 6202 13 10 ex 6202 13 90 6204 31 00 6204 32 90 6204 33 90 6204 39 19 6210 30 00		
16	Men's or boys' suits and ensembles, other than knitted or crocheted, of wool, of cotton or of man-made fibres, excluding ski suits; men's or boys' track suits with lining, with an outer shell of a single identical fabric, of cotton or of man-made fibres	0,80	1 250
	6203 11 00 6203 12 00 6203 19 10 6203 19 30 6203 21 00 6203 22 80 6203 23 80 6203 29 18 6211 32 31 6211 33 31		

Category	Description CN code 2005	Table of equivalence	
		pieces/kg	g/piece
(1)	(2)	(3)	(4)
17	Men's or boys' jackets or blazers, other than knitted or crocheted, of wool, of cotton or of man-made fibres	1,43	700
	6203 31 00 6203 32 90 6203 33 90 6203 39 19		
18	Men's or boys' singlets and other vests, underpants, briefs, nightshirts, pyjamas, bathrobes, dressing gowns and similar articles, other than knitted or crocheted		
	6207 11 00 6207 19 00 6207 21 00 6207 22 00 6207 29 00 6207 91 00 6207 92 00 6207 99 00		
	Women's or girls' singlets and other vests, slips, petticoats, briefs, panties, night-dresses, pyjamas, negligees, bathrobes, dressing gowns and similar articles, other than knitted or crocheted		
	6208 11 00 6208 19 00 6208 21 00 6208 22 00 6208 29 00 6208 91 00 6208 92 00 6208 99 00 ex 6212 10 10		
19	Handkerchiefs, other than knitted or crocheted	59	17
	6213 20 00 6213 90 00		
21	Parkas; anoraks, windcheaters, waister jackets and the like, other than knitted or crocheted, of wool, of cotton or of man-made fibres; upper parts of tracksuits with lining, other than category 16 or 29, of cotton or of man-made fibres	2,3	435
	ex 6201 12 10 ex 6201 12 90 ex 6201 13 10 ex 6201 13 90 6201 91 00 6201 92 00 6201 93 00 ex 6202 12 10 ex 6202 12 90 ex 6202 13 10 ex 6202 13 90 6202 91 00 6202 92 00 6202 93 00 6211 32 41 6211 33 41 6211 42 41 6211 43 41		
24	Men's or boys' nightshirts, pyjamas, bathrobes, dressing gowns and similar articles, knitted or crocheted	3,9	257
	6107 21 00 6107 22 00 6107 29 00 6107 91 00 6107 92 00 ex 6107 99 00		
	Women's or girls' night-dresses, pyjamas, negligees, bathrobes, dressing gowns and similar articles, knitted or crocheted		
	6108 31 00 6108 32 00 6108 39 00 6108 91 00 6108 92 00 ex 6108 99 00		
26	Women's or girls' dresses, of wool, of cotton or of man-made fibres	3,1	323
	6104 41 00 6104 42 00 6104 43 00 6104 44 00 6204 41 00 6204 42 00 6204 43 00 6204 44 00		
27	Women's or girls' skirts, including divided skirts	2,6	385
	6104 51 00 6104 52 00 6104 53 00 6104 59 00 6204 51 00 6204 52 00 6204 53 00 6204 59 10		
28	Trousers, bib and brace overalls, breeches and shorts (other than swimwear), knitted or crocheted, of wool, of cotton or of man-made fibres	1,61	620
	6103 41 00 6103 42 00 6103 43 00 ex 6103 49 00 6104 6100 6104 6200 6104 63 00 ex 6104 69 00		

Category	Description CN code 2005	Table of equivalence	
		pieces/kg	g/piece
(1)	(2)	(3)	(4)
29	Women's or girls' suits and ensembles, other than knitted or crocheted, of wool, of cotton or of man-made fibres, excluding ski suits; women's or girls' track suits with lining, with an outer shell of an identical fabric, of cotton or of man-made fibres	1,37	730
	6204 11 00 6204 12 00 6204 13 00 6204 19 10 6204 21 00 6204 22 80 6204 23 80 6204 29 18 6211 42 31 6211 43 31		
31	Brassières, woven, knitted or crocheted	18,2	55
	ex 6212 10 10 6212 10 90		
68	Babies' garments and clothing accessories, excluding babies' gloves, mittens and mitts of categories 10 and 87, and babies' stockings, socks and sockettes, other than knitted or crocheted, of category 88		
	6111 10 90 6111 20 90 6111 30 90 ex 6111 90 00 ex 6209 10 00 ex 6209 20 00 ex 6209 30 00 ex 6209 90 00		
73	Track suits of knitted or crocheted fabric, of wool, of cotton or of man-made textile fibres	1,67	600
	6112 11 00 6112 12 00 6112 19 00		
76	Men's or boys' industrial or occupational clothing, other than knitted or crocheted		
	6203 22 10 6203 23 10 6203 29 11 6203 32 10 6203 33 10 6203 39 11 6203 42 11 6203 42 51 6203 43 11 6203 43 31 6203 49 11 6203 49 31 6211 32 10 6211 33 10		
	Women's or girls' aprons, smock overalls and other industrial or occupational clothing, other than knitted or crocheted		
	6204 22 10 6204 23 10 6204 29 11 6204 32 10 6204 33 10 6204 39 11 6204 62 11 6204 62 51 6204 63 11 6204 63 31 6204 69 11 6204 69 31 6211 42 10 6211 43 10		
77	Ski suits, other than knitted or crocheted		
	ex 6211 20 00		
78	Garments, other than knitted or crocheted, excluding garments of categories 6, 7, 8, 14, 15, 16, 17, 18, 21, 26, 27, 29, 68, 72, 76 and 77		
	6203 41 30 6203 42 59 6203 43 39 6203 49 39 6204 61 85 6204 62 59 6204 62 90 6204 63 39 6204 63 90 6204 69 39 6204 69 50 6210 40 00 6210 50 00 6211 31 00 6211 32 90 6211 33 90 6211 41 00 6211 42 90 6211 43 90		
83	Overcoats, jackets, blazers and other garments, including ski suits, knitted or crocheted, excluding garments of categories 4, 5, 7, 13, 24, 26, 27, 28, 68, 69, 72, 73, 74, 75		
	6101 10 10 6101 20 10 6101 30 10 6102 10 10 6102 20 10 6102 30 10 6103 31 00 6103 32 00 6103 33 00 ex 6103 39 00 6104 31 00 6104 32 00 6104 33 00 ex 6104 39 00 6112 20 00 6113 00 90 6114 10 00 6114 20 00 6114 30 00		

Category	Description CN code 2005	Table of equivalence	
		pieces/kg	g/piece
(1)	(2)	(3)	(4)
GROUP III A			
33	Woven fabrics of synthetic filament yarn obtained from strip or the like of polyethylene or polypropylene, less than 3 m wide		
	5407 20 11		
	Sacks and bags, of a kind used for the packing of goods, not knitted or crocheted, obtained from strip or the like		
	6305 32 81 6305 32 89 6305 33 91 6305 33 99		
34	Woven fabrics of synthetic filament yarn obtained from strip or the like of polyethylene or polypropylene, 3 m or more wide		
	5407 20 19		
35	Woven fabrics of synthetic fibres (continuous), other than those for tyres of category 114		
	5407 10 00 5407 20 90 5407 30 00 5407 41 00 5407 42 00 5407 43 00 5407 44 00 5407 51 00 5407 52 00 5407 53 00 5407 54 00 5407 61 10 5407 61 30 5407 61 50 5407 61 90 5407 69 10 5407 69 90 5407 71 00 5407 72 00 5407 73 00 5407 74 00 5407 81 00 5407 82 00 5407 83 00 5407 84 00 5407 91 00 5407 92 00 5407 93 00 5407 94 00 ex 5811 00 00 ex 5905 00 70		
35 (a)	Of which: Other than unbleached or bleached		
	ex 5407 10 00 ex 5407 20 90 ex 5407 30 00 5407 42 00 5407 43 00 5407 44 00 5407 52 00 5407 53 00 5407 5400 5407 61 30 5407 61 50 5407 61 90 5407 69 90 5407 72 00 5407 73 00 5407 74 00 5407 82 00 5407 83 00 5407 84 00 5407 92 00 5407 93 00 5407 94 00 ex 5811 00 00 ex 5905 00 70		
36	Woven fabrics of continuous artificial fibres, other than those for tyres of category 114		
	5408 10 00 5408 21 00 5408 22 10 5408 22 90 5408 23 10 5408 23 90 5408 24 00 5408 31 00 5408 32 00 5408 33 00 5408 34 00 ex 5811 00 00 ex 5905 00 70		
36 (a)	Of which: Other than unbleached or bleached		
	ex 5408 10 00 5408 22 10 5408 22 90 5408 23 10 5408 23 90 5408 24 00 5408 32 00 5408 33 00 5408 34 00 ex 5811 00 00 ex 5905 00 70		
37	Woven fabrics of artificial staple fibres		
	5516 11 00 5516 12 00 5516 13 00 5516 14 00 5516 21 00 5516 22 00 5516 23 10 5516 23 90 5516 24 00 5516 31 00 5516 32 00 5516 33 00 5516 34 00 5516 41 00 5516 42 00 5516 43 00 5516 44 00 5516 91 00 5516 92 00 5516 93 00 5516 94 00 ex 5803 90 40 ex 5905 00 70		

Category	Description CN code 2005	Table of equivalence	
		pieces/kg	g/piece
(1)	(2)	(3)	(4)
37 (a)	Of which: Other than unbleached or bleached		
	5516 12 00 5516 13 00 5516 14 00 5516 22 00 5516 23 10 5516 23 90 5516 24 00 5516 32 00 5516 33 00 5516 34 00 5516 42 00 5516 43 00 5516 44 00 5516 92 00 5516 93 00 5516 94 00 ex 5803 90 40 ex 5905 00 70		
38 A	Knitted or crocheted synthetic curtain fabric including net curtain fabric		
	6005 31 10 6005 32 10 6005 33 10 6005 34 10 6006 31 10 6006 32 10 6006 33 10 6006 34 10		
38 B	Net curtains, other than knitted or crocheted		
	ex 6303 91 00 ex 6303 92 90 ex 6303 99 90		
40	Woven curtains (including drapes, interior blinds, curtain and bed valances and other furnishing articles), other than knitted or crocheted, of wool, of cotton or of man-made fibres		
	ex 6303 91 00 ex 6303 92 90 ex 6303 99 90 6304 19 10 ex 6304 19 90 6304 92 00 ex 6304 93 00 ex 6304 99 00		
41	Yarn of synthetic filament (continuous), not put up for retail sale, other than non textured single yarn untwisted or with a twist of not more than 50 turns/m		
	5401 10 12 5401 10 14 5401 10 16 5401 10 18 5402 10 10 5402 10 90 5402 20 00 5402 31 00 5402 32 00 5402 33 00 5402 39 10 5402 39 90 5402 49 10 5402 49 91 5402 49 99 5402 51 00 5402 52 00 5402 59 10 5402 59 90 5402 61 00 5402 62 00 5402 69 10 5402 69 90 ex 5604 20 00 ex 5604 90 00		
42	Yarn of continuous man-made fibres, not put up for retail sale		
	5401 20 10		
	Yarn of artificial fibres; yarn of artificial filaments, not put up for retail sale, other than single yarn of viscose rayon untwisted or with a twist of not more than 250 turns/m and single non textured yarn of cellulose acetate		
	5403 10 00 5403 20 00 ex 5403 32 00 ex 5403 33 00 5403 39 00 5403 41 00 5403 42 00 5403 49 00 ex 5604 20 00		
43	Yarn of man-made filament, yarn of artificial staple fibres, cotton yarn, put up for retail sale		
	5204 20 00 5207 10 00 5207 90 00 5401 10 90 5401 20 90 5406 10 00 5406 20 00 5508 20 90 5511 30 00		
46	Carded or combed sheep's or lambs' wool or other fine animal hair		
	5105 10 00 5105 21 00 5105 29 00 5105 31 00 5105 39 10 5105 39 90		
47	Yarn of carded sheep's or lambs' wool (woollen yarn) or of carded fine animal hair, not put up for retail sale		
	5106 10 10 5106 10 90 5106 20 10 5106 20 91 5106 20 99 5108 10 10 5108 10 90		

Category	Description CN code 2005	Table of equivalence	
		pieces/kg	g/piece
(1)	(2)	(3)	(4)
48	Yarn of combed sheep's or lambs' wool (worsted yarn) or of combed fine animal hair, not put up for retail sale		
	5107 10 10 5107 10 90 5107 20 10 5107 20 30 5107 20 51 5107 20 59 5107 20 91 5107 20 99 5108 20 10 5108 20 90		
49	Yarn of sheep's or lambs' wool or of combed fine animal hair, put up for retail sale		
	5109 10 10 5109 10 90 5109 90 10 5109 90 90		
50	Woven fabrics of sheep's or lambs' wool or of fine animal hair		
	5111 11 00 5111 19 10 5111 19 90 5111 20 00 5111 30 10 5111 30 30 5111 30 90 5111 90 10 5111 90 91 5111 90 93 5111 90 99 5112 11 00 5112 19 10 5112 19 90 5112 20 00 5112 30 10 5112 30 30 5112 30 90 5112 90 10 5112 90 91 5112 90 93 5112 90 99		
51	Cotton, carded or combed		
	5203 00 00		
53	Cotton gauze		
	5803 10 00		
54	Artificial staple fibres, including waste, carded, combed or otherwise processed for spinning		
	5507 00 00		
55	Synthetic staple fibres, including waste, carded, combed or otherwise processed for spinning		
	5506 10 00 5506 20 00 5506 30 00 5506 90 10 5506 90 90		
56	Yarn of synthetic staple fibres (including waste), put up for retail sale		
	5508 10 90 5511 10 00 5511 20 00		
58	Carpets, carpentines and rugs, knotted (made up or not)		
	5701 10 10 5701 10 90 5701 90 10 5701 90 90		
59	Carpets and other textile floor coverings, other than the carpets of category 58		
	5702 10 00 5702 31 10 5702 31 80 5702 32 10 5702 32 90 ex 5702 39 00 5702 41 00 5702 42 00 ex 5702 49 00 5702 51 00 5702 52 10 5702 52 90 ex 5702 59 00 5702 91 00 5702 92 10 5702 92 90 ex 5702 99 00 5703 10 00 5703 20 11 5703 20 19 5703 20 91 5703 20 99 5703 30 11 5703 30 19 5703 30 81 5703 30 89 5703 90 10 5703 90 90 5704 10 00 5704 90 00 5705 00 10 5705 00 30 ex 5705 00 90		
60	Tapestries, hand-made, of the type Gobelins, Flanders, Aubusson, Beauvais and the like, and needlework tapestries (e.g. petit point and cross stitch) made in panels and the like by hand		
	5805 00 00		

Category	Description CN code 2005	Table of equivalence	
		pieces/kg	g/piece
(1)	(2)	(3)	(4)
61	Narrow woven fabrics, and narrow fabrics (bolduc) consisting of warp without weft, assembled by means of an adhesive, other than labels and similar articles of category 62 Elastic fabrics and trimmings (not knitted or crocheted), made from textile materials assembled from rubber thread		
	ex 5806 10 00 5806 20 00 5806 31 00 5806 32 10 5806 32 90 5806 39 00 5806 40 00		
62	Chenille yarn (including flock chenille yarn), gimped yarn (other than metallised yarn and gimped horsehair yarn)		
	5606 00 91 5606 00 99		
	Tulle and other net fabrics but not including woven, knitted or crocheted fabrics, hand or mechanically-made lace, in the piece, in strips or in motifs		
	5804 10 11 5804 10 19 5804 10 90 5804 21 10 5804 21 90 5804 29 10 5804 29 90 5804 30 00		
	Labels, badges and the like of textile materials, not embroidered, in the piece, in strips or cut to shape or size, woven		
	5807 10 10 5807 10 90		
	Braids and ornamental trimmings in the piece; tassels, pompons and the like		
	5808 10 00 5808 90 00		
	Embroidery, in the piece, in strips or in motifs		
	5810 10 10 5810 10 90 5810 91 10 5810 91 90 5810 92 10 5810 92 90 5810 99 10 5810 99 90		
63	Knitted or crocheted fabric of synthetic fibres containing by weight 5 % or more elastomeric yarn and knitted or crocheted fabrics containing by weight 5 % or more of rubber thread		
	5906 91 00 ex 6002 40 00 6002 90 00 ex 6004 10 00 6004 90 00		
	Raschel lace and long-pile fabric of synthetic fibres		
	ex 6001 10 00 6003 30 10 6005 31 50 6005 32 50 6005 33 50 6005 34 50		
65	Knitted or crocheted fabric, other than those of categories 38 A and 63, of wool, of cotton or of man-made fibres		
	5606 00 10 ex 6001 10 00 6001 21 00 6001 22 00 ex 6001 29 00 6001 91 00 6001 92 00 ex 6001 99 00 ex 6002 40 00 6003 10 00 6003 20 00 6003 30 90 6003 40 00 ex 6004 10 00 6005 10 00 6005 21 00 6005 22 00 6005 23 00 6005 24 00 6005 31 90 6005 32 90 6005 33 90 6005 34 90 6005 41 00 6005 42 00 6005 43 00 6005 44 00 6006 10 00 6006 21 00 6006 22 00 6006 23 00 6006 24 00 6006 31 90 6006 32 90 6006 33 90 6006 34 90 6006 41 00 6006 42 00 6006 43 00 6006 44 00		
66	Travelling rugs and blankets, other than knitted or crocheted, of wool, of cotton or of man-made fibres		
	6301 10 00 6301 20 90 6301 30 90 ex 6301 40 90 ex 6301 90 90		

Category	Description CN code 2005	Table of equivalence	
		pieces/kg	g/piece
(1)	(2)	(3)	(4)
GROUP III B			
10	Gloves, mittens and mitts, knitted or crocheted	17	59
	6111 10 10 6111 20 10 6111 30 10 ex 6111 90 00 6116 10 20 6116 10 80 6116 91 00 6116 92 00 6116 93 00 6116 99 00	pairs	
67	Knitted or crocheted clothing accessories other than for babies; household linen of all kinds, knitted or crocheted; curtains (including drapes) and interior blinds, curtain or bed valances and other furnishing articles knitted or crocheted; knitted or crocheted blankets and travelling rugs, other knitted or crocheted articles including parts of garments or of clothing accessories		
	5807 90 90 6113 00 10 6117 10 00 6117 20 00 6117 80 10 6117 80 90 6117 90 00 6301 20 10 6301 30 10 6301 40 10 6301 90 10 6302 10 00 6302 40 00 ex 6302 60 00 6303 11 00 6303 12 00 6303 19 00 6304 11 00 6304 91 00 ex 6305 20 00 6305 32 11 ex 6305 32 90 6305 33 10 ex 6305 39 00 ex 6305 90 00 6307 10 10 6307 90 10		
67 (a)	Of which: Sacks and bags of a kind used for the packing of goods, made from polyethylene or polypropylene strip		
	6305 32 11 6305 33 10		
69	Women's and girls' slips and petticoats, knitted or crocheted	7,8	128
	6108 11 00 6108 19 00		
70	Panty-hose and tights of synthetic fibres, measuring per single yarn less than 67 decitex (6,7 tex)	30,4 pairs	33
	6115 11 00 6115 20 19		
	Women's full length hosiery of synthetic fibres		
	6115 93 91		
72	Swimwear, of wool, of cotton or of man-made fibres	9,7	103
	6112 31 10 6112 31 90 6112 39 10 6112 39 90 6112 41 10 6112 41 90 6112 49 10 6112 49 90 6211 11 00 6211 12 00		
74	Women's or girls' knitted or crocheted suits and ensembles, of wool, of cotton or of man-made fibres, excluding ski suits	1,54	650
	6104 11 00 6104 12 00 6104 13 00 ex 6104 19 00 6104 21 00 6104 22 00 6104 23 00 ex 6104 29 00		
75	Men's or boys' knitted or crocheted suits and ensembles, of wool, of cotton or of man-made fibres, excluding ski suit	0,80	1 250
	6103 11 00 6103 12 00 6103 19 00 6103 21 00 6103 22 00 6103 23 00 6103 29 00		

Category	Description CN code 2005	Table of equivalence	
		pieces/kg	g/piece
(1)	(2)	(3)	(4)
84	Shawls, scarves, mufflers, mantillas, veils and the like other than knitted or crocheted, of wool, of cotton or of man-made fibres		
	6214 20 00 6214 30 00 6214 40 00 6214 90 10		
85	Ties, bow ties and cravats other than knitted or crocheted, of wool, of cotton or of man-made fibres	17,9	56
	6215 20 00 6215 90 00		
86	Corsets, corset-belts, suspender belts, braces, suspenders, garters and the like, and parts thereof, whether or not knitted or crocheted	8,8	114
	6212 20 00 6212 30 00 6212 90 00		
87	Gloves, mittens and mitts, not knitted or crocheted		
	ex 6209 10 00 ex 6209 20 00 ex 6209 30 00 ex 6209 90 00 6216 00 00		
88	Stockings, socks and sockettes, not knitted or crocheted; other clothing accessories, parts of garments or of clothing accessories other than for babies, other than knitted or crocheted		
	ex 6209 10 00 ex 6209 20 00 ex 6209 30 00 ex 6209 90 00 6217 10 00 6217 90 00		
90	Twine, cordage, ropes and cables of synthetic fibres, plaited or not		
	5607 41 00 5607 49 11 5607 49 19 5607 49 90 5607 50 11 5607 50 19 5607 50 30 5607 50 90		
91	Tents		
	6306 21 00 6306 22 00 6306 29 00		
93	Sacks and bags, of a kind used for the packing of goods of woven fabrics, other than made from polyethylene or polypropylene strip		
	ex 6305 20 00 ex 6305 32 90 ex 6305 39 00		
94	Wadding of textile materials and articles thereof; textile fibres, not exceeding 5 mm in length (flock), textile dust and mill neeps		
	5601 10 10 5601 10 90 5601 21 10 5601 21 90 5601 22 10 5601 22 91 5601 22 99 5601 29 00 5601 30 00		
95	Felt and articles thereof, whether or not impregnated or coated, other than floor coverings		
	5602 10 19 5602 10 31 5602 10 39 5602 10 90 5602 21 00 ex 5602 29 00 5602 90 00 ex 5807 90 10 ex 5905 00 70 6210 10 10 6307 90 91		

Category	Description CN code 2005	Table of equivalence	
		pieces/kg	g/piece
(1)	(2)	(3)	(4)
96	Non-woven fabrics and articles of such fabrics, whether or not impregnated, coated, covered or laminated		
	5603 11 10 5603 11 90 5603 12 10 5603 12 90 5603 13 10 5603 13 90 5603 14 10 5603 14 90 5603 91 10 5603 91 90 5603 92 10 5603 92 90 5603 93 10 5603 93 90 5603 94 10 5603 94 90 ex 5807 90 10 ex 5905 00 70 6210 10 90 ex 6301 40 90 ex 6301 90 90 6302 22 10 6302 32 10 6302 53 10 6302 93 10 6303 92 10 6303 99 10 ex 6304 19 90 ex 6304 93 00 ex 6304 99 00 ex 6305 32 90 ex 6305 39 00 6307 10 30 ex 6307 90 99		
97	Nets and netting made of twine, cordage or rope and made up fishing nets of yarn, twine, cordage or rope		
	5608 11 11 5608 11 19 5608 11 91 5608 11 99 5608 19 11 5608 19 19 5608 19 30 5608 19 90 5608 90 00		
98	Other articles made from yarn, twine, cordage, cables or rope, other than textile fabrics, articles made from such fabrics and articles of category 97		
	5609 00 00 5905 00 10		
99	Textile fabrics coated with gum or amylaceous substances, of a kind used for the outer covers of books and the like; tracing cloth; prepared painting canvas; buckram and similar stiffened textile fabrics of a kind used for hat foundations		
	5901 10 00 5901 90 00		
	Linoleum, whether or not cut to shape; floor coverings consisting of a coating or covering applied on a textile backing, whether or not cut to shape		
	5904 10 00 5904 90 00		
	Rubberised textile fabric, not knitted or crocheted, excluding those for tyres		
	5906 10 00 5906 99 10 5906 99 90		
	Textile fabrics otherwise impregnated or coated; painted canvas being theatrical scenery, studio back-cloths, other than of category 100		
	5907 00 10 5907 00 90		
100	Textile fabrics impregnated, coated, covered or laminated with preparations of cellulose derivatives or of other artificial plastic materials		
	5903 10 10 5903 10 90 5903 20 10 5903 20 90 5903 90 10 5903 90 91 5903 90 99		
101	Twine, cordage, ropes and cables, plaited or not, other than of synthetic fibres		
	ex 5607 90 90		

Category	Description CN code 2005	Table of equivalence	
		pieces/kg	g/piece
(1)	(2)	(3)	(4)
109	Tarpaulins, sails, awnings and sunblinds		
	6306 11 00 6306 12 00 6306 19 00 6306 31 00 6306 39 00		
110	Woven pneumatic mattresses		
	6306 41 00 6306 49 00		
111	Camping goods, woven, other than pneumatic mattresses and tents		
	6306 91 00 6306 99 00		
112	Other made up textile articles, woven, excluding those of categories 113 and 114		
	6307 20 00 ex 6307 90 99		
113	Floor cloth, dish cloth and dusters, other than knitted or crocheted		
	6307 10 90		
114	Woven fabrics and articles for technical uses		
	5902 10 10 5902 10 90 5902 20 10 5902 20 90 5902 90 10 5902 90 90 5908 00 00 5909 00 10 5909 00 90 5910 00 00 5911 10 00 ex 5911 20 00 5911 31 11 5911 31 19 5911 31 90 5911 32 10 5911 32 90 5911 40 00 5911 90 10 5911 90 90		
GROUP IV			
115	Flax or ramie yarn		
	5306 10 10 5306 10 30 5306 10 50 5306 10 90 5306 20 10 5306 20 90 5308 90 12 5308 90 19		
117	Woven fabrics of flax or of ramie		
	5309 11 10 5309 11 90 5309 19 00 5309 21 10 5309 21 90 5309 29 00 5311 00 10 5803 90 90 5905 00 30		
118	Table linen, toilet linen and kitchen linen of flax or ramie, other knitted or crocheted		
	6302 29 10 6302 39 20 6302 52 00 ex 63 02 5900 6302 92 00 ex 6302 99 00		
120	Curtains (including drapes), interior blinds, curtain and bed valances and other furnishing articles, not knitted or crocheted, of flax or ramie		
	ex 6303 99 90 6304 19 30 ex 6304 99 00		
121	Twine, cordage, ropes and cables, plaited or not, of flax or ramie		
	ex 5607 90 90		

Category	Description CN code 2005	Table of equivalence	
		pieces/kg	g/piece
(1)	(2)	(3)	(4)
122	Sacks and bags, of a kind used for the packing of goods, used, of flax, other than knitted or crocheted		
	ex 6305 90 00		
123	Woven pile fabrics and chenille fabrics of flax or ramie, other than narrow woven fabrics		
	5801 90 10 ex 5801 90 90		
	Shawls, scarves, mufflers, mantillas, veils and the like, of flax or ramie, other than knitted or crocheted		
	6214 90 90		

ANNEX II

TARIFFS DISMANTLING SCHEDULE

DISMANTLING TABLE					
	Tariffs (2004)	2005	2006	2007	2008 and subsequent years
Raw materials	0	0	0	0	0
	1	0,5	0	0	0
	10	7	5	3	0
Yarn/fibres	0	0	0	0	0
	1	1	1	1	0
	5	4	4	3	0
	10	7	5	2	0
Fabrics	1	1	1	1	0
	5	4	4	2	0
	10	7	5	2	0
	15	12	9	5	0
Apparel	5	5	4	3	0
	10	7	5	2	0
	18	14	10	7	0
	22	16	12	8	0

ANNEX III

AGREED MINUTE ON MARKET ACCESS

The Parties recorded their understanding that non-tariff barriers related to all forms of hindrance to trade in the sector are not to be applied by either of the Parties. The Parties agree these non-tariff barriers include but are not limited to matters such as:

- any additional customs duties on the import or sale of products of Community or Serbian origin in excess of those set out in this Agreement, or any fees and charges in connection with importation or exportation in excess of the approximate cost of services rendered,
- any taxes which are higher than any such taxes imposed on the production or sale of equivalent domestic goods,
- technical regulations or standards, or conformity assessment or certification rules, procedures or practices going beyond the purposes for which they are required,
- any further barriers and controls within the territory of each Party hampering the free movement of goods after customs clearance and their release into free circulation,
- any indicative values resulting in effective application of minimum prices or arbitrary and fictitious prices or any customs valuation rules, procedures or practices giving rise to barriers to trade,
- rules, procedures or practices for pre-shipment inspection that are discriminatory, non-transparent, excessively lengthy or burdensome, and the imposition of customs controls for the clearance of goods to shipments that have already been subject of pre-shipment inspection,
- excessively burdensome, costly or arbitrary rules, procedures or practices concerning the certification of the origin of products or requiring direct shipment of goods from the country of origin to the country of destination,
- any non-automatic, discretionary or other licensing requirements, rules, procedures or practices imposing disproportionate burdens or having restrictive effects on imports. In particular application for automatic licenses submitted in an appropriate and complete form should be approved immediately on receipt, to the extent administratively feasible, but within a maximum of 10 working days,
- requirements or practices concerning marking, labelling, the description of composition of the product or the description of the manufacturing of products which, either in their formulation or in their application, are in any form discriminatory as compared with domestic products and no more trade restrictive than necessary to fulfil a legitimate objective,
- unduly long customs clearance delays or excessively burdensome, non-transparent or costly customs procedures, including inspection requirements, which have an unnecessary restrictive effect on imports,
- subsidies causing injury to the textiles and clothing industry of the other Party.

In order to facilitate legitimate trade, notwithstanding the need of effective control, the Parties undertake to:

- cooperate and exchange information on all issues concerning customs legislation and procedures, and in particular to deal promptly with problems faced by operators arising from measures covered by this Agreement,
- provide effective, non-discriminatory and prompt procedures enabling the right of appeal against customs and other agency administrative actions, ruling and decisions affecting import or export of goods,

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- establish an appropriate consultation mechanism between customs administrations and traders on customs regulations and procedures,
 - publish, as far as possible through electronic means, and publicise new legislation and general procedures related to customs, as well as any modification, no later than the entry into force of any such legislation and procedures,
 - cooperate with a view to reaching a common approach to issues relating to customs valuation, in particular the elaboration of a 'code of good practices' in relation to working methods and operational aspects, the use of indicative or reference indices, appropriate documentation to certify the accuracy of the customs value and the use of securities. The Parties agree to open negotiations on the 'code of good practices' upon application of this Agreement and to conclude them as soon as possible.
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ANNEX IV

Products subject to the suspension of the quantitative restrictions as referred to in Article 4(1) of this Agreement.

(The full product descriptions of the categories listed in this Annex are to be found in Annex I).

Categories:

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ANNEX V

TITLE I

CLASSIFICATION*Article 1*

1. The competent authorities of the Community undertake to inform Serbia of any changes in the Combined Nomenclature (CN) before the date of their entry into force in the Community.
2. The competent authorities of the Community undertake to inform the competent authorities of Serbia of any decisions relating to the classification of products subject to the present Agreement, within one month of their adoption at the latest. Such communication shall include:
 - (a) a description of the products concerned;
 - (b) the relevant category and the related CN codes;
 - (c) the reasons which have led to the decision.
3. Where a decision on classification results in a change of classification practice or a change of category of any product subject to this Agreement, the competent authorities of the Community shall provide 30 days' notice, from the date of the Community's communication, before the decision is put into effect.

Products shipped before the date of entry into effect of the decision shall remain subject to the earlier classification practice, provided that the goods in question are presented for importation into the Community within 60 days of that date.

4. Where a Community decision on classification resulting in a change of classification practice or a change of categorisation of any product subject to this Agreement affects a category subject to quantitative restrictions, the Parties agree to enter into consultation in accordance with the procedures described in Article 8 of this Agreement with a view to honouring the obligation under the third subparagraph of Article 9(1) of this Agreement.
5. In case of divergent opinions between Serbia and the competent Community authorities at the point of entry into the Community on the classification of products covered by this Agreement, classification shall provisionally be based on indications provided by the Community, pending consultations in accordance with Article 8 of this Agreement with a view to reaching agreement on definitive classification of the product concerned.

TITLE II

ORIGIN*Article 2*

1. Products originating in Serbia for export to the Community in accordance with the arrangements set out in this Agreement shall be accompanied by a certificate of origin issued by the Customs Administration of Serbia conforming to the model annexed to this Annex.
2. The certificate of origin shall be certified by the Customs Administration of Serbia, if the products in question can be considered products originating in Serbia within the meaning of the relevant rules in force in the Community.
3. However, the products in Group III may be imported into the Community in accordance with the arrangements established by this Agreement on production of a declaration by the exporter on the invoice or other commercial document relating to the products to the effect that the products in question originate in Serbia within the meaning of the relevant rules in force in the Community.

4. The certificate of origin referred to in paragraph 1 shall not be required for imports of goods covered by a movement certificate EUR. 1 issued in accordance with the relevant provisions of the autonomous tariff regime granted to Serbia by the Community.

Article 3

The certificate of origin shall be issued only on application having been made in writing by the exporter or, under the exporter's responsibility, by his authorised representative. The Customs Administration of Serbia shall ensure that the certificate of origin is properly completed and for this purpose they shall call for any necessary documentary evidence or carry out any check which they consider appropriate.

Article 4

Where different criteria for determining origin are laid down for products falling within the same category, the certificates or declarations of origin must contain a sufficiently detailed description of the goods on the basis of which the certificate was issued or the declaration drawn up.

Article 5

The discovery of slight discrepancies between the statements made in the certificate of origin and those made in the documents produced to the Customs Administration of Serbia for the purpose of carrying out the formalities for importing the products shall not, *ipso facto*, cast doubt upon the statements in the certificate.

TITLE III

DOUBLE-CHECKING SYSTEM

SECTION I

Exportation

Article 6

The Ministry of International Economic Relations of Serbia shall issue an export licence in respect of all consignments from Serbia of textile products subject to any definitive or provisional quantitative restrictions established under this Agreement, up to the relevant quantitative restrictions as may be modified by this Agreement, as well as of all consignments of textile products subject to a double-checking system without quantitative restrictions as provided for in it.

Article 7

1. For products subject to quantitative restrictions under this Agreement the export licence shall conform to the Model 1 annexed to this Annex and it shall be valid for exports throughout the customs territory to which the Treaty establishing the European Community applies.

2. Where quantitative restrictions have been introduced pursuant to this Agreement, each export licence must certify, *inter alia*, that the quantity of the product in question has been set off against the quantitative restriction established for the category of the products concerned and shall only cover one category of products subject to quantitative restrictions. It may be used for one or more consignments of the products in question.

3. For products subject to a double-checking system without quantitative restrictions the export licence shall conform to the Model 2 annexed to this Annex. It shall only cover one category of products and may be used for one or more consignments of the products in question.

Article 8

The competent authorities of the Community must be informed immediately of the withdrawal or modification of any export licence already issued.

Article 9

1. Exports of textile products subject to quantitative restrictions pursuant this Agreement shall be set off against the quantitative restrictions established for the year in which the shipment of the goods has been effected even if the export licence is issued after such shipment.
2. For the purpose of applying paragraph 1, shipment of goods is considered to have taken place on the date of their loading onto the exporting aircraft, vehicle or vessel.

Article 10

The presentation of an export licence, in application of Article 12 of this Annex, shall be effected not later than 31 March of the year following that in which the goods covered by the licence have been shipped.

*SECTION II***Importation***Article 11*

Importation into the Community of textile products subject to quantitative restrictions or to a double-checking system pursuant to this Agreement shall be subject to the presentation of an import authorisation.

Article 12

1. The competent authorities of the Community shall issue the import authorisation referred to in Article 11 of this Annex, within five working days of the presentation by the importer of the original of the corresponding export licence.
2. The import authorisations concerning products subject to quantitative restrictions under this Agreement shall be valid for six months from the date of their issue for imports throughout the customs territory to which the Treaty establishing the European Community is applicable.
3. The import authorisations for products subject to a double-checking system without quantitative restrictions shall be valid for six months from the date of issue for imports throughout the customs territory to which the Treaty establishing the European Community is applicable.
4. The competent authorities of the Community shall cancel the import authorisation already issued whenever the corresponding export licence has been withdrawn.

However, if the competent authorities of the Community are notified of the withdrawal or the cancellation of the export licence only after the importation of the products into the Community, the relevant quantities shall be set off against the quantitative restrictions established for the category and the quota year concerned.

Article 13

1. If the competent authorities of the Community find that the total quantities covered by export licences issued by the Ministry of International Economic Relations of Serbia for a particular category in any year exceed the quantitative restriction that may be established in accordance with the provisions of this Agreement for that category, as may be modified by the relevant provisions thereof, the said authorities may suspend the further issue of import authorisations. In this event, the competent authorities of the Community shall immediately inform the Ministry for International Economic Relations of Serbia and the special consultation procedure set out in Article 8 of this Agreement shall be initiated forthwith.
2. Exports of products of Serbian origin subject to quantitative restrictions or double-checking system and not covered by export licences of Serbia issued in accordance with the provisions of this Annex may be refused an import authorisation by the competent Community authorities.

However, without prejudice to Article 6 of this Agreement, if the import of such products is allowed into the Community by the competent authorities of the Community, the quantities involved shall not be set off against the appropriate quantitative restrictions established pursuant to this Agreement, without the express agreement of the Ministry for International Economic Relations of Serbia.

TITLE IV

**FORM AND PRODUCTION OF EXPORT CERTIFICATES AND CERTIFICATES OF ORIGIN, AND
COMMON PROVISIONS CONCERNING EXPORTS TO THE COMMUNITY***Article 14*

1. The export licence and the certificate of origin may comprise additional copies duly indicated as such. They shall be made out in English or French. If they are completed by hand, entries must be in ink and in printed script.

These documents shall measure 210 x 297 mm. The paper used shall be white writing paper, sized, not containing mechanical pulp, and weighing not less than 25 g/m². If the documents have several copies only the top copy, which is the original, shall be printed with the guilloche pattern background. This copy shall be clearly marked as 'original' and the other copies as 'copies'. Only the original shall be accepted by the competent authorities of the Community as being valid for the purpose of export to the Community in accordance with the provisions of this Agreement.

2. Each document shall bear a standardised serial number, whether or not printed, by which it can be identified.

This number shall be composed of the following elements:

- a two-digit number identifying the exporting entity as follows: XS,
- two digits identifying the intended Member State of customs clearance as follows:
 - AT = Austria
 - BL = Benelux
 - CY = Cyprus
 - CZ = Czech Republic
 - DE = Germany
 - DK = Denmark
 - EE = Estonia
 - EL = Greece
 - ES = Spain
 - FI = Finland
 - FR = France
 - GB = United Kingdom
 - HU = Hungary
 - IE = Ireland
 - IT = Italy
 - LT = Lithuania
 - LV = Latvia
 - MT = Malta

- PL = Poland
 - PT = Portugal
 - SE = Sweden
 - SI = Slovenia
 - SK = Slovakia,
-
- a one-digit number identifying quota year, corresponding to the last figure in the respective year, e.g. 4 for 2004, 5 for 2005, 6 for 2006 and 7 for 2007,
 - a two-digit number from 01 to 99, identifying the particular issuing office concerned in exporting entity,
 - a five-digit number running consecutively from 00001 to 99999 allocated to the intended Member State of customs clearance.

Article 15

The export licence and the certificate of origin may be issued after the shipment of the products to which they relate. In such cases they must bear the endorsement 'délivré à posteriori' or the endorsement 'issued retrospectively'.

Article 16

1. In the event of a theft, loss or destruction of an export licence or a certificate of origin, the exporter may apply to the Ministry of International Economic Relations of Serbia in case of an export licence, or the Customs Administration of Serbia, in case of a certificate of origin, which issued the document for a duplicate to be made out on the basis of the export documents in his possession. The duplicate of any such certificate or licence so issued shall bear the endorsement 'duplicata' or 'duplicate'.

2. The duplicate shall bear the date of the original export licence or certificate of origin.

TITLE V

ADMINISTRATIVE COOPERATION

Article 17

The Parties shall cooperate closely in the implementation of the provisions of this Annex. To this end, contacts and exchanges of views, including on technical matters, shall be facilitated by both Parties.

Article 18

In order to ensure the correct application of this Annex, the Parties offer mutual assistance for the checking of the authenticity and the accuracy of export licences and certificates of origin issued or of any declarations made within the terms of this Annex.

Article 19

Serbia shall transmit to the Community the names and addresses of the authorities competent to issue and verify the export licences and the certificates of origin, together with specimens of the stamps used by these authorities and specimen signatures of officials responsible for signing the export licences and the certificates of origin. Serbia shall also notify the Community of any change in this information.

Article 20

1. Subsequent verification of certificates of origin or export licences shall be carried out at random, or whenever the competent Community authorities have reasonable doubt as to the authenticity of the certificate or licence or as to the accuracy of the information regarding the true origin of the products in question.
2. In such cases, the competent authorities in the Community shall return the certificate of origin or the export licence or a copy thereof to the Ministry for International Economic Relations of Serbia in case of an export licence, or to the Customs Administration of Serbia, in case of a certificate of origin, giving, where appropriate, the reasons of form or substance which justify an enquiry. If the invoice has been submitted, such invoice or a copy thereof shall be attached to the certificate or to the licence or their copies. The authorities shall also forward any information that has been obtained suggesting that the particulars given on the said certificate or licence are inaccurate.
3. The provisions of paragraph 1 shall also apply to subsequent verifications of the declarations of origin provided for in Article 2 of this Annex.
4. The results of the subsequent verifications carried out in accordance with paragraphs 1 and 2 shall be communicated to the competent authorities of the Community within three months at the latest. The information communicated shall indicate whether the disputed certificate, licence or declaration applies to the goods actually exported and whether these goods are eligible for export under the arrangements established by this Agreement. The information shall also include at the request of the Community, copies of all the documentation necessary to fully determine the facts, and in particular the true origin of the goods.
5. Should such verifications reveal systematic irregularities in the use of declarations of origin, the Community may subject imports of the products in question to Article 2(1) of this Annex. For the purpose of subsequent verification of certificates of origin, copies of the certificates as well as any export documents referring to them shall be kept for at least two years by the issuing authority.
6. Recourse to the random verification procedure specified in this Article must not constitute an obstacle to the release into free circulation of the products in question.

Article 21

1. Where the verification procedure referred to in Article 20 of this Annex or where information available to the competent authorities of the Community or of Serbia indicates or appears to indicate that the provisions of this Agreement are being circumvented or infringed, the two Parties shall cooperate closely and with the appropriate urgency in order to prevent any such circumvention or infringement.
2. To this end, the Ministry for International Economic Relations of Serbia in case of an export licence, or the Customs Administration of Serbia, in case of a certificate of origin, shall, on their own initiative or at the request of the Community, carry out appropriate inquiries, or arrange for such inquiries to be carried out, concerning operations which are, or appear to the Community to be, in circumvention or infringement of this Annex. Serbia shall communicate the results of these inquiries to the Community, including any other pertinent information enabling the cause of the circumvention or infringement, including the true origin of the goods to be determined.
3. By agreement between the Parties, officials designated by the Community may be present at the inquiries referred to in paragraph 2.
4. In pursuance of the cooperation referred to in paragraph 1, the competent authorities of the Parties shall exchange any information considered by either of them to be of use in preventing circumvention or infringement of the provisions of this Agreement. These exchanges may include information on the production of textile products in Serbia and on the trade in the type of products covered by this Agreement between Serbia and third countries, particularly where the Community has reasonable grounds to consider that the products in question may be in transit across the territory of Serbia prior to their importation into the Community. This information may include at the request of the Community copies of all available relevant documentation.
5. Where the provisions of this Annex have not been applied correctly, the Community may take the measures set out in Article 6(3) of this Agreement, or any other appropriate measure.

Specimen of Certificate of Origin referred to in Article 2(1) of Annex V

1. Exporter (name, full address, country) Exportateur (nom, adresse complète, pays)	ORIGINAL		2. N°	
	3. Quota year Année contingentaie		4. Category number Numéro de catégorie	
5. Consignee (name, full address, country) Destinataire (nom, adresse complète, pays)	CERTIFICATE OF ORIGIN (Textile products) CERTIFICAT D'ORIGINE (Produits textiles)			
	6. Country of origin Pays d'origine		7. Country of destination Pays de destination	
8. Place and date of shipment – Means of transport Lieu et date d'embarquement – Moyen de transport	9. Supplementary details Données supplémentaires			
10. Marks and numbers – Number and kind of packages – DESCRIPTION OF GOODS Marques et numéros – Nombre et nature des colis – DÉSIGNATION DES MARCHANDISES			11. Quantity (1) Quantité (1)	12. FOB value (2) Valeur fob (2)
			13. CERTIFICATION BY THE COMPETENT AUTHORITY – VISA DE L'AUTORITÉ COMPÉTENTE I, the undersigned, certify that the goods described above originated in the country shown in box N° 6 in accordance with the provisions in force in the European Community. Je soussigné certifie que les marchandises désignées ci-dessus sont originaires du pays figurant dans la case 6, conformément aux dispositions en vigueur dans la Communauté européenne.	
14. Competent authority (name, full address, country) Autorité compétente (nom, adresse complète, pays)			At – A, on – le (Signature) (Stamp – Cachet)	

(1) Show net weight (kg) and also quantity in the unit prescribed for category where other than net weight – Indiquer le poids net en kilogrammes ainsi que la quantité dans l'unité prévue pour la catégorie si cette unité n'est pas le poids net.
 (2) In the currency of the sale contract – Dans la monnaie du contrat de vente.

Specimen of Export Licence referred to in Article 7(1) of Annex V, Model 1

(1) Show net weight (kg) and also quantity in the unit prescribed for category where other than net weight – Indiquer le poids net en kilogrammes ainsi que la quantité dans l'unité prévue pour la catégorie si cette unité n'est pas le poids net.
 (2) In the currency of the sale contract – Dans la monnaie du contrat de vente.

1. Exporter (name, full address, country) Exportateur (nom, adresse complète, pays)	ORIGINAL		2. N°	
	3. Quota year Année contingentaie		4. Category number Numéro de catégorie	
5. Consignee (name, full address, country) Destinataire (nom, adresse complète, pays)	EXPORT LICENCE (Textile products) LICENCE D'EXPORTATION (Produits textiles)			
	6. Country of origin Pays d'origine		7. Country of destination Pays de destination	
8. Place and date of shipment – Means of transport Lieu et date d'embarquement – Moyen de transport	9. Supplementary details Données supplémentaires			
10. Marks and numbers – Number and kind of packages – DESCRIPTION OF GOODS Marques et numéros – Nombre et nature des colis – DÉSIGNATION DES MARCHANDISES			11. Quantity (1) Quantité (1)	12. FOB value (2) Valeur fob (2)
			13. CERTIFICATION BY THE COMPETENT AUTHORITY – VISA DE L'AUTORITÉ COMPÉTENTE I, the undersigned, certify that the goods described above have been charged against the quantitative limit established for the year shown in box N° 3 in respect of the category shown in box N° 4 by the provisions regulating trade in textile products with the European Community. Je soussigné certifie que les marchandises désignées ci-dessus ont été imputées sur la limite quantitative fixée pour l'année indiquée dans la case 3 pour la catégorie désignée dans la case 4 dans le cadre des dispositions régissant les échanges de produits textiles avec la Communauté européenne.	
14. Competent authority (name, full address, country) Autorité compétente (nom, adresse complète, pays)			At – A, on – le (Signature) (Stamp – Cachet)	

Specimen of Export Licence referred to in Article 7(3) of Annex V, Model 2

1. Exporter (name, full address, country) Exportateur (nom, adresse complète, pays)	ORIGINAL		2. N°
5. Consignee (name, full address, country) Destinataire (nom, adresse complète, pays)	3. Export year Année d'exportation		4. Category number Numéro de catégorie
	EXPORT LICENCE (Textile products) LICENCE D'EXPORTATION (Produits textiles)		
8. Place and date of shipment – Means of transport Lieu et date d'embarquement – Moyen de transport	6. Country of origin Pays d'origine 7. Country of destination Pays de destination 9. Supplementary details Données supplémentaires NON-RESTRAINED TEXTILE CATEGORY CATÉGORIE TEXTILE NON LIMITÉE		
10. Marks and numbers – Number and kind of packages – DESCRIPTION OF GOODS Marques et numéros – Nombre et nature des colis – DÉSIGNATION DES MARCHANDISES		11. Quantity (1) Quantité (1)	12. FOB value (2) Valeur fob (2)
13. CERTIFICATION BY THE COMPETENT AUTHORITY – VISA DE L'AUTORITÉ COMPÉTENTE I, the undersigned, certify that the goods described above originated in the country shown in box N° 6, in accordance with the provisions in force in the Agreement on trade in textile products between the European Community and Serbia. Je soussigné certifie que les marchandises désignées ci-dessus sont originaires du pays figurant dans la case 6, conformément aux dispositions en vigueur dans l'accord sur le commerce des produits textiles entre la Communauté européenne et la Serbie.			
14. Competent authority (name, full address, country) Autorité compétente (nom, adresse complète, pays)	At – A, on – le (Signature) (Stamp – Cachet)		

(1) Show net weight (kg) and also quantity in the unit prescribed for category where other than net weight – Indiquer le poids net en kilogrammes ainsi que la quantité dans l'unité prévue pour la catégorie si cette unité n'est pas le poids net.
 (2) In the currency of the sale contract – Dans la monnaie du contrat de vente.

ANNEX VI

COTTAGE INDUSTRY AND FOLKLORE PRODUCTS ORIGINATING IN SERBIA

1. The exemption provided for in Article 12 of this Agreement in respect of cottage industry products shall apply to the following types of product only:

- (a) fabrics woven on looms operated solely by hand or foot, being fabrics of a kind traditionally made in the cottage industry of Serbia;
- (b) garments or other textile articles of a kind traditionally made in the cottage industry of Serbia obtained manually from the fabrics referred to above and sewn exclusively by hand without the aid of any machine;
- (c) traditional folklore products of Serbia made by hand, in a list to be agreed between the Parties.

Exemption shall be granted in respect only of products covered by a certificate conforming to the specimen annexed to this Annex and issued by the Customs Administration of Serbia. These certificates must indicate the reasons justifying their issuance. The competent authorities of the Community will accept them after having checked that the products concerned have fulfilled the conditions established in this Annex. The certificates concerning the products envisaged in point (c) above must bear a stamp 'FOLKLORE' marked clearly. In the case of a difference of opinion between the Parties concerning the nature of these products, consultations shall be held within one month in order to resolve these differences.

Should imports of any product covered by this Annex reach proportions liable to cause problems within the Community, consultations with Serbia shall be initiated as soon as possible, with a view to resolving the situation by the adoption if necessary of a quantitative restriction, in accordance with the procedure laid down in Article 8 of this Agreement.

2. Titles IV and V of Annex V shall apply *mutatis mutandis* to the products covered by paragraph 1 of this Annex.

Appendix to Annex VI

1. Exporter (name, full address, country) Exportateur (nom, adresse complète, pays)	ORIGINAL		2. N°
3. Consignee (name, full address, country) Destinataire (nom, adresse complète, pays)	CERTIFICATE in regard to HANDLOOMS, TEXTILE HANDICRAFTS and TRADITIONAL TEXTILE PRODUCTS, of the COTTAGE INDUSTRY, issued in conformity with and under the conditions regulating trade in textile products with the European Community ----- CERTIFICAT relatif aux TISSUS TISSÉS SUR MÉTIERS À MAIN, aux PRODUITS TEXTILES FAITS À LA MAIN, et aux PRODUITS TEXTILES RELEVANT DU FOLKLORE TRADITIONNEL, DE FABRICATION ARTISANALE, délivré en conformité avec et sous les conditions régissant les échanges de produits textiles avec la Communauté européenne.		
6. Place and date of shipment – Means of transport Lieu et date d'embarquement – Moyen de transport	4. Country of origin Pays d'origine	5. Country of destination Pays de destination	
8. Marks and numbers – Number and kind of packages – DESCRIPTION OF GOODS Marques et numéros – Nombre et nature des colis – DÉSIGNATION DES MARCHANDISES	7. Supplementary details Données supplémentaires		
11. CERTIFICATION BY THE COMPETENT AUTHORITY – VISA DE L'AUTORITÉ COMPÉTENTE I, the undersigned, certify that the consignment described above includes only the following textile products of the cottage industry of the country shown in box N° 4: (a) fabric woven on looms operated solely by hand or foot (handlooms) (2) (b) garments or other textile articles obtained manually from the fabrics described under a) and sewn solely by hand without the aid of any machine (handicrafts) (2) (c) traditional folklore handicraft textile products made by hand, as defined in the list agreed between the European Community and the country shown in box N° 4. Je soussigné certifie que l'envoi décrit ci-dessus contient exclusivement les produits textiles suivants relevant de la fabrication artisanale du pays figurant dans la case 4: (a) tissus tissés sur des métiers actionnés à la main ou au pied (handlooms) (2) (b) vêtements ou autres articles textiles obtenus manuellement à partir de tissus décrits sous a) et cousus uniquement à la main sans l'aide d'une machine (handicrafts) (2) (c) produits textiles relevant du folklore traditionnel fabriqués à la main, comme définis dans la liste convenue entre la Communauté européenne et le pays indiqué dans la case 4.			
12. Competent authority (name, full address, country) Autorité compétente (nom, adresse complète, pays)	At – A, on – le (Signature) (Stamp – Cachet)		

(1) In the currency of the sale contract – Dans la monnaie du contrat de vente.
 (2) Delete as appropriate – Biffer la (les) mention(s) inutile(s)

ANNEX VII

DECLARATION BY THE COMMUNITY

The Community undertakes to assist Serbia with questions which may arise from the application of the provisions of this Agreement in the context of Serbia's accession to the WTO.
