BIJLAGE

The three Institutions have agreed that a second reading agreement should be based on a so-called "package approach" covering the following issues:

1. Duty of care/international obligations
2. Animal welfare
3. Communication of information
4. Comitology
5. Agency
6. Registration/Data sharing
7. Authorisation, including substitution
8. Other issues

1. DUTY OF CARE/INTERNATIONAL OBLIGATIONS

Council Common Position	EP amendment	Result of the 6th trilogue
Recital 4 a Does not exist.	Amendment 2 ***(4a) REACH should be so designed and applied as to avoid weakening the competitiveness of European trade and industry or damaging trade with third countries. The Regulation must not impose any requirements on the European Union's trading partners other than such as would be compatible with the free-trade principles in force under WTO provisions.***	The trade aspects are strengthened by rewording recital (3) as follows: (3) A high level of human health and environmental protection should be ensured in the approximation of legislation on substances, with the goal of achieving sustainable development. That legislation should be applied in a non-discriminatory manner whether substances are traded on the internal market or internationally ***in accordance with the Community's international commitments***.
Recital 14 (14) Responsibility for the management of the risks of substances should lie with the ***natural or legal persons*** that manufacture, import, place on the market or use these substances. Information on the implementation of this Regulation should be easily accessible, ***in particular*** for ***SMEs***.	Amendment 7 (14) Responsibility for the management of***, and provision of information on,*** the risks of substances should lie with the ***enterprises*** that manufacture, import, place on the market or use these substances. Information on the implementation of this Regulation should be easily accessible, ***particularly*** for ***very small businesses, which should not be disproportionately penalised by the implementation procedures.***	A new recital with a view to explaining that the duty of care is effectively covered by fulfilling the duties of this and other associated legislation is added.
Article 1.1 1. The purpose of this Regulation is to ensure a high level of protection of human health and the environment ***as well as*** the free circulation of substances on the internal market while enhancing competitiveness and innovation.	Amendment 26 1. The purpose of this Regulation is to ensure a high level of protection of human health and the environment, the free circulation of substances on the internal market***, increased transparency and the promotion of non-animal testing,*** while enhancing competitiveness and innovation ***in accordance with the duty of care, and having due regard for the obligations entered into by the EU and its Member***	The trade aspect is covered by recital (3). (3) A high level of human health and environmental protection should be ensured in the approximation of legislation on substances, with the goal of achieving sustainable development. That legislation should be applied in a non-discriminatory manner whether substances are traded on the internal market or internationally ***in accordance with the Community's international commitments.***

	States in the framework of international trade agreements, in particular within the WTO.	Note: See Amendment 26 for animal welfare aspect under heading "Animal welfare".
Article 1.3 a, b, and c Do not exist.	Amendment 28 3a. Any manufacturer, importer or downstream user performing or intending to perform operations involving a substance or preparation, or an article containing such a substance or preparation, including the manufacturing, importation and application thereof, who knows or could reasonably have foreseen that these operations could adversely affect human health or the environment, shall make every effort that may reasonably be required of him to prevent, limit or remedy such effects. 3b. Any manufacturer, importer or downstream user that supplies, in the pursuit of his profession or business, a substance or preparation, or an article containing such a substance or preparation, to a manufacturer, importer or downstream user shall, to the extent this may reasonably be required, ensure adequate communication and information exchange, including where appropriate technical assistance, reasonably necessary to prevent, limit or remedy adverse effects on human health or the environment. 3c. This includes the duty to describe, document and notify in an appropriate and transparent fashion the risks stemming from the production, use and disposal of each substance. Producers and downstream users shall select a substance for production and use on the basis of the safest substances available.	A new recital explaining that the duty of care is effectively covered by fulfilling the duties of this Regulation and other associated legislation is added. ***Recital (new)*** ***This Regulation lays down specific duties and obligations on manufacturers, importers and downstream users of substances on their own, in preparations and in articles. The Regulation is based on the principle that industry should manufacture, import or use substances or place them on the market with such responsibility and care as may be required to ensure that, under reasonably foreseeable conditions, human health and the environment are not adversely affected.*** ***All available and relevant information on substances on their own, in preparations and in articles should be collected to assist in identifying hazardous properties, and recommendations about risk management measures should systematically be conveyed through supply chains, as reasonably necessary, to prevent adverse effects on human health and the environment. In addition, communication of technical advise to support risk management should be encouraged in the supply chain, where appropriate.***

Article 14.7 a and b Do not exist.	Amendment 48 ***7a. The manufacturer or importer of a substance or preparation who supplies such a substance or preparation to a downstream user shall, at the request of the downstream user and in so far as this can reasonably be requested, supply the information needed to assess the effects of the substance or preparation on human health or the environment in the context of the operations or use indicated by the downstream user in his request.*** ***7b. The downstream user shall supply, at the request of his supplier and in so far as this can reasonably be requested, the information needed by the supplier to assess the effects of the substance or preparation on human health or the environment in the context of the operations or use of the substance or preparation by the downstream user.***	**It was agreed that the elements of the EP amendment are covered by Articles 31, 32 and 36.**

2. ANIMAL WELFARE

Council Common Position	EP amendment	Result of the 6th trilogue
Recital 58 a Does not exist.	Amendment 17 ***(58a) In order to prevent duplication of animal testing, interested parties should have a period of 90 days during which they may comment on testing proposals that include vertebrate animal tests. Comments received during this period should be taken into account by the registrant or the downstream user.***	A new recital is added: (linked to amendment 66): ***(58a) In order to prevent unnecessary animal testing, interested parties should have a period of 45 days during which they may provide scientifically valid information and studies that address the relevant substance and hazard end-point, which is addressed by the testing proposal. The scientifically valid information and studies received by the Agency shall be taken into account for decisions on testing proposals.***
Article 1.1 1. The purpose of this Regulation is to ensure a high level of protection of human health and the environment ***as well as*** the free circulation of substances on the internal market while enhancing competitiveness and innovation.	Amendment 26 1. The purpose of this Regulation is to ensure a high level of protection of human health and the environment, the free circulation of substances on the internal market***, increased transparency and the promotion of non-animal testing,*** while enhancing competitiveness and innovation ***in accordance with the duty of care, and having due regard for the obligations entered into by the EU and its Member States in the framework of international trade agreements, in particular within the WTO***.	In order to address the animal welfare element of Amendment 26 paragraph 1 is added as follows: 1. The purpose of this Regulation is to ensure a high level of protection of human health and the environment, ***including promotion of alternative methods for assessment of hazards of substances,*** as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation.
Article 2.4 a Does not exist.	Amendment 32 ***4a. This Regulation shall apply without prejudice to the prohibitions and restrictions laid down in Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products[(1)], concerning:*** ***(i) the prohibition of animal testing of finished***	New Recital and a new paragraph (b) in Article 2.4 are introduced in order to respond to the concern regarding testing of substances in cosmetic products on animals. *Recital (New)* ***(xx) This Regulation should apply without prejudice to the prohibitions and restrictions laid down in Council Directive 76/768/EEC of 27 July 1976 on the***

	cosmetic products and the ingredients or combinations of ingredients thereof; and ***(ii) the marketing of cosmetic products of which some or all of the ingredients, or the final formulation, have been tested on animals.*** ***To the extent that substances used only as cosmetic ingredients are covered by this Regulation, no animal testing that is prohibited pursuant to Directive 76/768/EEC as amended shall be permitted for the purposes of the same assessment required by this Regulation with regard to such substances.*** _____ ***(1) OJ L 262, 27.7.1976, p. 169. Directive as amended by Directive 2003/15/EC (OJ L 66, 11.3.2003, p. 26) and as last amended by Commission Directive 2006/65/EC (OJ L 198, 20.7.2006)***	***approximation of the laws of the Member States relating to cosmetic products in that so far as substances are used and marketed as cosmetic ingredients and are within the scope of this Regulation, a phase-out of testing on vertebrate animals for the purpose of protecting human health as specified in Directive 76/768/EEC should take place with regard to the uses of those substances in cosmetics.*** *Article 2.4* This Regulation shall apply without prejudice to: **(a)** Community workplace and environmental legislation, including Council Directive 89/391/EEC(2) of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work, Council Directive 96/61/EC(3) of 24 September 1996 concerning integrated pollution prevention and control; Directive 98/24/EC(4), Directive 2000/60/EC(5) of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy and Directive 2004/37/EC(6). ***(b) Council Directive 76/768/EEC(7) of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products as regard to testing involving vertebrate animals within the scope of that Directive.*** _____ (1)-(7) references to the relevant OJ issues

Article 12.2 a Does not exist.	Amendment 42 ***2a. Priority shall be given to in vitro methods and the use of (quantitative) structure activity relationships ((Q)SARs). To this end, the Agency shall make available to companies a list of tests, databases and approved models.***	This issue is addressed in the context of Amendment 45 (Article 13.2.1.a).
Article 13.1 1. Information on intrinsic properties of substances ***may*** be generated by means other than tests, in particular through the use of qualitative or quantitative structure-activity relationship models or from information from structurally related substances (grouping or read-across), provided that the conditions set out in Annex XI are met. Testing in accordance with Annex VIII, section 8.6 and 8.7, Annex IX and Annex X may be omitted where justified by information on exposure and implemented risk management measures as specified in Annex XI, section 3.	Amendment 43 1. Information on intrinsic properties of substances ***, in particular for human toxicity, shall*** be generated ***whenever possible*** by means other than ***vertebrate animal*** tests, in particular through the use of qualitative or quantitative structure-activity relationship models or from information from structurally related substances (grouping or read-across), provided that the conditions set out in Annex XI are met***, or toxicogenomics***. Testing in accordance with Annex VIII, section 8.6 and 8.7, Annex IX and Annex X may be omitted where justified by information on exposure and implemented risk management measures as specified in Annex XI, section 3.	This issue is addressed in the context of Amendment 45 (Article 13.2.1.a) and by the following text: *Article 13* 1. Information on intrinsic properties of substances ***may*** be generated by means other than tests, ***provided that the conditions set out in Annex XI are met. In particular for human toxicity, information shall be generated whenever possible by means other than vertebrate animal tests, through the use of alternative methods, for example, in vitro methods or*** qualitative or quantitative structure-activity relationship models or from information from structurally related substances (grouping or read-across) ~~provided that the conditions set out in Annex XI are met.~~ Testing in accordance with Annex VIII, section 8.6 and 8.7, Annex IX and Annex X may be omitted where justified by information on exposure and implemented risk management measures as specified in Annex XI, section 3.
Article 13.2.1 a Does not exist.	Amendment 45 ***These methods shall be regularly reviewed and improved with a view to reducing experimentation on vertebrate animals and the number of animals***	Recitals (36) and (43) are amended to read as below and the Commission will make the statement set out in Annex B to this Note. In Article 13 a new paragraph 1a is inserted and paragraph 2 is amended. *Article 13* ***1a. These methods shall be regularly reviewed and improved with a view to reducing experimentation on vertebrate animals and the number of animals***

	involved. In particular, if the European Centre for the Validation of Alternative Methods (ECVAM) declares an alternative test method valid and ready for regulatory acceptance, the Agency shall submit within 14 days a draft decision amending the relevant Annex(es) to this Regulation, in accordance with the procedure provided for in Article 130, with a view to replacing the animal test method with the alternative one.	***involved. The Commission, following consultation with relevant stakeholders, shall, as soon as possible, make a proposal, if appropriate, to amend the test methods Regulation, and Annexes of this Regulation, if relevant, so as to replace, reduce or refine animal testing. Modifications of the test methods Regulation shall be adopted in accordance with the procedure specified in paragraph 2 and of Annexes of this Regulation in accordance with Article 130.***
	———————	2. Where tests on substances are required to generate information on intrinsic properties of substances, they shall be conducted in accordance with the test methods laid down in a Commission Regulation adopted in accordance with the procedure referred to in Article 132(3), ~~which shall be revised as appropriate in particular to refine, reduce or replace animal testing~~ or in accordance with other international test methods recognised by the Commission or the Agency as being appropriate. Information on intrinsic properties of substances may be generated in accordance with other test methods provided that the conditions set out in Annex XI are met.
———————		———————
Recitals ***(36) Internationally accepted test methods should be recognised and other test methods should be adopted by the Commission and revised as appropriate, in particular to refine, reduce or replace animal testing.***		Recitals ***(36) The Commission, Member States, industry and other stakeholders should continue to contribute to the promotion of alternative test methods on an international and national level including computer supported methodologies, in vitro methodologies, such as appropriate, those based on toxicogenomics, and other relevant methodologies. The Community's strategy to promote alternative test methods is a priority and the Commission should ensure that***

(43) It is necessary to reduce to a minimum the number of vertebrate animals used for experimental purposes in accordance with the provisions of Directive 86/609/EEC. Wherever possible the use of animals should be avoided by recourse to alternative methods validated by the European Centre for the Validation of Alternative Methods or other international bodies and recognised by the Commission or the Agency as appropriate.		***within its future Research Framework Programmes and initiatives such as the Community Action Plan on the Protection and Welfare of Animals 2006-2010 this remains a priority topic. Participation of stakeholders and initiatives involving all interested parties should be sought.*** ***(43) In accordance with the provisions of Directive 86/609/EEC, it is necessary to replace, reduce or refine experiments on vertebrate animals. Implementation of this Regulation should be based on the use of alternative test methods, suitable for the assessment of health and environmental hazards of chemicals, wherever possible. The use of animals should be avoided by recourse to alternative methods validated by the Commission or international bodies, or recognised by the Commission or the Agency as appropriate to meet the information requirements under this Regulation. To this end, the Commission, following consultation with relevant stakeholders, should propose to amend the test methods Regulation or this Regulation, where appropriate, to replace, reduce or refine animal testing. The Commission and the Agency should ensure that reduction of animal testing is a key consideration in the development and maintenance of guidance for stakeholders and in the Agency's own procedures.***

Article 39.1 a Does not exist.	Amendment 66 ***1a. In order to prevent duplication of animal testing, any testing proposal involving tests on vertebrate animals shall be open for comment by interested parties for a period of 90 days. All comments received shall be taken into account by the registrant or the downstream user, who shall notify the Agency whether, in the light of the comments received, he nonetheless believes that it is necessary to carry out the proposed test and of his reasons therefor.***	The following new paragraph is inserted (linked to amendment 12) Article 39 *Examination of testing proposals* 1. The Agency shall examine any testing proposal set out in a registration or downstream user report for provision of the information specified in Annexes IX and X for a substance. …. ***1a. Information relating to testing proposals involving tests on vertebrate animals shall be published on the Agency website. The Agency shall publish on its website the name of the substance, the hazard end-point for which vertebrate testing is proposed, and the date by which any third party information is required. It shall invite third parties to submit, using the format provided by the Agency, scientifically valid information and studies that address the relevant substance and hazard end-point, and addressed by the testing proposal, within 45 days of the date of publication. All such scientifically valid information and studies received shall be taken into account by the Agency in preparing its decision in accordance with Article 39.(2).***
Article 39.1 b Does not exist.	Amendment 67 ***1b. The European Centre for the Validation of Alternative Methods (ECVAM) shall be consulted before a decision as referred to in paragraph 2 on a testing proposal that includes vertebrate animal tests is drafted.***	This issue is addressed in the context of Amendment 45 (Article 13.2.1.a) and by the Commission Statement in Annex B.

Article 49.1 1. The Agency shall notify any draft decision under Articles 39, 40 or 45 to the registrant(s) or downstream user(s) concerned, informing them of their right to comment within 30 days of receipt. If the concerned registrant(s) or downstream user(s) wish to comment, they shall provide their comments to the Agency. The Agency in turn shall inform the competent authority of the submission of the comments without delay. The competent authority (for decisions taken under Article 45) and the Agency (for decisions taken under Articles 39 and 40) shall take any comments received into account and may amend the draft decision accordingly.	Amendment 72 1. The Agency shall notify any draft decision under Articles 39, 40 or 45, ***together with any comments by stakeholders and the European Centre for the Validation of Alternative Methods (ECVAM),*** to the registrant(s) or downstream user(s) concerned**,** informing them of their right to comment within 30 days of receipt. If the concerned registrant(s) or downstream user(s) wish to comment, they shall provide their comments to the Agency. The Agency in turn shall inform the competent authority of the submission of the comments without delay. The competent authority (for decisions taken under Article 45) and the Agency (for decisions taken under Articles 39 and 40) shall take any comments received into account and may amend the draft decision accordingly.	This issue is addressed in the context of Amendment 66 (Article 39.1.a) and by the Commission Statement in Annex B.
Article 75.1 da Does not exist.	Amendment 122 ***(da) a Committee for Alternative Test Methods, which shall be responsible for developing and implementing an integrated strategy to speed up the development, validation and legal acceptance of non-animal test methods, and to ensure their use in intelligent stepwise risk assessment to meet the requirements of this Regulation. The Committee shall be responsible for allocating funding for alternative test methods provided through the registration fee. The Committee shall consist of experts from the European Centre for the Validation of Alternative Methods, animal welfare organisations and other relevant stakeholders.*** ***Every year the Committee shall produce a report to be presented by the Agency to the European Parliament and the Council on the progress made on the development, validation and legal acceptance of non-animal test methods, the use of such methods in***	The concern is addressed in the context of amendment 45 (Article 13.2.1.a) and in the following text: ***Article 116*** ***2.(a)(new) Every three years the Agency, in accordance with the objective of promoting non-animal testing methods, shall submit to the Commission a report on the status of implementation and use of non-animal test methods and testing strategies used to generate information on intrinsic properties and for risk assessment to meet the requirements of this Regulation.*** ***The first report shall be submitted by…***** 3. Every five years the Commission shall publish a general report on 1) the experience acquired with the operation of this Regulation, including the information referred to in paragraphs 1, 2 ***and 2(a) and*** ***2) the amount and distribution of funding made***

	intelligent stepwise risk assessment to meet the requirements of this Regulation, and the amount and distribution of funding for alternative test methods.	***available by the European Commission for the development and evaluation of alternative test methods.*** ** *4 years*

3. COMMUNICATION OF INFORMATION

Council Common Position	EP amendment	Result of the 6th trilogue
Recital 85 (85) The structure of the Agency should be suitable for the tasks that it should fulfil. Experience with similar Community agencies provides some guidance in this respect but the structure should be adapted to meet the specific needs of this Regulation.	Amendment 21 (85) The structure of the Agency should be suitable for the tasks that it should fulfil. Experience with similar Community agencies provides some guidance in this respect but the structure should be adapted to meet the specific needs of this Regulation. ***In this respect, a centre of excellence specialised in communication of the risks and dangers associated with certain substances and preparations should be created within the Agency.***	A new recital is introduced to take account of concerns behind Amendment 125: ***Recital*** ***(85(bis)) The effective communication of information on chemical risks and how they can be managed is an essential part of the REACH system. Best practice from the chemicals and other sectors should be considered in the preparation of guidance by the Agency to all stakeholders.***
Article 3.25 25) Identified use: means a use of a substance on its own or in a preparation, or a use of a preparation, that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user;	Amendment 34 25) Identified use: means a use of a substance on its own or in a preparation, or a use of a preparation, that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user***, and that is communicated to the downstream user concerned***;	It was agreed not the amend Article 3.25. 25) Identified use: means a use of a substance on its own or in a preparation, or a use of a preparation, that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user;
Article 8 a Does not exist.	Amendment 40 ***Article 8a*** ***European quality mark*** ***By …. * the Commission shall present to the European Parliament and the Council a report and, if appropriate, a legislative proposal on the creation of a European quality mark designed to identify and promote articles which, at each stage of the production process, have been produced in compliance with the requirements stemming from this Regulation.***	A new recital is introduced to respond to the issues raised on this amendment. ***(xy) REACH will generate information on substances and their uses. Available information, including that generated by REACH, should be used by the relevant actor in the application and implementation of appropriate Community legislation, for example those covering products, and Community voluntary instruments, such as the eco-labelling scheme. The Commission should consider in the review and development of relevant EU legislation and voluntary instruments how REACH generated***

	——— **** Two years after the entry into force of this Regulation.***	***information should be used, and examine possibilities for establishing a European quality mark.***
Article 31.1	Amendment 61	Article 31 is modified as follows: *Article 31* *Requirements for Safety Data Sheets*
1. The supplier of a substance or preparation shall provide the recipient of the substance or preparation with a safety data sheet compiled in accordance with Annex II: (a) where a substance or preparation meets the criteria for classification as dangerous in accordance with Directives 67/548/EEC or 1999/45/EC, or (b) where a substance is persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII.	1. The supplier of a substance or a preparation shall provide the recipient of the substance or preparation with a safety data sheet compiled in accordance with Annex II: (a) where a substance or preparation meets the criteria for classification as dangerous in accordance with Directives 67/548/EEC or 1999/45/EC; or (b) where a substance is persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII***; or*** ***(ba) where a substance has been identified in accordance with Article 56 (f)***.	1. The supplier of a substance or a preparation shall provide the recipient of the substance or preparation with a safety data sheet compiled in accordance with Annex II: (a) where a substance or preparation meets the criteria for classification as dangerous in accordance with Directives 67/548/EEC or 1999/45/EC, or (b) where a substance is persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII, or ***(c) where a substance is included for other reasons than contained in paragraphs (a) and (b) in the list established in accordance with Article 58(1).*** [2. unchanged] 3. The supplier shall provide the recipient at his request with a safety data sheet compiled in accordance with Annex II, where a preparation does not meet the criteria for classification as dangerous in accordance with Articles 5, 6 and 7 of Directive 1999/45/EC, but contains: (a) in an individual concentration of = 1% by weight for non-gaseous preparations and = 0,2% by volume for gaseous preparations at least one substance posing human health or environmental hazards, or

		(b) in an individual concentration of = 0,1% by weight for non-gaseous preparations at least one substance that is persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex ***XIII or has been included in the list established in accordance with Article 58(1),*** or (c) a substance for which there are Community workplace exposure limits. [4. unchanged]
Article 32.4 ***4. Any producer or importer of an article containing a substance meeting the criteria in Article 56 and identified according to Article 58(1) in a concentration above 0.1 % weight by weight (w/w), shall provide the recipient of the article with sufficient information to allow safe use of the article including, as a minimum, the name of the substance. This obligation shall extend to all recipients of articles in the supply chain.***	Amendment 63 ***deleted***	It was agreed to move the provisions of 32.(4) to a specific Article on "Communication of information on substances in articles". See Amendment 64.
Article 33 a Does not exist.	Amendment 64 ***Article 33a*** ***Duty to communicate information on substances contained in articles*** ***1. Any manufacturer or importer of a substance listed in Annex XIV, or a preparation or article containing such a substance, shall at the request of the downstream user, in so far as this may reasonably be required, furnish the information necessary to assess the effects of the substance on human health or the environment with respect to the operations and uses indicated in that request.***	The following new Article 32a is introduced, Article 3 is modified (see 3.31a and 3.33 below), and a new paragraph 1a is introduced in Article 137. ***Article 32a (new)*** ***Duty to Communicate information on Substances in Articles*** ***1 Any supplier of an article containing a substance meeting the criteria in Article 56 and identified according to Article 58(1) in a concentration above 0,1 % weight by weight (w/w) shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that***

	2. The information requirements specified in paragraph 1 shall apply mutatis mutandis up the supply chain. ***3. Downstream users who incorporate into an article a substance or preparation for which a safety data sheet was established, and those who subsequently handle or further process that article, shall pass on the safety data sheet to any recipient of the article or its derivative. Recipients shall not include consumers.*** ***Consumers shall have the right to ask the producer or importer for information on the substances present in an article produced or imported by him.*** ***Producers or importers shall, on request and within 15 working days, enable any individual consumer to obtain, free of charge, full details of safety and use information concerning the substances present in any article they have produced or imported.***	***substance.*** ***2. On request by a consumer any supplier of an article containing a substance meeting the criteria in Article 56 and identified according to Article 58(1) in a concentration above 0,1 % weight by weight (w/w) shall provide the consumer with sufficient information, available to the supplier, to allow safe use of the article including as a minimum, the name of that substance.*** ***The relevant information shall be provided, free of charge, within 45 days of receipt of the request.*** _____ The Presidency suggests that an additional definition be introduced in Article 3: ***(31 a) Supplier of an article means any producer or importer of an article, distributor or other actor in the supply chain placing an article on the market.*** _____ The Presidency suggests that the definition in Article 3 of Recipient of an article be amended as follows: (33) Recipient of an article means an industrial or professional user, ***or a distributor***, being supplied with an article but does not include consumers. ____ ***Article 137*** ***1a (new). By …*, the Commission shall carry out a review to assess whether or not to extend the scope of Article 32a to cover other dangerous substances, taking into account the practical experience in implementing that Article. On the basis of this review, the Commission may, if appropriate, present***

		legislative proposals to extend this obligation. ____ ****12 years after the entry into force of this Regulation***
Article 76.2 ma Does not exist.	Amendment 125 ***(ma) establishing and maintaining a centre of excellence for risk communication; providing centralised, coordinated resources in the area of information on the safe use of chemical substances, preparations and articles; facilitating the sharing of best practice in the risk communication sector.***	It was agreed to address this issue in Article 122 and in Article 76.2 (see Agency part) as follows: *Article 122* *Communication to the public of information on risks of substances* The competent authorities of the Member States shall inform the general public about the risks arising from substances where this is considered necessary for the protection of human health or the environment. The ~~Commission~~ ***Agency, in consultation with competent authorities and stakeholders and drawing as appropriate on relevant best practice,*** shall ~~draw up guidelines~~ ***provide guidance for the communication of information on the risks and safe use of chemical substances, on their own, in preparations or in articles,*** ~~in accordance with the procedure referred to in Article 132(3)~~ with a view to coordinating Member States in these activities.

4. COMITOLOGY

Council Common Position	EP amendment	Result of the 6th trilogue
Does not exist	No EP amendment	In accordance with the agreement between the legal services a new recital on comitology is introduced. ***In particular, power should be conferred on the Commission to amend the Annexes in certain cases, to set rules on test methods, to varying the percentage of dossiers selected for compliance checking and to modify the criteria for their selection~~, to determine the qualifications required for the members of the Board of Appeals and the procedures for these Boards~~ and to set the criteria defining what constitutes adequate justification that testing is technically not possible. Since these measures are of general scope and are designed to amend non-essential elements of this Regulation or supplement this Regulation by the addition of new non-essential elements, they should be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Council Decision 1999/468/EC.***
Article 7.8 8. Any measures for the implementation of paragraphs 1 to 7 shall be adopted in accordance with the procedure referred to in Article 132(3).	*Comitology* No EP amendment.	It was agreed that Article 132(3) should continue to apply.

Article 13.2 subpara 1 2. Where tests on substances are required to generate information on intrinsic properties of substances, they shall be conducted in accordance with the test methods laid down in a Commission Regulation adopted in accordance with the procedure referred to ***in Article 132(3)***, which shall be revised as appropriate in particular to refine, reduce or replace animal testing, or in accordance with other international test methods recognised by the Commission or the Agency as being appropriate.	*Comitology* Amendment 44 2. Where tests on substances are required to generate information on intrinsic properties of substances, they shall be conducted in accordance with the test methods laid down in a Commission Regulation adopted in accordance with the procedure referred to in Article ***132(3a)***, which shall be revised as appropriate in particular to refine, reduce or replace animal testing, or in accordance with other international test methods recognised by the Commission or the Agency as being appropriate.	It was agreed that Article ***132(3a)*** in accordance with the new Comitology Decision should apply. In addition the text is redrafted as follows: 2. Where tests on substances are required to generate information on intrinsic properties of substances, they shall be conducted in accordance with the test methods laid down in a Commission Regulation. ***The Commission shall adopt this Regulation, designed to amend the non-essential elements of this Regulation by supplementing it*** in accordance with the procedure referred to in Article ***132(3a)***, which shall be revised as appropriate in particular to refine, reduce or replace animal testing, or in accordance with other international test methods recognised by the Commission or the Agency as being appropriate
Article 40.7 7. The Commission may, after consulting with the Agency, take a decision to vary the percentage of dossiers selected and amend or include further criteria in paragraph 5 in accordance with the procedure referred to in Article ***132(3)***.	*Comitology* Amendment 70 7. The Commission may, after consulting with the Agency, take a decision to vary the percentage of dossiers selected and amend or include further criteria in paragraph 5 in accordance with the procedure referred to in Article ***132(3a)***.	It was agreed that Article 132(3a) in accordance with the new Comitology decision should apply.

Article 44.3 3. In cases where two or more Member States have expressed an interest in evaluating the same substance and they cannot agree who should be the competent authority, the competent authority for the purposes of Articles 45, 46 and 47 shall be determined in accordance with the following procedure. The Agency shall refer the matter to the Member State Committee, in order to agree which authority shall be the competent authority, taking into account the Member State in which the manufacturer(s) or importer(s) is located, the respective proportions of total Community gross domestic product, the number of substances already being evaluated by a Member State and the expertise available. If, within 60 days of the referral, the Member State Committee reaches unanimous agreement, the Member States concerned shall adopt substances for evaluation accordingly. If the Member State Committee fails to reach a unanimous agreement, the Agency shall submit the conflicting opinions to the Commission, which shall decide which authority shall be the competent authority, in accordance with the procedure referred to in Article ***132(3)***, and the Member States concerned shall adopt substances for evaluation accordingly.	*Comitology* No EP amendment.	It was agreed that Article 132(3) should continue to apply.

Article 46.2 2. In order to ensure a harmonised approach to requests for further information, the Agency shall monitor draft decisions under Article 45 and shall develop criteria and priorities. Where appropriate, implementing measures shall be adopted in accordance with the procedure referred to in Article ***132(3)***.	*Comitology* Amendment 71 2. In order to ensure a harmonised approach to requests for further information, the Agency shall monitor draft decisions under Article 45 and shall develop criteria and priorities. Where appropriate, implementing measures shall be adopted in accordance with the procedure referred to in Article ***132(3a)***.	It was agreed that Article 132(3) should continue to apply.
Article 50.7 7. If the Member State Committee fails to reach unanimous agreement, the Commission shall prepare a draft decision to be taken in accordance with the procedure referred to **in Article 132(3).**	*Comitology* No EP amendment.	It was agreed that Article 132(3) should continue to apply.
Article 57 title and 57.1 introductory part Article 57 Inclusion of substances in Annex ***XIV*** 1. Whenever a decision is taken to include in Annex ***XIV*** substances referred to in Article 56, such a decision shall be taken in accordance with the procedure referred to in Article ***132(3)***. It shall specify for each substance:	*Comitology* Amendment 81 Article 57 Inclusion of substances in Annex ***XIV(b)*** 1. Whenever a decision is taken to include in Annex ***XIV(b)*** substances referred to in Article 56, such a decision shall be taken in accordance with the procedure referred to in Article ***132(3a).*** It shall specify for each substance:	It was agreed that Article 132(3a) in accordance with the new Comitology decision should apply.
Article 57.8 8. Substances which as a result of new information no longer meet the criteria of Article 56 shall be removed from Annex XIV in accordance with the procedure referred to in Article ***132(3)***.	*Comitology* Amendment 92 8. Substances which as a result of new information no longer meet the criteria of Article 56 shall be removed from Annex XIV in accordance with the procedure referred to in Article ***132(3a)***.	It was agreed that Article 132(3a) in accordance with the new Comitology Decision should apply.

Article 58.8 and 58.9 <u>Only 58.9 relevant for comitology</u> [8. If, within 30 days of the referral, the Member State Committee reaches a ***unanimous*** agreement on the identification, the Agency shall ***include the substance in the list referred to in paragraph 1. The Agency may include that substance in its recommendations under*** Article 57(3).] 9. If the Member State Committee fails to reach a unanimous agreement, the Commission shall prepare a draft proposal on the identification of the substance within three months of receipt of the opinion of the Member State Committee. A final decision on the identification of the substance shall be taken in accordance with the procedure referred to in Article ***132(3)***.	*Including Comitology* Amendment 96 [8. If, within 30 days of the referral, the Member State Committee reaches a ***qualified majority*** agreement ***that the substance satisfies the criteria for authorisation and should be included in Annex XIV(b),*** the Agency shall***, within 15 working days, recommend to the Commission that the substance be included in Annex XIV(b), as provided for in*** Article 57(3).] 9. If the Member State Committee fails to reach a ***qualified majority*** agreement, ***it shall adopt an opinion within 30 days of the referral. The Agency shall transmit that opinion to the Commission within 15 working days, including information on any minority view within the Committee.*** A final decision on the identification of the substance shall be taken in accordance with the procedure referred to in Article ***132(3a)***.	It was agreed that the wording in the Common Position should be retained in the entire article. It was agreed that Article 132(3) should continue to apply.
Article 63.8 8. The Commission shall prepare a draft authorisation decision within three months of receipt of the opinions from the Agency. A final decision granting or refusing the authorisation shall be taken in accordance with the procedure referred to in Article ***132(2)***.	*Comitology* Amendment 113 8. The Commission shall prepare a draft authorisation decision within three months of receipt of the opinions from the Agency. A final decision granting or refusing the authorisation shall be taken in accordance with the procedure referred to in Article ***132(3a)***.	It was agreed that Article ***132(3)*** should apply, in addition a new recital is added:. ***(zz) It is convenient that final decisions granting or refusing the authorisations be adopted by the Commission pursuant to a regulatory procedure in order to allow for an examination of their wider implications within the Member States and to more closely associate these.***

Article 67.1 subpara 1 1. When there is an unacceptable risk to ***human health or the environment***, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Community-wide basis, Annex XVII shall be amended in accordance with the procedure referred to in Article ***132(3)*** by adopting new restrictions, or amending current restrictions in Annex XVII, for the manufacture, use or placing on the market of substances on their own, in preparations or in articles, pursuant to the procedure set out in Articles 68 to 72. Any such decision shall take into account the socio-economic impact of the restriction, including the availability of alternatives.	*Comitology* Amendment 117 1. When there is an unacceptable risk to ***the environment or to human health, including that of vulnerable populations and citizens exposed early in life or continuously to mixtures of pollutants***, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Community-wide basis, Annex XVII shall be amended in accordance with the procedure referred to in Article ***132(3a)*** by adopting new restrictions, or amending current restrictions in Annex XVII, for the manufacture, use or placing on the market of substances on their own, in preparations or in articles, pursuant to the procedure set out in Articles 68 to 72. Any such decision shall take into account the socio-economic impact of the restriction, including the availability of alternatives.	It was agreed that the wording in the Common Position should be retained for the entire article apart from the Comitology reference. It was agreed that Article ***132(3a)*** in accordance with the new Comitology Decision should apply.
Article 67.2 2. For a substance on its own, in a preparation or in an article which meets the criteria for classification as carcinogenic, mutagenic or toxic to reproduction, category 1 or 2, and could be used by consumers and for which restrictions to consumer use are proposed by the Commission, Annex XVII shall be amended in accordance with the procedure referred to in Article ***132(3)***. Articles 68 to 72 shall not apply.	*Comitology* Amendment 118 2. For a substance on its own, in a preparation or in an article which meets the criteria for classification as carcinogenic, mutagenic or toxic to reproduction, category 1 or 2, and could be used by consumers and for which restrictions to consumer use are proposed by the Commission, Annex XVII shall be amended in accordance with the procedure referred to in Article ***132(3a)***. Articles 68 to 72 shall not apply.	It was agreed that Article ***132(3a***) in accordance with the new Comitology Decision should apply.

Article 68.5 5. The Agency shall maintain a list of substances for which a dossier conforming to the requirements of Annex XV is planned or underway by either the Agency or a Member State for the purposes of a proposed restriction. If a substance is on the list, no other such dossier shall be prepared. If it is proposed by either a Member State or the Agency that an existing restriction listed in Annex XVII should be re-examined a decision on whether to do so shall be taken in accordance with the procedure referred to in Article ***132(2)*** based on evidence presented by the Member State or the Agency.	*Comitology* No EP Amendment.	It was agreed that Article 132(2) should continue to apply.
Article 72 1. If the conditions laid down in Article 67 are fulfilled, the Commission shall prepare a draft amendment to Annex XVII, within three months of receipt of the opinion of the Committee for Socio-economic Analysis or by the end of the deadline established under Article 70 if that Committee does not form an opinion, whichever is the earlier. Where the draft amendment diverges from the original proposal or if it does not take the opinions from the Agency into account, the Commission shall annex a detailed explanation of the reasons for the differences. 2. A final decision shall be taken in accordance with the procedure referred to in Article ***132(3)***. The Commission shall send the draft amendment to the Member States at least 45 days before voting.	*Comitology* Amendment 120 1. ***Where a substance is already regulated in Annex XVII, and*** if the conditions laid down in Article 67 are fulfilled, the Commission shall prepare a draft amendment to Annex XVII, within three months of receipt of the opinion of the Committee for Socio-economic Analysis or by the end of the deadline established under Article 70 if that Committee does not form an opinion, whichever is the earlier. Where the draft amendment diverges from the original proposal or if it does not take the opinions from the Agency into account, the Commission shall annex a detailed explanation of the reasons for the differences. 2. A final decision shall be taken in accordance with the procedure referred to in Article ***132(3a)***. The Commission shall send the draft amendment to the Member States at least 45 days before voting. ***2a. Where a substance has not been regulated before***	It was agreed that the wording of the Common Position should be retained but that Article ***132(3a)*** in accordance with the new Comitology Decision should apply.

	in Annex XVII, the Commission shall submit a proposal to the European Parliament and the Council to amend Annex XVII within the time limit specified in paragraph 1.	
Article 73.1 1. The fees that are required according to Article 6(4), Article 7(1) and (5), Article 9(2), Article 11(4), Article 17(2), Article 18(2), Article 19(3), Article 22(5), Article 61(7) and Article 91(3) shall be specified in a Commission Regulation adopted in accordance with the procedure referred to **in Article 132(3)** by …*. _____ * One year after entry into force of this Regulation.	*Comitology* No EP amendment.	It was agreed that Article 132(3) should continue to apply.
Article 88.4 4. The qualifications required for the members of the Board of Appeal shall be determined by the Commission in accordance with the procedure referred to in Article ***132(3)***.	*Comitology* Amendment 144 4. The qualifications required for the members of the Board of Appeal shall be determined by the Commission in accordance with the procedure referred to in Article ***132(3a)***.	***It was agreed that Article 132(3) should continue to apply.***
Article 92.4 4. The procedures for the Board of Appeal shall be determined by the Commission in accordance with the procedure referred to in Article ***132(3)***.	*Comitology* Amendment 147 4. The procedures for the Board of Appeal shall be determined by the Commission in accordance with the procedure referred to in Article ***132(3a)***.	***It was agreed that Article 132(3) should continue to apply.***

Article 122 The competent authorities of the Member States shall inform the general public about the risks arising from substances where this is considered necessary for the protection of human health or the environment. The Commission shall draw up guidelines in accordance with the procedure referred to **in Article 132(3**) with a view to coordinating Member States in these activities.	*Comitology* No EP amendment on Comitology.	It was agreed to amend Article 122 in order to respond to Amendment 125 concerning risk communication (see Article 76.2). The question on comitology is no longer relevant due to the changes agreed to in Article 122.
Article 128.2 2. The Commission shall take a decision in accordance with the procedure referred to in **Article 132(3**) within 60 days of receipt of the information from the Member State. This decision shall either: (a) authorise the provisional measure for a time period defined in the decision; or (b)require the Member State to revoke the provisional measure.	*Comitology* No EP amendment.	It was agreed that Article 132(3) should continue to apply.
Article 130 The Annexes may be amended in accordance with the procedure referred to in Article ***132(3)***.	*Comitology* Amendment 155 The Annexes may be amended in accordance with the procedure referred to in Article ***132(3a)***.	It was agreed that Article ***132(3a)*** in accordance with the new Comitology Decision should apply.

Article 131 ***The measures necessary*** for the efficient implementation of this Regulation shall be adopted in accordance with the procedure referred to in Article 132(3).	*Comitology* Amendment 156 ***Where,*** for the efficient implementation of this Regulation***, it proves necessary to adopt measures for which the powers have not been provided elsewhere in this Regulation, these measures*** shall be adopted: ***(a)*** in accordance with the procedure referred to in Article 132(3), ***when the measures to be adopted are measures of general scope designed to apply essential provisions of this Regulation;*** ***(b) in accordance with the procedure referred to in Article 132(3a), when the measures to be adopted are measures of general scope designed to amend non-essential elements of this Regulation.***	It was agreed that the wording of the Common Position should be redrafted as follows**:** The measures necessary ***to put into effect efficiently the provisions*** of this Regulation shall be adopted in accordance wit the procedure referred to in Article 132 (3).
Article 132.3 a Does not exist.	Amendment 157 ***3a. Where reference is made to this paragraph, Articles 5a and 7 of Decision 1999/468/EC as amended by Decision 2006/512/EC shall apply.***	It was agreed that the following paragraph 3a be introduced in Article 132: ***3a. Where reference is made to this paragraph, Articles 5a, paragraphs 1 to 4,and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.***
Article 137.4 4. The Commission shall carry out a review of Annexes ***I***, IV and V by …, with a view to proposing amendments, if appropriate, to them in accordance with the procedure referred to in Article ***132(3)***.	*Comitology* Amendment 160 4. The Commission shall carry out a review of Annexes IV and V by …*, with a view to proposing amendments, if appropriate, to them in accordance with the procedure referred to in Article ***132(3a)***.	It was agreed to redraft the Article as follows: 4. The Commission shall carry out a review of Annexes I, IV and V by …, with a viewto proposing amendments, if appropriate, to them in accordance with the procedure referred to in Article ***130.***

ANNEX XI, POINT 3.3 3.3. The Commission shall adopt ***criteria defining what constitutes adequate justification under Section 2 in*** accordance with the procedure referred to in Article ***132(3)*** by …*.	*Comitology* Amendment 170 3.3. The Commission shall adopt criteria defining what constitutes adequate justification under Section 2 in accordance with the procedure referred to in Article ***132(3a)*** by …*.	It was agreed that Article 132(3a) in accordance with the new Comitology Decision should apply and to redraft as follows: 3.3. The Commission shall adopt ***the measures designed to amend non-essential elements of this Regulation by supplementing it***, in accordance with the procedure referred to in Article ***132(3a), to set the criteria defining what constitutes adequate justification under Section 3.2 by...**** * 18 months after entry force of this Regulation.

5. AGENCY

Council Common Position	EP amendment	Result of the 6th trilogue
Article 7.7 a Does not exist.	Amendments 39 ***7a. The Agency shall provide guidelines to help the producers and importers of articles as well as the competent authorities.***	It was agreed to introduce a specific reference to Article 7 in Article 76.2 (f) as follows: 2. The Secretariat shall undertake the following tasks: (e) … (f) providing technical and scientific guidance and tools where appropriate for the operation of this Regulation in particular to assist the development of chemical safety reports (in accordance with Article 14, Article 31(1) and Article 36(4)), application of Article 10(a)(viii), Article 11(3) and Article 19(2) by industry and especially by SMEs, ***and technical and scientific guidance for the application of Article 7 by producers and importers of articles;*** (g) …
Article 75.1 da Does not exist.	Amendment 122 ***(da) a Committee for Alternative Test Methods, which shall be responsible for developing and implementing an integrated strategy to speed up the development, validation and legal acceptance of non-animal test methods, and to ensure their use in intelligent stepwise risk assessment to meet the requirements of this Regulation. The Committee shall be responsible for allocating funding for alternative test methods provided through the registration fee. The Committee shall consist of experts from the European Centre for the Validation of Alternative Methods, animal welfare organisations and other relevant stakeholders.***	It was agreed to address this concern in the context of amendment 45 (Article 13.2.1.a).

	Every year the Committee shall produce a report to be presented by the Agency to the European Parliament and the Council on the progress made on the development, validation and legal acceptance of non-animal test methods, the use of such methods in intelligent stepwise risk assessment to meet the requirements of this Regulation, and the amount and distribution of funding for alternative test methods.	
Article 76.2 ma Does not exist.	Amendment 125 ***(ma) establishing and maintaining a centre of excellence for risk communication; providing centralised, coordinated resources in the area of information on the safe use of chemical substances, preparations and articles; facilitating the sharing of best practice in the risk communication sector.***	It was agreed to introduce the following text in a new sub-paragraph (ga) as part of the response to Amendment 125. (See also Amendment to Article 122 in section 3. Communication of Information) (g) … ***(ga) providing guidance to stakeholders including Member State competent authorities on communication to the public of information on the risks and safe use of substances, on their own, in preparations or in articles.*** (h) …
Article 76.3 c (c) at the Commission's request, drawing up an opinion on any other aspects concerning the safety of substances on their own, in preparations or in articles.	Amendment 126 (c) at the Commission's ***or the European Parliament's*** request, drawing up an opinion on any other aspects concerning the safety of substances on their own, in preparations or in articles.	It was agreed to address this issue as follows: (c) at the ***Executive Director's*** request, drawing up an opinion on any other aspects concerning the safety of substances on their own, in preparations or in articles. As a consequence It was agreed to amend point (b) of the same Article as follows: (b) at the ***Executive Director's*** request, providing technical and scientific support …

Article 76.4 d (d) identifying enforcement strategies, as well as best practice in enforcement;	Amendment 127 (d) identifying enforcement strategies, as well as best practice in enforcement***, taking particular account of the specific problems for SMEs***;	It was agreed to address the concern behind this Amendment in Article 76.4 (g) (g) liaising with industry***, taking particular account of the specific needs of SMEs,*** and other stakeholders, including relevant international organisations, as necessary.
Article 78.1 1. The Management Board shall be composed of one representative from each Member State and a maximum of six representatives appointed by the Commission, including three individuals from interested parties without voting rights. Each Member State shall nominate a member to the Management Board. The members thus nominated shall be appointed by the Council.	Amendment 129 1. The Management Board shall be composed of one representative from each Member State**,** and a maximum of six representatives appointed by the Commission ***and two representatives nominated by the European Parliament.*** ***In addition, four representatives of*** interested parties ***(industry and consumer, worker and environmental protection organisations) shall be nominated by the Commission as members of the Management Board*** without voting rights**.** ***The members of the Management Board shall be nominated in such a way as to ensure the highest levels of competence, a wide range of relevant specialist knowledge and (without prejudice to such characteristics) the broadest possible geographical distribution within the European Union.***	It was agreed that the wording be modified as follows: 1. The Management Board shall be composed of one representative from each Member State and a maximum of six representatives appointed by the Commission, including three individuals from interested parties without voting rights, ***and in addition two independent persons appointed by the European Parliament***. Each Member State shall nominate a member to the Management Board. The members thus nominated shall be appointed by the Council.
Article 82.1 1. The Agency shall be managed by its Executive	Amendment 133 1. The Agency shall be managed by its Executive	See amendment 142 (Article 87).

Director, ***who shall perform his duties in the interests of the Community, and independently of any specific interests.***	Director.	
Article 82.2 (ja) Does not exist.	Amendment134 ***(ja) establishing and maintaining contact with the European Parliament and ensuring that a regular dialogue is held with that institutions's relevant committee;***	It was agreed to introduce the following subparagraph (ja) in order to ensure appropriate reporting and a flow of information from the European Chemicals Agency to the EP: ***(ja) establishing and maintaining regular dialogue with the European Parliament.***
		It was agreed to ensure consistency, that a new point (ka) be added to Article 82.2 as follows: ***(ka) rectifying a decision made by the Agency on appeal and after consulting with the chairman of the Board of Appeal.*** [(#)] [(#)] ***Commission technical point Nr 31***
Article 82.3.a Does not exist.	Amendment 135 ***3a. Once the general report and the programmes have been approved by the Management Board, the Executive Director shall forward them to the European Parliament, the Council, the Commission and the Member States, and shall arrange for them to be published.***	It was agreed to redraft Article 82 in the following way to ensure appropriate reporting and a flow of information from the European Chemicals Agency to the EP: *Article 82* *Duties and powers of the Executive Director* 1. The Agency shall be managed by its Executive Director, who shall perform his duties in the interest of the Community, and independently of any specfic interests. 2. … 3. Each year the Executive Director shall submit the following to the Management Board for approval: (a)… (b)…

		(c)… (d)… (e)… ***The Executive Director shall, following adoption by the Management Board, forward the work programme for the coming year and the multi-annual work programme to the Member States, the European Parliament, the Council, and the Commission, and shall have them published.*** ***The Executive Director shall, following adoption by the Management Board, forward the Agency's general report to the Member States, the European Parliament, the Council, the Commission, the European Economic and Social Committee, and the Court of Auditors, and shall have it published.*** In addition, consequential changes must be made in Article 77 (Powers of the Management Board). *Article 77* *Powers of the Management Board* The Management Board shall appoint the Executive Director pursuant to Article 83 and an accounting officer in accordance with Article 43 of Regulation (EC, Euratom) No 2343/2002. It shall adopt: (a) by 30 April each year, the general report of the Agency for the previous year ~~and forward it by 15 June at the latest to the Member States, the European Parliament, the Council, the Commission, the European Economic and Social Committee and the Court of Auditors~~; (b) by 31 October each year the work programme of the

		Agency for the coming year ~~and forward it to the Member States, the European Parliament, the Council and the Commission~~; (c) …..
Article 83.1 ***1. The Commission shall propose candidates for the post of the Executive Director based on a list following publication of the post in the Official Journal of the European Union and other press or internet sites as appropriate.***	Amendment 136 ***deleted***	It was agreed to incorporate this paragraph (Article 83.1) into Article 83.2 in a redrafted format (See Amendment 137 below).
Article 83.2 subpara 1	Amendment 137	It was agreed that the Executive Director would be invited to introduce himself/herself to the EP as soon as possible before his/her appointment. This would initiate and facilitate the regular dialogue between the Executive Director and the EP. *Article 83* *Appointment of the Executive Director*
		1 ***Delete.***
2. The Executive Director of the Agency shall be appointed by the Management Board	2. The Executive Director of the Agency shall be appointed by the Management Board ***from among a list of candidates proposed by the Commission following a public-selection procedure advertised by means of a call for expressions of interest published in the Official Journal of the European Union and in other periodicals or on Internet sites. Prior to nomination the candidate designated by the Management Board shall be asked as soon as possible to make a statement before the European Parliament and to answer questions from Parliament's Members.***	2. The Executive Director of the Agency shall be appointed by the Management Board, ***on the basis of list of candidates proposed by the Commission following a call for expressions of interest published in the Official Journal of European Communities and in other periodicals or on Internet sites.***
on the grounds of merit and documented administrative and management skills, as well as his relevant experience in the fields of chemical safety or regulation. The Management Board shall take its	***The Executive Director shall be nominated*** on the grounds of merit and documented administrative and management skills, as well as his relevant experience in the fields of chemical safety or regulation. The	***The Executive Director shall be appointed*** on the grounds of merit and documented administrative and management skills, as well as his relevant experience in the fields of chemical safety or regulation. The

decision by a two-thirds majority of all members with a right to vote.	Management Board shall take its decision by a two-thirds majority of all members with a right to vote.	Management Board shall take its decision by a two-thirds majority of all members with a right to vote. ***Before being appointed, the candidate selected by the Management Board shall be invited as soon as possible to make a statement before the European Parliament and to answer questions from Parliament's Members.***
Article 85.1-3	Amendment 139	It was agreed that members of the Management Board should not simultaneously be members of the Forum.
1. Each Member State shall appoint, for a three-year term, which shall be renewable, one member to the Forum. Members shall be chosen for their role and experience in enforcement of chemicals legislation and shall maintain relevant contacts with the Member State competent authorities.	1. Each Member State shall appoint, for a three-year term, which shall be renewable, one member to the Forum. Members shall be chosen for their role and experience in enforcement of chemicals legislation and shall maintain relevant contacts with the Member State competent authorities.	1. Each Member State shall appoint, for a three-year term, which shall be renewable, one member to the Forum. Members shall be chosen for their role and experience in enforcement of chemicals legislation and shall maintain relevant contacts with the Member State competent authorities.
The Forum should aim to have a broad range of relevant expertise among its members. To this end the Forum may co-opt a maximum of five additional members chosen on the basis of their specific competence. These members shall be appointed for a term of three years, which shall be renewable.	The Forum shall aim to have a broad range of relevant expertise among its members. To this end the Forum may coopt a maximum of five additional members chosen on the basis of their specific competence. These members shall be appointed for a term of three years, which shall be renewable.	The Forum should aim to have a broad range of relevant expertise among its members. To this end the Forum may co-opt a maximum of five additional members chosen on the basis of their specific competence. These members shall be appointed for a term of three years, which shall be renewable. ***Members of the Management Board may not be members of the Forum***.
The members of the Forum may be accompanied by scientific and technical advisers.	The members of the Forum may be accompanied by scientific and technical advisers.	The members of the Forum may be accompanied by scientific and technical advisers.
The Executive Director of the Agency or his representative and representatives of the Commission shall be entitled to attend all the meetings of the Forum and its working groups. Stakeholders may also ***be invited to*** attend meetings as observers, ***as appropriate, at the request of Forum members, or the Management Board***.	The Executive Director of the Agency or his representative and representatives of the Commission shall be entitled to attend all the meetings of the Forum and its working groups. Stakeholders may also attend meetings as observers. ***Members of the Forum may not be members of the Management Board.***	The Executive Director of the Agency or his representative and representatives of the Commission shall be entitled to attend all the meetings of the Forum and its working groups. Stakeholders may also be invited to attend meetings as observers, as appropriate, at the request of Forum members, or the Management Board.

2. The members of the Forum appointed by a Member State shall ensure that there is appropriate co-ordination between the tasks of the Forum and the work of their Member State competent authority. 3. The members of the Forum shall be supported by the scientific and technical resources available to the competent authorities of the Member States. Each Member State competent authority shall facilitate the activities of the Forum and its working groups. ***The Member States shall refrain from giving the Forum members, or their scientific and technical advisers and experts any instruction which is incompatible with the individual tasks of those persons or with the tasks and responsibilities of the Forum.***	2. The members of the Forum appointed by a Member State shall ensure that there is appropriate coordination between the tasks of the Forum and the work of their Member State competent authority. 3. The members of the Forum shall be supported by the scientific and technical resources available to the competent authorities of the Member States. Each Member State competent authority shall facilitate the activities of the Forum and its working groups.	2. The members of the Forum appointed by a Member State shall ensure that there is appropriate co-ordination between the tasks of the Forum and the work of their Member State competent authority. 3. The members of the Forum shall be supported by the scientific and technical resources available to the competent authorities of the Member States. Each Member State competent authority shall facilitate the activities of the Forum and its working groups. The Member States shall refrain from giving the Forum members, or their scientific and technical advisers and experts any instruction which is incompatible with the individual tasks of those persons or with the tasks and responsibilities of the Forum.
Article 86.1 1. Where, in accordance with Article 76, a Committee is required to ***take a decision***, provide an opinion or consider whether a Member State dossier conforms with the requirements of Annex XV, it shall appoint one of its members as a rapporteur. The Committee concerned may appoint a second member to act as co-rapporteur. ***For each case, rapporteurs and co-rapporteurs shall undertake to act in the interests of the Community and shall make a declaration of commitment to fulfil their duties and a declaration of interests in writing.*** A member of a Committee shall not be appointed rapporteur for a particular case if he indicates any interest that might be prejudicial to the independent consideration of that case. The Committee concerned may replace the rapporteur or co-rapporteur by another one of its members at any time, if, for example, they are unable to fulfil their duties within the prescribed time limits, or if a potentially prejudicial interest comes to light.	Amendment 140 1. Where, in accordance with Article 76, a Committee is required to provide an opinion or consider whether a Member State dossier conforms with the requirements of Annex XV, it shall appoint one of its members as a rapporteur. The Committee concerned may appoint a second member to act as co-rapporteur. A member of a Committee shall not be appointed rapporteur for a particular case if he indicates any interest that might be prejudicial to the independent consideration of that case. The Committee concerned may replace the rapporteur or co-rapporteur by another one of its members at any time, if, for example, they are unable to fulfil their duties within the prescribed time limits, or if a potentially prejudicial interest comes to light.	It was agreed to delete "take a decision" and retain the rest of the text of the Common Position. 1. Where, in accordance with Article 76, a Committee is required to ~~take a decision~~, provide an opinion or consider whether a Member State dossier conforms with the requirements of Annex XV, it shall appoint one of its members as a rapporteur. The Committee concerned may appoint a second member to act as co-rapporteur. For each case, rapporteurs and co-rapporteurs shall undertake to act in the interests of the Community and shall make a declaration of commitment to fulfil their duties and a declaration of interests in writing. A member of a Committee shall not be appointed rapporteur for a particular case if he indicates any interest that might be prejudicial to the independent consideration of that case. The Committee concerned may replace the rapporteur or co-rapporteur by another one of its members at any time, if, for example, they are unable to fulfil their duties within the prescribed time limits, or if a potentially prejudicial interest comes to light.

Article 87 *Article 87* ***Qualifications and interests*** 1. The membership of the Committees and of the Forum shall be made public. ***Individual members may request that their names not be made public if they believe that such publication could place them at risk. The Executive Director shall decide whether to agree to such requests.*** When each appointment is published, the professional qualifications of each member shall be specified. 2. Members of the Management Board, the Executive Director ***and*** members of the Committees ***and*** of the Forum shall make a declaration of commitment to fulfil their duties and a declaration of interests ***which could be considered to be prejudicial to their independence. These declarations shall be made annually in writing.***	Amendment 142 *Article 87* ***Independence*** 1. The membership of the Committees and of the Forum shall be made public. When each appointment is published, the professional qualifications of each member shall be specified. 2. Members of the Management Board, the Executive Director, members of the Committees***, members*** of the Forum***, members of the Board of Appeal, experts and scientific and technical advisers shall not have economic or other interests in the chemical sector which may prejudice their impartiality. They shall undertake to act independently and in the public interest and*** shall ***each year*** make a declaration of ***their financial*** interests***. Any indirect interests relating to the chemical industry shall be declared in a register held by the Agency and accessible to the public on request at the Agency's offices***. ***Member States shall refrain from giving the members of the Risk Assessment Committee, of the Socio-Economic Analysis Committee, of the Forum or of the Board of Appeal, or their scientific and technical advisers and experts, any instruction which is incompatible with the individual tasks of those persons or with the tasks, responsibilities and***	It was agreed to make the annual declarations of interest public, in order to increase openness and transparency. The text would read as follows: *Article 87* *Qualification and interests* 1. The membership of the Committees and of the Forum shall be made public. Individual members may request that their names not be made public if they believe that such publication could place them at risk. The Executive Director shall decide whether to agree to such requests. When each appointment is published, the professional qualifications of each member shall be specified. 2. Members of the Management Board, the Executive Director and members of the Committees and of the Forum shall make a declaration of commitment to fulfill their duties and a declaration of interests which could be considered to be prejudicial to their independence. These declarations shall be made annually in writing ***and, without prejudice to paragraph 1, shall be entered in a register held by the Agency which is accessible to the public, on request, at the Agency's offices.***

	independence of the Agency. ***The Agency's code of practice shall specify measures relating to the application of this article.***	
3. At each of their meetings, members of the Management Board, the Executive Director, members of the Committees ***and*** of the Forum and any experts participating in the meeting shall declare any interests which could be considered to be prejudicial to their independence with respect to any points on the agenda. Anyone declaring such interests shall ***not*** participate in any voting ***on the relevant agenda point.***	3. At each of their meetings, members of the Management Board, the Executive Director, members of the Committees***, members*** of the Forum and any experts ***and scientific and technical advisers*** participating in the meeting shall declare any interests which could be considered to be prejudicial to their independence with respect to any points on the agenda. Anyone declaring such interests shall ***participate neither in the discussion of the relevant agenda points nor*** in any voting ***thereupon. Such declarations shall be made publicly accessible.***	3. At each of their meetings, members of the Management Board, the Executive Director, members of the Committees and of the Forum and any experts participating in the meeting shall declare any interests which could be considered to be prejudicial to their independence with respect to any points on the agenda. Anyone declaring such interests shall not participate in any voting on the relevant agenda point. Consequential Change in Article 84.1 and 84.2: 1. Each Member State may nominate candidates to membership of the Committee for Risk Assessment. The Executive Director shall establish a list of the nominees, which shall be published on the Agency's website, ***without prejudice to Article 87.1***. The Management Board shall appoint the members of the Committee from this list, including at least one member but not more than two from the nominees of each Member State that has nominated candidates. Members shall be appointed for their role and experience in performing the tasks specified in Article 76(3). 2. Each Member State may nominate candidates to membership of the Committee for Socio-economic Analysis. The Executive Director shall establish a list of the nominees, which shall be published on the Agency's website, ***without prejudice to Article 87.1***. The Management Board shall appoint the members of the Committee from this list, including at least one member but not more than two from the nominees of each Member State that has nominated candidates. Members shall be appointed for their role and

		experience in performing the tasks specified in Article 76(3).
Article 88.3 subpara 1 3. The Chairman, the other members and the alternates shall be appointed by the Management Board on the basis of their relevant experience and expertise in the field of chemical safety, natural sciences or regulatory and judicial procedures ***from a list of qualified candidates adopted by the Commission.***	Amendment 143 3. The Chairman, the other members and the alternates shall be appointed by the Management Board ***from among a list of qualified candidates proposed by the Commission following a public-selection procedure advertised by means of a call for expressions of interest published in the Official Journal of the European Union and in other periodicals or on Internet sites. The members of the Board of Appeal shall be selected*** on the basis of their relevant experience and expertise in the field of chemical safety, natural sciences or regulatory and judicial procedures.	It was agreed to introduce a public-selection procedure. The text reads as follows: 3. The Chairman, the other members and the alternates shall be appointed by the Management Board ***on the basis of a list of candidates proposed by the Commission following a call for expressions of interest published in the Official Journal of European Communities and in other periodicals or on Internet sites. They shall be appointed*** on the basis of their relevant experience…
Article 89.2 and 3 ***2. The Members of the Board of Appeal shall be independent. In making their decisions they shall not be bound by any instructions.*** 3. The members of the Board of Appeal may not perform any other duties in the Agency. ***The function of the Members may be a part-time function.***	Amendment 145 **deleted** 3. The members of the Board of Appeal may not perform any other duties in the Agency.	It was agreed to delete the possibility of part-time function of the members of the Board of Appeal. Otherwise the text of the Common Position will be retained. The text reads as follows: 2. The Members of the Board of Appeal shall be independent. In making their decisions they shall not be bound by any instructions. 3. The members of the Board of Appeal may not perform any other duties in the Agency. ~~The function of the Members may be a part-time function.~~

Article 133 *Artcle 133* ***Transitional measures regarding the Agency*** 1. The Commission shall ***provide*** the necessary support towards ***the setting up*** of the Agency. 2. For that purpose, until such time as the Executive Director ***is appointed*** in accordance with Article 83, the Commission, on behalf of the Agency, ***thereby*** using the budget provided for the latter, may appoint personnel, including a person who shall fulfil the ***administrative*** functions of the Executive Director on an interim basis, and conclude other contracts.	Amendment 158 *Artcle 133* ***Preparation of establishment of the Agency*** 1. The Commission shall ***afford*** the necessary support ***towards the establishment*** of the Agency. 2. For that purpose, until such time as the Executive Director ***assumes his duties following his appointment by the Management Board*** in accordance with Article 83, the Commission, on behalf of the Agency, ***and*** using the budget provided for the latter, may: ***(a)*** appoint personnel, including a person who shall fulfil the functions of the Executive Director on an interim basis; and ***(b)*** conclude other contracts.	It was agreed to redraft Article 133 as follows: *Article 133* ***Preparation of establishment of the Agency*** 1. The Commission shall ***afford*** the necessary support ***towards the establishment*** of the Agency. 2. For that purpose, until such time as the Executive Director ***assumes his duties following his appointment by the Management Board of the Agency*** in accordance with Article 83, the Commission, on behalf of the Agency, ***and*** using the budget provided for the latter, may: **(a)** appoint personnel, including a person who shall fulfil the administrative functions of the Executive Director on an interim basis; and **(b)** conclude other contracts.

6. REGISTRATION/DATA SHARING

Council Common Position	EP amendment	Result of the 6th trilogue
Recital 51 a Does not exist.	Amendment 14 ***(51a) If a manufacturer of a substance or an importer of a substance, either on its own or in a preparation, does not intend to submit a registration for a substance, he must notify the Agency and his downstream users accordingly.***	It was agreed to respond to Amendment 14 by modifying Recital 50 taking into account the modification of Article 28 as response to Amendment 55 (see below).
Article 3.29 29. Per year means per calendar year unless stated otherwise.	Amendment 35 29) Per year: means per calendar year. ***Save in the case of new substances, and*** unless stated otherwise***, quantities per year shall be calculated on the basis of the average production volumes for the three immediately preceding calendar years during which the substance has actually been produced by the manufacturer;***	It was agreed to follow the ideas behind this Amendment but that the text should be modified as follows: *Article 3* 29) Per year: means per calendar year. Unless stated otherwise***, for phase-in substances that have been imported or manufactured for at least three consecutive years, quantities per year shall be calculated on the basis of the average production or import volumes for the three preceding calendar years;***
Article 3 points 35 and 36 35) Exposure scenario: means the set of conditions that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These exposure scenarios may cover one specific process or use or several processes or uses as appropriate;	Amendment 121 (ENVI) ARTICLE 3, POINT 35 35. Exposure scenario means the set of conditions ***including risk management measures*** that describe how the substance is manufactured or used during its life-cycle and how the manufacturer ***and*** importer controls, or recommends ***to*** downstream users ***that they may*** control exposures of humans and the environment. These exposure scenarios may cover one specific process or use or several processes or uses, as appropriate, ***where these processes or uses may be described in terms of use and exposure categories, as defined.*** Amendment 122 (ENVI)	It was agreed to introduce the following changes to the text: 35. Exposure scenario: means the set of conditions, ***including operational conditions and risk management measures***, that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These exposure scenarios may cover one specific process or use or several processes or uses as appropriate;

36) Use and exposure category: means an exposure scenario covering a wide range of processes or uses;	ARTICLE 3, POINT 36 36. Use and exposure category means ***themain use categories (e.g. industrial use,professional use, consumer use) and thesignificant routes of exposure (e.g. oral, dermal, inhalation, environmental) and patterns of exposure (e.g. frequent, accidental, occasional, continuous).***	36. Use and exposure category: means an exposure scenario covering a wide range of processes or uses, ***where the processes or uses are communicated, as a minimum, in terms of the brief general description of use***;
Article 7.1 a Does not exist.	Amendment 37 ***1a. Paragraph 1(a) shall not apply to substances which are ingredients added to tobacco products within the meaning of Article 2(1) and (5) of Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products[1].*** ***[1] OJ L 194, 18.7.2001, p. 26.***	It was agreed that the wording in the Common Position should be retained. The Commission Statement in Annex C responds to the concern and clarifies specific effects of tobacco additives will be addressed in the context of a forthcoming review of the Tobacco Products Directive.
		<u>In order to guarantee consistency and workability, it was agreed to modify paragraph 1 of Article 23 as follows:</u> *Article 23* *Specific provisions for phase-in substances* 1. Article 5, Article 6, Article 7(1), ***Article 17, Article 18(#)*** and Article 21 shall not apply until …* to the following substances : (a) phase-in substances classified as carcinogenic, mutagenic or toxic to reproduction, category 1 or 2, in accordance with Directive 67/548/EEC and manufactured in the Community or imported, in quantities reaching 1 tonne or more per year per manufacturer or per importer, at least once after …**; (b) phase-in substances classified as very toxic to aquatic organisms which may cause long-term adverse

		effects in the aquatic environment (R50/53) in accordance with Directive 67/548/EEC, and manufactured in the Community or imported in quantities reaching 100 tonnes or more per year per manufacturer or per importer, at least once after ...*; (c) phase-in substances manufactured in the Community or imported, in quantities reaching 1 000 tonnes or more per year per manufacturer or per importer, at least once after **. 2. Article 5, Article 6, Article 7(1), ***Article 17, Article 18(#)*** and Article 21 shall not apply until *** to phase-in substances manufactured in the Community or imported, in quantities reaching 100 tonnes or more per year per manufacturer or per importer, at least once after **. 3. Article 5, Article 6, Article 7(1), ***Article 17, Article 18(#)*** and Article 21 shall not apply until **** to phase-in substances manufactured in the Community or imported, in quantities reaching 1 tonne or more per year per manufacturer or per importer, at least once after ** * ~~3 years~~ ***42 months*** after entry into force of this Regulation. ** Date of entry into force of this Regulation. *** 6 years after entry into force of this Regulation **** 11 years after entry into force of this Regulation _____ As a consequence of the postponement of the deadline of the dead line the following changes will be introduced into other Articles: *Article 7* *Registration and notification of substances in articles* ……

		7. From ….* paragraphs 2, 3 and 4 of this Article shall apply 6 months after a substance is identified in accordance with Article 58(1). * **48** months after entry into force of this Regulation. *Article 42* *Procedure and time periods for examination of testing proposals* 1. In the case of non phase-in substances, the Agency shall prepare a draft decision in accordance with Article 39(2) within 180 days of receiving a registration or downstream user report containing a testing proposal. 2. In the case of phase-in substances, the Agency shall prepare the draft decisions in accordance with Article 39(2): (a) by * for all registrations received by ** containing proposals for testing in order to fulfil the information requirements in Annexes IX and X; (b) by *** for all registrations received by **** containing proposals for testing in order to fulfil the information requirements in Annex IX only; (c) by ***** for any registrations containing testing proposals received by ******. 3. The list of registration dossiers being evaluated under Article 39 shall be made available to Member States. * **66 months** after entry into force of this Regulation. ** **42 moths** after entry into force of this Regulation. *** 9 years after entry into force of this Regulation. **** 6 years after entry into force of this Regulation. ***** 15 years after entry into force of this Regulation. ******11 years after entry into force of this Regulation. *Article 43* *Criteria for substance evaluation*

		…… 2. The Agency shall use the criteria in paragraph 1 for the purpose of compiling a draft Community rolling action plan which shall cover a period of three years and shall specify substances to be evaluated each year. Substances shall be included if there are grounds for considering (either on the basis of a dossier evaluation carried out by the Agency or on the basis of any other appropriate source, including information in the registration dossier) that a given substance constitutes a risk to human health or the environment. The Agency shall submit the first draft rolling action plan to the Member States by …*. The Agency shall submit draft annual updates to the rolling action plan to the Member States by 28 February each year. The Agency shall adopt the final Community rolling action plan on the basis of an opinion from the Member State Committee set up under Article 75(1)(e) (hereinafter referred to as "the Member State Committee") and shall publish the plan on its website, identifying the Member State who will carry out the evaluation of the substances listed therein as determined according to Article 44. * **54 months** after entry into force of this Regulation. *Article 115* *Transitional arrangements* The obligations set out in Article 112 shall apply from …**. ** ~~3 years~~ ***42 months*** after entry into force of this Regulation. (#) *an error in the text of the Common Position*

Article 14.1 subpara 1 1. Without prejudice to Article 4 of Directive 98/24/EC, a chemical safety assessment shall be performed and a chemical safety report completed for all substances subject to registration in accordance with this Chapter if the registrant manufactures or imports such a substance in quantities of 10 tonnes or more per year.	Amendment 46 1. Without prejudice to Article 4 of Directive 98/24/EC, a chemical safety assessment shall be performed and a chemical safety report completed for all substances subject to registration in accordance with this Chapter.	It was agreed that paragraph 1 of Article 137 should be modified as follows: 1. By …*, the Commission shall carry out a review to assess whether or not to extend the application of the obligation to perform a chemical safety assessment and to document it in a chemical safety report to substances not covered by this obligation because they are not subject to registration or subject to registration but manufactured or imported in quantities of less than 10 tonnes per year. ***However, for substances meeting the criteria for classification as carcinogenic, mutagenic or toxic for reproduction, category 1 or 2, in accordance with Directive 67/548/EEC, the review shall be carried out by …**. When carrying out the review the Commission shall take into account all relevant factors, including:*** ***1) costs for the manufacturers and importers for the chemical safety reports*** ***2) distribution of costs between actors in the supply chain and the downstream user*** ***3) benefits for the human health and the environment.*** ***On the basis of these reviews, the Commission may, if appropriate, present legislative proposals to extend this obligation.*** * 12 years after entry into force of this Regulation. ** 7 years after entry into force of this Regulation.
Article 23 a Does not exist.	Amendment 51 ***Article 23a*** ***Notification of intention not to register a substance*** ***1. Manufacturers or importers of a substance, either on its own or in a preparation, who do not intend to***	It was agreed that Amendment 51 should be addressed in the context of Amendment 55 and by introducing a new recital as follows: ***Recital (new):*** ***Manufacturers and importers of a substance on its***

	submit an application for registration of the substance shall notify the Agency and downstream users of their intention. ***2. The notification referred to in paragraph 1 shall be forwarded*** ***(a) 12 months before the deadline laid down in Article 23(1) for phase-in substances manufactured or imported in quantities reaching 1 000 tonnes or more per year;*** ***(b) 24 months before the deadline laid down in Article 23(2) for phase-in substances manufactured or imported in quantities reaching 100 tonnes or more per year;*** ***(c) 36 months before the deadline laid down in Article 23(3) for phase-in substances manufactured or imported in quantities reaching 1 tonne or more per year.*** ***3. Should the manufacturer or importer fail to notify the Agency or downstream users of his intention not to register the substance, he shall be required to submit a registration application for the substance.***	***own or in a preparation should be encouraged to communicate with their downstream users of the substance with regard to whether they intend to register the substance. Such information should be provided to a downstream user sufficiently in advance of the relevant registration dead-line if the manufacturer or importer does not intend to register the substance in order for the downstream user to look for alternative sources of supply.***
Article 25.3 3. Any study summaries or robust study summaries of studies submitted in the framework of a registration under this Regulation at least ***10*** years previously can be used for the purposes of registration by another manufacturer or importer.	Amendment 169 (ENVI) + two other articles with the same reference 3. Any study summaries or robust study summaries of studies relating to both animal and non-animal tests submitted in the framework of a registration under this Regulation at least ***15*** years previously may be made freely available by the Agency to any other registrants or potential registrants.	It was agreed to amend Article 25.3 as follows: *3. Any study summaries or robust study summaries of studies submitted in the framework of a registration under this Regulation at least **12** years previously can be used for the purposes of registration by another manufacturer or importer.* *Consequently, change 10 years to 12 years in Article 26.3 and Article 27.1.*

Article 27.6 6. Within one month from the receipt of the information referred to in paragraph 5, the Agency shall give the potential registrant permission to refer to the information requested by him in his registration dossier. Provided he makes the full study report available to the potential registrant, the previous registrant(s) shall have a claim on the potential registrant for an equal share of the cost incurred by him, which shall be enforceable in the national courts.	Amendment 52 6. Within one month from the receipt of the information referred to in paragraph 5**,** the Agency shall give the potential registrant permission to refer to the information requested by him in his registration dossier. Provided he makes the full study report available to the potential registrant, the previous registrant(s) shall have a claim on the potential registrant for ***a fair*** share of the cost incurred by him, which shall be enforceable in the national courts. ***The sharing of the actual costs incurred by the original registrant(s) for the study concerned shall be calculated in a way which is proportional to each party's production/import volume.*** ***Where the original total cost has already been shared between two or more registrants, any subsequent potential registrant(s) shall pay each registrant a fair share of his contribution to costs.***	It was agreed that the text be modified as follows: 6. Within one month from the receipt of the information referred to in paragraph 5, the Agency shall give the potential registrant permission to refer to the information requested by him in his registration dossier ***subject to the potential registrant providing, upon request by the Agency, proof that he has paid the previous registrant(s) for that information, a share of cost incurred. The previous registrant(s) shall have a claim on the potential registrant for a proportionate share of the cost incurred by him. Calculation of the proportionate share may be facilitated by the guidance adopted by the Agency in accordance with Article 76(2)(f).*** Provided he makes the full study report available to the potential registrant, the previous registrant(s) shall have a claim on the potential registrant for an equal share of the cost incurred by him, which shall be enforceable in the national courts.
Article 28.2 a Does not exist. ***5***. The Agency shall by …* publish on its website a list of the substances refered to in paragraph 1(a) and (d). That list shall comprise only the names of subtances	Amendment 55 ***2a. If the period referred to in paragraph 2 has elapsed, the Agency shall, upon request by a downstream user of a substance that has not been pre-registered, permit late notification to the register of substances by any person other than the original supplier of that substance to the downstream user for a further six months after the publication of the register. Such notification shall enable the potential registrant to benefit from the transitional regime set out in Chapter 5 of Title II.***	The contents of this amendment were agreed, but the order of paragraphs will be changed, a new paragraph 5 introduced and paragraph 6 (former 4) reworded. An additional sentence in Recital 50 in connection to Amendment 58 was agreed as a consequence. The modified text in Article 28 responds also to Amendment 51. *Article 28* *Duty to pre-register for phase in substances* [1-3 unchanged.] ***4***. The Agency shall by …* publish on its website a list of the substances refered to in paragraph 1(a) and (d). That list shall comprise only the names of subtances

including their EINECS and CAS number if available and other identity codes.		including their EINECS and CAS number if available and other identity codes. ***5. After the publication of the list a downstream user of a substance not appearing on the list may notify the Agency of his interest in the substance, his contact details and the details of his current supplier. The Agency shall publish on its website the name of the substance and on request provide contact details of the downstream user to a potential registrant.***
4. Potential registrants who manufacture or import for the first time a phase-in substance in quantities of 1 tonne or more per year after …**, shall be entitled to rely on Article 23 provided that they submit the information referred to in paragraph 1 of this Article to the Agency within six months of first manufacturing or importing the substance and no later than 12 months before the relevant deadline in Article 23.		***6***. Potential registrants who manufacture or import for the first time a phase-in substance in quantities of 1 tonne or more per year after …**, shall be entitled to rely on Article 23 provided that they submit the information referred to in paragraph 1 of this Article to the Agency within six months of first manufacturing or importing the substance ***in quantities of 1 tonne or more per year*** and no later than 12 months before the relevant deadline in Article 23.
6. Manufacturers or importers of phase-in substances in quantities of less than 1 tonne per year that appear on the list published by the Agency in accordance with paragraph 5 of this Article, as well as downstream users of those substances and third parties holding information on those substances, may submit the information referred to in paragraph 1 of this Article or any other relevant information to the Agency for those substances, with the intention of being part of the substance information exchange forum as referred to in Article 29.		***7.*** Manufacturers or importers of phase-in substances in quantities of less than 1 tonne per year that appear on the list published by the Agency in accordance with paragraph 5 of this Article, as well as downstream users of those substances and third parties holding information on those substances, may submit the information referred to in paragraph 1 of this Article or any other relevant information to the Agency for those substances, with the intention of being part of the substance information exchange forum as referred to in Article 29.

Article 29	Amendment 58	It was agreed that the text of Article 29.1 should be modified in respond to proposed amendments concerning the first sub-paragraph of Article 30.1 to read as follows. Consequently Recital 50 will also be modified:
1. All manufacturers and importers who have submitted information to the Agency in accordance with Article 28 for the same phase-in substance shall be participants in a substance information exchange forum (SIEF).	1. All manufacturers**,** importers ***and formulators*** who have submitted information to the Agency in accordance with Article 28 for the same phase-in substance shall be participants in a substance information exchange forum (SIEF).	1. All ***potential registrants, downstream users and third parties*** who have submitted information to the Agency in accordance with Article 28***, or whose information is held by the Agency in accordance with Article 15,*** for the same phase-in substance***, or registrants who have submitted a registration for that phase-in substance before the deadline in Article 23(3),*** shall be participants in a substance information exchange forum (SIEF).
2. The aim of each SIEF shall be to: (a) facilitate, for the purposes of registration, the exchange of the information specified in Article 10(a) (vi) and (vii) between manufacturers and importers, thereby avoiding the duplication of studies; and (b) agree classification and labelling where there is a difference in the classification and labelling of the substance.		2. The aim of each SIEF shall be to: (a) facilitate, for the purposes of registration, the exchange of the information specified in Article 10(a) (vi) and (vii) between ***potential registrants***, thereby avoiding the duplication of studies; and (b) agree classification and labelling where there is a difference in the classification and labelling of the substance ***between potential registrants***.
3. SIEF participants shall provide other participants with existing studies, react to requests by other participants for information, collectively identify needs for further studies and arrange for them to be carried out. Each SIEF shall be operational until …*		3. SIEF participants shall provide other participants with existing studies, react to requests by other participants for information, collectively identify needs for further studies ***for the purposes of paragraph 2 (a)*** and arrange for ***such studies*** to be carried out . Each SIEF shall be operational until …*. * 11 years after entry into force of this Regulation. ———
		Recital 50:

		In order to avoid duplication of work, and in particular to avoid duplication of testing, registrants of phase-in substances should pre-register as early as possible with a database managed by the Agency. A system should be established to provide for Substance Information Exchange Fora (SIEF) to help ***exchange of information on the substances that have been registered. SIEF participants should include all relevant actors submitting information to the Agency on the same phase-in substance. They should include both potential registrants, who must provide and be supplied with any information relevant to the registration of their substances, and other participants, who may receive financial compensation for studies they hold but are not entitled to request information.*** In order to ensure the smooth functioning of that system they should fulfil certain obligations. If a member of a SIEF does not fulfil his obligations, he should be penalised accordingly but other members should be enabled to continue preparing their own registration. ***In cases where a substance has not been pre-registered, measures should be taken to help downstream users find alternative sources of supply.***
Article 30.1 1. Before testing is carried out in order to meet the information requirements for the purposes of registration, a SIEF participant shall inquire whether a relevant study is available by communicating within his SIEF. If a relevant study involving tests on vertebrate animals is available within the SIEF, a participant of that SIEF shall request that study ***by …*****.* If a relevant	Amendment 59 1. Before testing is carried out in order to meet the information requirements for the purposes of registration, a SIEF participant shall inquire whether a relevant study is available by communicating within his SIEF ***and consulting the lists published by the Agency in accordance with Article 28(5) and (5a)***. If a relevant study involving tests is available, a participant of SIEF	The proposed amendments to the first sub-paragraph are addressed in the response to Amendment 58. It was agreed to modify Article 30.1 as follows: 1. Before testing is carried out in order to meet the information requirements for the purposes of registration, a SIEF participant shall inquire whether a relevant study is available by communicating within his SIEF. If a relevant study involving tests on vertebrate animals is available within the SIEF, a participant of that SIEF shall request that study. If a relevant study

study not involving tests on vertebrate animals is available within the SIEF, a SIEF participant may request that study ***by ….***** Within two weeks of the request, the owner of the study shall provide proof of its cost to the participant(s) requesting it. The participant(s) and the owner shall make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non discriminatory way. This may be facilitated by following any cost sharing guidance which is based on those principles and is adopted by the Agency in accordance with Article 76(2)(f). If they cannot reach such an agreement, the cost shall be shared equally. The owner shall give permission to refer to the full study report for the purpose of registration within two weeks of receipt of payment. Registrants are only required to share in the costs of information that they are required to submit to satisfy their registration requirements. _____ ***** 20 months after entry into force of this Regulation.***	shall request that study. Within ***one month*** of the request, the owner of the study shall provide proof of its cost to the participant(s) requesting it. The participant(s) and the owner shall make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non discriminatory way ***and in proportion to each party's production volume***. This may be facilitated by following any cost sharing guidance which is based on those principles and is adopted by the Agency in accordance with Article 76(2)(f). If they cannot reach such an agreement, the cost shall be shared ***in a fair way***. The owner shall give permission to refer to the full study report for the purpose of registration within two weeks of receipt of payment. Registrants are only required to share in the costs of information that they are required to submit to satisfy their registration requirements.	not involving tests on vertebrate animals is available within the SIEF, a SIEF participant may request that study. Within **one month** of the request, the owner of the study shall provide proof of its cost to the participant(s) requesting it. The participant(s) and the owner shall make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non discriminatory way. This may be facilitated by following any cost sharing guidance which is based on those principles and is adopted by the Agency in accordance with Article 73(2)(f). If they cannot reach such an agreement, the cost shall be shared equally. The owner shall give permission to refer to the full study report for the purpose of registration within two weeks of receipt of payment. Registrants are only required to share in the costs of information that they are required to submit to satisfy their registration requirements.

ANNEX VIII, COLUMNS 1 AND 2, POINT 8.4.2 AND 8.4.3 Column 1 8.4.2. In vitro cytogenicity study in mammalian cells Column 2 8.4.2. The study does not usually need to be conducted - if adequate data from an *in vivo* cytogenicity test are available or - the substance is known to be carcinogenic category 1 or 2 or mutagenic category 1, 2 or 3. Column 2 8.4.3. The study does not usually need to be conducted if adequate data from a reliable in vivo mammalian gene mutation test are available. 8.4. Appropriate *in vivo* mutagenicity studies ***shall be considered in case of a positive result in any of the genotoxicity studies*** in Annex VII or VIII.	Amendment 345 (as tabled for ENVI Committee) Column 1 8.4.2. In vitro cytogenicity study in mammalian cells ***or in vitro micronucleus study*** Column 2 **8.4.2** ***These studies (8.4.2 and 8.4.3) do not usually*** need to be conducted - if adequate data from an in vivo test are available or - the substance is known to be carcinogenic category 1 or 2 or mutagenic category 1, 2 or 3, ***or the registrant implements and, where necessary, recommends risk management measure as if this were the case; or*** ***- the chemical safety assessment pursuant to Annex I indicates that the risk to health/environment with regard to exposure for the identified uses is not relevant or is adequately controlled, taking into account risk management measures. Annex XI.3 applies.*** Column 2 8.4.3. ***A positive result in any of the in vitro*** mutagenicity studies in Annex V or VI ***may be confirmed by conducting another in vitro test to confirm the likely mechanism and/or repeating the study together with the use of an appropriate exogenous metabolic system (e.g., human microsomal enzymes).***	It was agreed that point 8.4.2 should be modified as follows: Column 1 8.4.2. In vitro cytogenicity study in mammalian cells ***or in vitro micronucleus study*** Column 2 8.4.2. The study does not usually need to be conducted - if adequate data from an *in vivo* cytogenicity test are available or - the substance is known to be carcinogenic category 1 or 2 or mutagenic category 1, 2 or 3. Column 2 8.4.3. The study does not usually need to be conducted if adequate data from a reliable in vivo mammalian gene mutation test are available. Appropriate *in vivo* mutagenicity studies shall be considered in case of a positive result in any of the genotoxicity studies in Annex VII or VIII.
ANNEX VIII, COLUMNS 1 AND 2, POINT 8.7	Amendment 167 (= ENVI 346)	<u>It was agreed that the wording in the Common Position should be retained</u>.

Column 1 8.7. Reproductive toxicity **8.7.1.** ***Screening for reproductive/developmental toxicity, one species (OECD 421 or 422), if there is no evidence from*** **available information on structurally related substances, from (Q)SAR estimates or from in vitro methods** ***that the substance may be a developmental toxicant*****.** **Column 2** **8.7.1.** ***This study does not need to be conducted if:*** ***– the substance is known to be a genotoxic carcinogen and appropriate risk management measures are implemented; or*** ***– the substance is known to be a germ cell mutagen and appropriate risk management measures are implemented; or*** ***– relevant human exposure can be excluded in accordance with Annex XI section 3; or*** ***– a pre-natal developmental toxicity study (section 8.7.2 of this Annex) or a two-generation reproductive toxicity study (section 8.7.3 of this Annex) is available.*** ***If a substance is known to have an adverse effect on fertility, meeting the criteria for classification as Repr Cat 1 or 2: R60, and the available data are adequate to support a robust risk assessment, then no further testing for fertility will be necessary. However, testing for development toxicity must be considered.*** ***If a substance is known to cause developmental toxicity, meeting the criteria for classification as Repr Cat 1 or 2: R61, and the available data are adequate to support a robust risk assessment, then no further testing for developmental toxicity will be necessary. However, testing for effects on fertility must be considered.***	Column 1 8.7. Reproductive toxicity 8.7.1. ***An initial assessment of this endpoint shall take into consideration all*** available ***toxicological*** information ***(e.g. from the 28-day or 90-day study), in particular information*** on structurally related substances, from (Q)SAR estimates or from in vitro methods. Column 2 8.7.1 ***If the initial assessment shows that there is evidence that the substance may be a developmental or reproductive toxicant and the company does not introduce and recommend appropriate risk management measures as if it were classified as reprotoxic category 1 or 2, then suitable further reprotoxicity testing shall be performed by the registrant.*** ***The conditions stated for these studies in Annex IX apply.***	In addition it was agreed to introduce review of the data requirements in ANNEX VIII, COLUMNS 1 AND 2, POINT 8.7 as follows: *Article 137* *Review* *(new)* ***In accordance with the objective of promoting non-animal testing and the replacement, reduction or refinement of animal testing required under this Regulation, the Commission shall review the testing requirements of Section 8.7 of Annex VIII by*** (*) ***from entry into force of this Regulation. On the basis of this review while ensuring a high level of protection of health and the environment, the Commission may propose an amendment in accordance with the procedure referred to in Article 132(3a).*** (*) ***12 years***

In cases where there are serious concerns about the potential for adverse effects on fertility or development, either a pre-natal developmental toxicity study (Annex IX, section 8.7.2) or a two-generation reproductive toxicity study (Annex IX, section 8.7.3) may be proposed by the registrant instead of the screening study.		
-	Amendment 353 (ENVI) ANNEX XI, POINT 1.5, PARAGRAPH 3 A (new) The endpoints for classification and for risk assessment of substances that are complex and of variable composition may also be determined from data on their significant constituents using their highest concentration in the substance. The Agency, after consulting relevant stakeholders and other interested parties, shall issue a detailed and scientifically justified methodology for the grouping of substances within five years from the adoption of this Regulation	It was agreed that the following sentence be added at the end of Annex XI section 1.5. (Grouping of substances and read-across approach): ***The Agency, after consulting with the relevant stakeholders and other interested parties, shall issue guidance on technically and scientifically justified methodology for the grouping of substances sufficiently in advance of the first registration dead-line for phase-in substances.***

7. AUTHORISATION, INCLUDING SUBSTITUTION

Council Common Position	EP amendment	Result of the 6th trilogue
Does not exist	Does not exist	It was agreed, in order to respond to various amendments voted by the European Parliament, that the following recitals be introduced. ***(new 1)*** ***Substitution of a substance on its own, in a preparation or in an article should be required when manufacture, use or placing on the market of that substance causes an unacceptable risk to human health or to the environment, taking into account the availability of suitable safer alternative substances and technologies, and the socio-economic benefits from the uses of the substance posing an unacceptable risk.*** ***Substitution of a substance of very high concern by suitable alternative substances or technologies should be considered by all those applying for authorisations of uses of such substances on their own, in preparations or for incorporation of substances into articles by making an analysis of alternatives, the consequent risks of using any alternative and the technical and economic feasibility of substitution.*** ***The possibility of introducing restrictions on the manufacturing, placing on the market and use of dangerous substances, preparations and articles applies to all substances falling within the scope of REACH, with minor exemptions. Restrictions on the placing on the market and the use of substances which are carcinogenic, mutagenic or toxic to reproduction, categories 1 or 2 for their use by consumers on their own or in preparations should continue to be introduced.***

		(new 2) ***Adverse effects on human health and the environment from substances of very high concern should be prevented through the application of appropriate risk management measures to ensure that any risks from the uses of a substance are adequately controlled, and with a view to progressively substituting these substances with a suitable safer substance. Risk management measures should be applied to ensure, when substances are manufactured, placed on the market and used, that exposure to these substances including discharges, emissions and losses, throughout the whole life-cycle is below the threshold level beyond which adverse effects may occur. For any substance for which authorisation has been granted, and for any other substance for which it is not possible to establish a safe level of exposure, measures should always be taken to minimise, as far as technically and practically possible, exposure and emissions with a view to minimising the likelihood of adverse effects. Measures to ensure adequate control should be identified in any Chemical Safety Report. These measures should be applied and, where appropriate, recommended to other actors down the supply chain.***
(64) Methodologies to establish thresholds for carcinogenic and mutagenic substances may be developed taking into account the outcomes of RIPs. The relevant Annex may be amended on the basis of these methodologies to allow thresholds where appropriate to be used in the context of authorising the use of carcinogenic and mutagenic substances.	Amendment 20RECITAL 64 ***deleted***	***It was agreed that recital 64 be modified as follows:*** ***(64) Methodologies to establish thresholds for carcinogenic and mutagenic substances may be developed taking into account the outcomes of RIPs. The relevant Annex may be amended on the basis of these methodologies to allow thresholds where appropriate to be used, while ensuring high level of protection of human health and the environment. ~~in the context of authorising the use of carcinogenic and mutagenic substances.~~***

Article 54 *Article 54* *Aim of authorisation* The aim of this Title is to ensure ***the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are eventually replaced by suitable alternative substances or technologies where these are economically and technically viable.***	Amendment 73 The aim of this Title is to ensure ***that substances of very high concern are replaced by safer alternative substances or technologies, where available. Where no such alternatives are available, and where the benefits to society outweigh the risks connected with the use of such substances, the aim of this Title is to ensure that the use of substances of very high concern is properly controlled and that alternatives are encouraged. Its provisions are underpinned by the precautionary principle.***	It was agreed that Article 54 should be modified as follows: *Article 54* *Aim of authorisation* ***and considerations for substitution*** The aim of this Title is to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are ***progressively*** replaced by suitable alternative substances or technologies where these are economically and technically viable. ***To this end all manufacturers, importers and downstream users applying for authorisations shall analyse the availability of alternatives, consider their risks, and the technical and economic feasibility of substitution.***
Article 56 f (f) substances - such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) or (e) - ***for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) and*** which are identified on a case-by-case basis in accordance with the procedure set out in Article 58.	Amendment 78 (f) substances - such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) or (e) - which are identified ***as giving rise to a similar level of concern as substances listed in points (a) to (e)*** on a case-by-case basis in accordance with the procedure set out in Article 58.	It was agreed that the wording of Article 56(f) in the Common Position should be retained and that paragraph 4a be introduced in Article 137: ____ ***Art 137*** ***4 a The Commission shall carry out a review of Annex XIII by 18 months after entry into force of this Regulation, to assess the adequacy of the criteria for the identification substances which are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative, with a view to proposing an amendment to it, if appropriate, in accordance with the procedure referred to in Article 132(3a).*** _____ In addition, it was agreed that recital 66 should be modified as follows: (66) Experience at international level shows that

(66) Experience at international level shows that substances with characteristics rendering them persistent, liable to bioaccumulate and toxic, or very persistent and very liable to bioaccumulate, present a very high concern, while criteria have been developed allowing the identification of such substances. For certain other substances concerns are sufficiently high to address them in the same way on a case by case basis.		substances with characteristics rendering them persistent, liable to bioaccumulate and toxic, or very persistent and very liable to bioaccumulate, present a very high concern, while criteria have been developed allowing the identification of such substances. For certain other substances concerns are sufficiently high to address them in the same way on a case by case basis. ***The criteria in Annex XIII should be reviewed taking into account the current and any new experience in the identification of the above mentioned substances, and if appropriate, be amended with a view to ensuring a high level of protection for human health and the environment.***
Article 56 fb Does not exist.	Amendment 80 ***(fb) substances which are ingredients added to tobacco products within the meaning of Article 2(1) and (5) of Directive 2001/37/EC on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products.***	It was agreed that the wording in the Common Position should be retained. The Commission Statement in Annex C responds to the concern clarifying that specific effects of tobacco additives will be addressed in the context of a forthcoming review of the Tobacco Products Directive.

Article 57.2 a Does not exist.	Amendment 85 ***2a. Such exemptions shall not be granted to uses or categories of uses for substances referred to in Article 56 which are ingredients added to tobacco products within the meaning of Article 2(1) and (5) of Directive 2001/37/EC on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products, notwithstanding Article 12 of that Directive.***	It was agreed that the wording in the Common Position should be retained. The Commission Statement in Annex C responds to the concern clarifying that specific effects of tobacco additives will be addressed in the context of a forthcoming review of the Tobacco Products Directive.
Article 57.3 ca Does not exist.	Amendment 89 ***(ca) substances which are ingredients added to tobacco products within the meaning of Article 2(1) and (5) of Directive 2001/37 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products.***	It was agreed that the wording in the Common Position should be retained. The Commission Statement in Annex C responses to the concern clarifying that specific effects of tobacco additives will be addressed in the context of a forthcoming review of the Tobacco Products Directive.
Article 57.6 6. A substance listed in Annex XIV may be subjected to new restrictions under the procedure outlined in Title VIII covering the risks to human health or the environment from the use of the substance in article(s).	Does not exist	It was agreed, in response to various amendments voted by the European Parliament that Article 57(6) should be modified as follows: 6. A substance listed in Annex XIV may be subjected to new restrictions under the procedure outlined in Title VIII covering the risks to human health or the environment from the ***presence*** of the substance in ***(an)*** article(s).

Article 59.2	Amendment 99	It was agreed that Article 59(2) should be modified as follows:
2. ***Without prejudice to paragraph 3,*** an authorisation shall be granted if	2. An authorisation shall be granted ***only*** if***:***	2. Without prejudice to paragraph 3, an authorisation shall be granted if
	(a) suitable alternative substances or technologies do not exist, and measures are in place to minimise exposure, and	
	(b) it is demonstrated that the social and economic advantages outweigh the risks to human health or the environment which arise from the use of the substance, and	
the risk to human health or the environment from the use of a substance arising from the intrinsic properties specified in ***Annex XIV*** is adequately controlled in accordance with section 6.4 of Annex I and as documented in the applicant's chemical safety report. The Commission shall take into account all discharges, emissions and losses known at the time of decision.	***(c)*** the risk to human health or the environment from the use of a substance arising from the intrinsic properties specified in ***Annex XIV(a)*** is adequately controlled in accordance with section 6.4 of Annex I and as documented in the applicant's chemical safety report. The Commission shall take into account all discharges, emissions and losses known at the time of decision.	the risk to human health or the environment from the use of a substance arising from the intrinsic properties specified in Annex XIV is adequately controlled in accordance with section 6.4 of Annex I and as documented in the applicant's chemical safety report***, taking into account the opinion of the Risk Assessment Committee of the Agency referred to in Article 63(4)(a). When granting the authorisation, and in any conditions imposed therein, t***he Commission shall take into account all discharges, emissions and losses, ***including risks arising from diffuse or dispersive uses,*** known at the time of ***the*** decision.
The Commission shall not consider the risks to human health arising from the use of a substance in a medical device regulated by Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC of 14 June 1993 concerning medical devices or Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical		The Commission shall not consider the risks to human health arising from the use of a substance in a medical device regulated by Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC of 14 June 1993 concerning medical devices or Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. _____

devices.		[1] OJ L 189, 20.7.1990, p. 17. Directive as last amended by Regulation (EC) No 1882/2003. [2] OJ L 169, 12.7.1993, p. 1. Directive as last amended by Regulation (EC) No 1882/2003. [3]OJ L 331, 7.12.1998, p. 1. Directive as last amended by Regulation (EC) No 1882/2003.
Article 59.3 ***3. Paragraph 2 shall not apply to:*** ***(a) substances meeting the criteria in Article 56 (a), (b), (c) and (f) for which it is not possible to determine a threshold in accordance with section 6.4 of Annex I;*** ***(b) substances meeting the criteria in Article 56 (d) and (e).***	Amendment 100 ***deleted***	It was agreed that Article 59(3) should be modified as follows: 3. Paragraph 2 shall not apply to: (a) substances meeting the criteria in Article 56 (a), (b), (c) ~~and~~ ***or*** (f)***,*** for which it is not possible to determine a threshold in accordance with section 6.4 of Annex I; (b) substances meeting the criteria in Article 56 (d) ***or*** ~~and,~~ (e) ***(c) substances identified under Article 56 (f~~) having endocrine disrupting properties or those~~ having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties***. In addition it was agreed to introduce a review on whether to include endocrine disruptors in paragraph (c): *Article 137* ***(new) By(*) after entry into force of this Regulation the Commission shall carry out a review to assess whether or not, taking into account latest developments in scientific knowledge, to extend the scope of Article 59(3) to substances identified under Article 56(f) as having endocrine disrupting properties. On the basis of this review the Commission may, if appropriate, put forward legislative proposals.*** (*)***six years***

Article 59.4 introductory part 4. ***If an authorisation cannot be granted under paragraph 2 or for substances listed in paragraph 3, an authorisation may be granted if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies. This*** decision shall be taken after consideration of all of the following elements: (a) the risk posed by the uses of the substance; (b) the socio-economic benefits arising from its use and the socio-economic implications of a refusal to authorise as demonstrated by the applicant or other interested parties; (c) the analysis of the alternatives submitted by the applicant under Article 61(4)(e) and any third party contributions submitted under Article 63(2); (d) available information on the risks to human health or the environment of any alternative substances or technologies.	Amendment 101 4. ***The*** decision ***to grant authorisation pursuant to paragraph 2*** shall be taken after consideration of all of the following elements:	It was agreed that Article 59(4) be modified as follows: 4. If an authorisation cannot be granted under paragraph 2 or for substances listed in paragraph 3, an authorisation may ***only*** be granted if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies. This decision shall be taken after consideration of all of the following elements ***and taking into account the opinions of the Risk Assessment Committee and of the Socio-Economic Analysis Committee of the Agency referred to in Article 63(4)(a) and (b):*** (a) the risk posed by the uses of the substance***, including the appropriateness and effectiveness of the risk management measures proposed;*** (b) the socio-economic benefits arising from its use and the socio-economic implications of a refusal to authorise as demonstrated by the applicant or other interested parties; (c) the analysis of the alternatives submitted by the applicant under Article 61(4)(e) ***or any substitution plan submitted by the applicant under Article 61(4)(ea) ~~or 61(5)(b)~~,*** and any third party contributions submitted under Article 63(2); (d) available information on the risks to human health or the environment of any alternative substances or technologies.
Does not exist.	Does not exist.	It was agreed that the following paragraph 4a be introduced in Article 59: ***4a. When assessing whether suitable alternative substances or technologies are available, all relevant aspects shall be taken into account by the***

		Commission, including: ***(a) whether the transfer to alternatives would result in reduced overall risks to human health and the environment, taking into account the appropriateness and effectiveness of risk management measures;*** ***(b) technical and economic feasibility of alternatives for the applicant.***
Article 59.7 7. ***Where an application for authorisation includes the information specified in Article 61(5)(b), this information shall be considered in determining the duration of the time-limited review period in paragraph 8 of this Article.***	Amendment 102 7. ***The duration of the time-limited authorisation will be determined on the basis of the information specified in Article 61(4)(eb) and taking into account other available information.***	It was agreed that paragraph 7 will be deleted as a consequence of the modification of paragraph 8: ~~***7. Where an application for authorisation includes the information specified in Article 61(5)(b), this information shall be considered in determining the duration of the time-limited review period in paragraph 8 of this Article.***~~
Article 59.8 8. Authorisations shall be subject to ***a time-limited*** review ***(whose duration shall be determined on a case-by-case basis) without prejudice to any decision on a future review period and shall normally*** be subject to conditions, including monitoring.	Amendment 103 8. Authorisations shall be subject to review ***periods and to the presentation of substitution plans, and may*** be subject to ***other*** conditions, including monitoring. ***Authorisations shall be subject to a time-limit not exceeding five years.***	It was agreed that Article 59(8) be modified as follows: 8. Authorisations shall be subject to a time-limited review ~~(whose duration shall be determined on a case-by-case basis)~~ without prejudice to any decision on a future review period and shall normally be subject to conditions, including monitoring. ***The duration of the time-limited review for any authorisation shall be determined on a case by case basis taking into account all relevant information including the elements listed in paragraphs 4(a) to (d), as appropriate.*** ~~***all relevant information, including the analysis of alternatives under Article 61.4(c) and any substitution plan provided under Article 61.4(ea) or 61.5(b).***~~
Article 60.1 subpara 1-3 1. Authorisations ***granted in accordance with Article 59*** shall be regarded as valid until the Commission	Amendment 105 1. Authorisations shall be regarded as valid until the Commission decides ***on a new application,*** provided	It was agreed that Article 60 be modified as follows: *Article 60* *Review of Authorisations* 1. Authorisations granted in accordance with Article 59 shall be regarded as valid until the Commission decides

decides ***to amend or withdraw the authorisation in the context of a review***, provided that the holder of the authorisation submits a ***review report*** at least 18 months before the expiry of the time-limit***ed review period***. Rather than re-submitting all elements of the original application for the current authorisation, the ***holder of an authorisation*** may submit only the number of the current authorisation, ***subject to the second, third and fourth subparagraphs.***	that the holder of the authorisation submits a ***new application*** at least 18 months before the expiry of the time-limit. Rather than re-submitting all elements of the original application for the current authorisation, the ***applicant*** may submit only***:***	to amend or withdraw the authorisation in the context of a review, provided that the holder of the authorisation submits a review report at least 18 months before the expiry of the time-limited review period. Rather than re-submitting all elements of the original application for the current authorisation, the holder of an authorisation may submit only the number of the current authorisation, subject to the second, third and fourth subparagraphs.
A holder of an authorisation granted in accordance with Article 59 shall submit an update of any substitution plan included in his application. If the holder cannot demonstrate that the risk is adequately controlled, he shall submit an update of the socio-economic analysis, analysis of alternatives and substitution plan contained in the original application***.***	***(a)*** the number of the current authorisation, ***(b)*** an update of the socio-economic analysis, analysis of alternatives and substitution plan contained in the original application, ***(c)*** an update of the chemical safety report.	A holder of an authorisation granted in accordance with Article 59 shall submit an update of ***the analysis of alternatives referred to in Article 61(4)(e), including information about any relevant research and development activities by the applicant, if appropriate, and*** any substitution plan ***submitted under Article 61(4)(ea). If the update of the analysis of alternatives shows that there is a suitable alternative available taking into account the elements in Article 59 paragraph 4a, he shall submit a substitution plan, including a timetable for proposed actions by the applicant.*** If the holder cannot demonstrate that the risk is adequately controlled, he shall ***also*** submit an update of the socio-economic analysis ~~, analysis of alternatives and substitution plan~~ contained in the original application.
If he can now demonstrate that the risk is adequately controlled, he shall submit an update of the chemical safety report. If any other elements of the original application have changed, he shall also submit updates of these element(s).		If he can now demonstrate that the risk is adequately controlled, he shall submit an update of the chemical safety report. If any other elements of the original application have changed, he shall also submit updates of these element(s). ***When any updated information is submitted in accordance with this paragraph, any decision to amend or withdraw the authorisation in the context of the review shall be taken according to the procedure***

		in Article 63 applied mutatis mutandis. 3. In its review decision the Commission may, ***if circumstances have changed and*** taking into account the principle of proportionality, amend or withdraw the authorisation, if under the changed circumstances it would not have been granted ***or if suitable alternatives in accordance with Article 59(4a) become available. In the latter case the Commission shall require the holder of the authorisation to present a substitution plan if he has not already done so as part of their application or update.*** In cases where there is a serious and immediate risk for human health or the environment, the Commission may suspend the authorisation pending the review, taking into account the principle of proportionality. 4.-6. [unchanged]
Article 61.4 and 61.5 4. An application for authorisation shall include the following information: (a) the identity of the substance(s), as referred to in section 2 of Annex VI; (b) the name and contact details of the person or persons making the application; (c) a request for authorisation, specifying for which use(s) the authoris ation is sought and covering the use of the substance in preparations and/or the incorporation of the substance in articles, where this is	Amendment 110 4. An application for authorisation shall include the following information: (a) the identity of the substance(s), as referred to in section 2 of Annex VI; (b) the name and contact details of the person or persons making the application; (c) a request for authorisation, specifying for which use(s) the authorisation is sought and covering the use of the substance in preparations and/or the incorporation of the substance in articles, where this is	*It was agreed that Article 61 be modified as follows:* *Article 61* *Applications for authorisations* [1.-3. Unchanged.] 4. An application for authorisation shall include the following information: (a) the identity of the substance(s), as referred to in section 2 of Annex VI; (b) the name and contact details of the person or persons making the application; (c) a request for authorisation, specifying for which use(s) the authorisation is sought and covering the use of the substance in preparations and/or the incorporation of the substance in articles, where this is relevant;

relevant; (d) unless already submitted as part of the registration, a chemical safety report in accordance with Annex I covering the risks to human health and/or the environment from the use of the substance(s) arising from the intrinsic properties specified in Annex XIV; (e) an analysis of the alternatives considering their risks and the technical and economic feasibility of substitution.	relevant; (d) unless already submitted as part of the registration, a chemical safety report in accordance with Annex I covering the risks to human health and/or the environment from the use of the substance(s) arising from the intrinsic properties specified in Annex XIV; (e) an analysis of the alternatives considering their risks and the technical and economic feasibility of substitution. (ea) a socio-economic analysis conducted in accordance with Annex XVI; (eb) a substitution plan, including research and development and a timetable for proposed actions by the applicant.	(d) unless already submitted as part of the registration, a chemical safety report in accordance with Annex I covering the risks to human health and/or the environment from the use of the substance(s) arising from the intrinsic properties specified in Annex XIV; (e) an analysis of the alternatives considering their risks and the technical and economic feasibility of substitution, ***and including information about any relevant research and development activities by the applicant, if appropriate***; ***(ea) where the analysis referred to in paragraph (e) shows that suitable alternatives are available, taking into account the elements in Article 59(4a), ~~and the risks are not adequately controlled~~, a substitution plan including a timetable for proposed actions by the applicant.***
5. The application may include: (a) a socio-economic analysis conducted in accordance with Annex XVI; (b) where appropriate a substitution plan, including research and development and a timetable for proposed actions by the applicant. (c) a justification for not considering risks to human health and the environment arising either from: (i) emissions of a substance from an installation for which a permit was granted in accordance with Council Directive 96/61/EC; or (ii) discharges of a substance from a point source	5. The application may also include a justification for not considering risks to human health and the environment arising either from: (i) emissions of a substance from an installation for which a permit was granted in accordance with Directive 96/61/EC; or (ii) discharges of a substance from a point source	5. The application may include: (a) a socio-economic analysis conducted in accordance with Annex XVI; ~~(b) where *not required under paragraph 4(ea)*, a substitution plan, including research and development and a timetable for proposed actions by the applicant;~~ (b) a justification for not considering risks to human health and the environment arising either from: (i) emissions of a substance from an installation for which a permit was granted in accordance with Directive 96/61/EC; or

governed by the requirement for prior regulation referred to in Article 11(3)(g) of Directive 2000/60/EC and legislation adopted under Article 16 of that Directive. 6. The application shall not include the risks to human health arising from the use of a substance in a medical device regulated by Directives 90/385/EEC, 93/42/EEC or 98/79/EC. 7. An application for an authorisation shall be accompanied by the fee required in accordance with Title IX.	governed by the requirement for prior regulation referred to in Article 11(3)(g) of Directive 2000/60/EC and legislation adopted under Article 16 of that Directive. 6. The application shall not include the risks to human health arising from the use of a substance in a medical device regulated by Directives 90/385/EEC, 93/42/EEC or 98/79/EC. 7. An application for an authorisation shall be accompanied by the fee required in accordance with Title IX.	(ii) discharges of a substance from a point source governed by the requirement for prior regulation referred to in Article 11(3)(g) of Directive 2000/60/EC and legislation adopted under Article 16 of that Directive. 6. – 7. [unchanged]
Article 62 1. If an application has been made for a use of a substance, a subsequent applicant may refer to the parts of the previous application submitted in accordance with Article 61(4)(d) and (5)(a) and (b), provided that the subsequent applicant has permission from the previous applicant to refer to these parts of the application. 2. If an authorisation has been granted for a use of a substance, a subsequent applicant may refer to the parts of the holder's application submitted in accordance with Article 61(4)(d) and (5)(a) and (b), provided that the subsequent applicant has permission from the holder of the authorisation to refer to these parts of the application.	Does not exist	In response to various amendments voted in the European Parliament, it was agreed that Article 62 should be modified as follows: 1. If an application has been made for a use of a substance, a subsequent applicant may refer to the ***appropriate*** parts of the previous application submitted in accordance with Article 61(4)(d), ~~***and***~~ ***(e), (ea) and*** (5)(a) ~~and (b)~~, provided that the subsequent applicant has permission from the previous applicant to refer to these parts of the application. 2. If an authorisation has been granted for a use of a substance, a subsequent applicant may refer to the ***appropriate*** parts of the holder's application submitted in accordance with Article 61(4)(d), ~~***and***~~ ***(e), (ea) and*** (5)(a) ~~and (b)~~, provided that the subsequent applicant has permission from the holder of the authorisation to refer to these parts of the application. ***2a. Before referring to any previous application in accordance with paragraphs 1 and 2, the subsequent applicant shall update the information of the original application as necessary.***

Article 63.2 2. The Agency shall make available on its web-site broad information on uses, taking into account Articles 117 and 118 on access to information, for which applications have been received, with a deadline by which information on alternative substances or technologies may be submitted by interested third parties.	Does not exist	In response to various amendments voted in the European Parliament, the Presidency suggests that Article 63.2 be modified as follows: 2. The Agency shall make available on its web-site broad information on uses, taking into account Articles 117 and 118 on access to information, for which applications have been received, ***and for reviews of authorisations***, with a deadline by which information on alternative substances or technologies may be submitted by interested third parties.
Article 63.4 4. The draft opinions shall include the following elements: (a) Committee for Risk Assessment: an assessment of the risk to human health and/or the environment arising from the use(s) of the substance as described in the application and***, if relevant,*** an assessment of the risks arising from possible alternatives; (b) Committee for Socio-economic Analysis: an assessment of the socio-economic factors and the availability, suitability and technical feasibility of alternatives associated with the use(s) of the substance as described in the application***, when an application is made in accordance with Article 61(5)***.	Amendment 112 4. The draft opinions shall include the following elements: (a) Committee for Risk Assessment: an assessment of the risk to human health and/or the environment arising from the use(s) of the substance as described in the application and an assessment of the risks arising from possible alternatives; (b) Committee for Socio-economic Analysis: an assessment of the socio-economic factors and the availability, suitability and technical feasibility of alternatives associated with the use(s) of the substance as described in the application.	It was agreed that Article 63(4) should be modified as follows: 4. The draft opinions shall include the following elements: (a) Committee for Risk Assessment: an assessment of the risk to human health and/or the environment arising from the use(s) of the substance***, including the appropriateness and effectiveness of the risk management measures,*** as described in the application and, if relevant, an assessment of the risks arising from possible alternatives; (b) Committee for Socio-economic Analysis: an assessment of the socio-economic factors and the availability, suitability and technical feasibility of alternatives associated with the use(s) of the substance as described in the application, when an application is made in accordance with Article 61~~(5)~~***, and of any third party contributions submitted under paragraph 2***.
		It was agreed that paragraph 9 of Article 63 should be modified as follows**:**

		9. Summaries of the Commission decisions, including the authorisation number***, and reasons of the decision, in particular, where suitable alternatives exist,*** shall be published in the Official Journal of the European Union and shall be made publicly available in a database established and kept up to date by the Agency.

8. OTHER ISSUES

8.1 Intellectual Property Rights

Council Common Position	EP Amendment	Result of the 6th trilogue
Article 9.2 2. For the purpose of paragraph 1, the manufacturer or importer or producer of articles shall notify the Agency of the following information: (a) the identity of the manufacturer or importer or producer of articles as specified in section 1 of Annex VI; (b) the identity of the substance, as specified in section 2 of Annex VI; (c) the classification of the substance as specified in section 4 of Annex VI, if any; (d) the estimated quantity as specified in section 3.1 of Annex VI; (e) the list of customers referred to in paragraph 1, including their names and addresses. The notification shall be accompanied by the fee required in accordance with Title IX. The period set out in paragraph 1 shall begin at receipt of the notification at the Agency.	Amendment 139 (as tabled for ENVI Committee) 2. For the purpose of paragraph 1, the manufacturer or importer or producer of articles shall notify the Agency of the following information ***for substances that are placed on the market***: (a) the identity of the manufacturer or importer or producer of articles as specified in section 1 of Annex VI; (b) the identity of the substance, as specified in section 2 of Annex VI; (c) the classification of the substance as specified in section 4 of Annex VI, if any; (d) the estimated quantity as specified in section 3.1 of Annex VI; (e) ***if relevant,*** the list of customers to ***which the substance if being supplied***. The notification shall be accompanied by the fee required in accordance with Title IX. The period set out in paragraph 1 shall begin at receipt of the notification at the Agency.	It was agreed to address the concern by modifying paragraph 7 of Article 9 as follows: 7. The Agency may decide to extend the five-year exemption period by a further maximum of five years or, in the case of substances to be used exclusively in the development of medicinal products for human or veterinary use ***or for substances that are not placed on the market***, for a further maximum of ten years, upon request if the manufacturer or importer or producer of articles can demonstrate that such an extension is justified by the research and development programme.

Article 117.2.d (d) links between a manufacturer or importer and his downstream users.	Amendment 302 (as tabled for ENVI Committee) (d) links between a manufacturer or importer and his downstream users ***and his retailers involved***. ***(da) any information on onsite-isolated and transported isolated intermediates.***	It was agreed that points (b) and (e) of Article 117.2 should be modified as follows: (b) ***without prejudice to Article 7(6) and Article 63(2),*** the precise use, function or application of a substance or preparation***, including precise information about use as an intermediate***; (d) links between a manufacturer or importer and his ***distributors or*** downstream users.
Does not exist	Amendment 303 (as tabled for ENVI Committee) Article 117. 4 (A) and (B)(NEW) ***4a. Whenever a request for access to documents* for *which the applicant has requested confidentiality is made under Regulation (EC) No 1049/2001 to the Agency, the Agency shall perform the consultation of the third party provided for in Article 4(4) of Regulation (EC) No 1049/2001 in accordance with the second and third subparagraphs.*** ***The Agency shall inform the registrant and, where appropriate, the potential registrant, downstream user or other party concerned of this request.*** ***The Agency shall inform the applicant, as well as the registrant, the potential registrant, the downstream user or other party concerned of its decision with regard to the application for access to the documents. Any of these may, in accordance with Articles 87, 88 and 89, appeal to the Board of Appeal against that decision, within 15 days of the decision. Such an appeal shall have suspensive effect. The Board of Appeal shall decide on the appeal within 30 days.***	It was agreed that Amendment 303 (ENVI) should be taken into account by introducing a new Recital as follows: ***Recital (New)*** ***Disclosure of information under this Regulation is subject to the specific requirements of Regulation 1049/2001 on public access to documents held by the Community Institutions. The Regulation sets binding deadlines for the release of information as well as procedural guarantees, including the right of appeal. The Management Board should adopt the practical arrangements for application of these requirements to the Agency.*** In addition, it was agreed to modify paragraph 3 of Article 117 as follows: *Article 117* 3. The management board shall adopt the practical arrangements for implementing Regulation (EC) No 1049/2001***, including appeals or remedies necessary for reviewing a partial or full rejection of a confidentiality request,*** by .....*

	4b. While an appeal is pending or while an appeal may yet be introduced, the Agency and any competent authority of a Member State shall continue to keep the information in question confidential.	** 12 months after entry into force of this Regulation.*
Article 118	Amendment 304 (as tabled for ENVI Committee)	It was agreed that the text should be modified as follows: *Article 118* *Electronic public access*
1. The following information held by the Agency on substances whether on their own, in preparations or in articles, shall be made publicly available, free of charge, over the Internet in accordance with Article 76(2)(d): (a) the trade name(s) of the substance; (b) the name in the IUPAC Nomenclature, for dangerous substances within the meaning of Directive 67/548/EEC; (c) if applicable, the name of the substance as given in EINECS; (d) the classification and labelling of the substance; (e) physicochemical data concerning the substance and on pathways and environmental fate; (f) the result of each toxicological and ecotoxicological study; (g) any derived no-effect level (DNEL) or predicted no-effect concentration (PNEC) established in accordance with AnnexI; (h) the guidance on safe use provided in accordance with sections 4 and 5 of AnnexVI; (i) analytical methods if requested in accordance with Annexes IX or X which make it possible to detect a dangerous substance when discharged into the environment as well as to determine the direct exposure of humans.	1. The following information held by the Agency on substances whether on their own, in preparations or in articles, shall usually be made publicly available, free of charge, over the Internet in accordance with Article 76(2)(d): **deleted** **deleted** (c) if applicable, the name of the substance as given in EINECS; (d) the classification and labelling of the substance; (e) physicochemical data concerning the substance and on pathways and environmental fate; (f) the result of each toxicological and ecotoxicological study; (g) any derived no-effect level (DNEL) or predicted no-effect concentration (PNEC) established in accordance with AnnexI; (h) the guidance on safe use provided in accordance with sections 4 and 5 of AnnexVI; (i) analytical methods if requested in accordance with Annexes IX or X which make it possible to detect a dangerous substance when discharged into the environment as well as to determine the direct exposure of humans.	1. The following information held by the Agency on substances whether on their own, in preparations or in articles, shall be made publicly available, free of charge, over the Internet in accordance with Article 76(2)(d): ~~(a) the trade name(s) of the substance;~~ (b) the name in the IUPAC Nomenclature, for dangerous substances within the meaning of Directive 67/548/EEC without prejudice to paragraph ***2(da), 2(db), and 2(dc);*** (c) if applicable, the name of the substance as given in EINECS; (d) the classification and labelling of the substance; (e) physicochemical data concerning the substance and on pathways and environmental fate; (f) the result of each toxicological and ecotoxicological study; (g) any derived no-effect level (DNEL) or predicted no-effect concentration (PNEC) established in accordance with AnnexI; (h) the guidance on safe use provided in accordance with sections 4 and 5 of AnnexVI; (i) analytical methods if requested in accordance with Annexes IX or X which make it possible to detect a dangerous substance when discharged into the environment as well as to determine the direct exposure of humans.
2. The following information on substances whether on their own, in preparations or in articles, shall be made	2. The following information on substances whether on their own, in preparations or in articles, shall be made	2. The following information on substances whether on their own, in preparations or in articles, shall be made

publicly available, free of charge, over the Internet in accordance with Article 76(2)(d) except where a party submitting the information submits a justification in accordance with Article 10(a)(xi), accepted as valid by the Agency, as to why such publication is potentially harmful for the commercial interests of the registrant or any other party concerned: (a) if essential to classification and labelling, the degree of purity of the substance and the identity of impurities and/or additives which are known to be dangerous; (b) the total tonnage band (i.e. 1-10 tonnes, 10-100 tonnes, 100-1 000 tonnes or over 1 000 tonnes) within which a particular substance has been registered; (c) the study summaries or robust study summaries of the information referred to in paragraph 1(e) and (f); (d) information, other than that listed in paragraph 1, contained in the safety data sheet.	publicly available, free of charge, over the Internet in accordance with Article 76(2)(d) except where a party submitting the information submits a justification accepted as valid by the Agency, as to why such publication is potentially harmful for the commercial interests of the registrant or any other party concerned: (a) if essential to classification and labelling, the degree of purity of the substance and the identity of impurities and/or additives which are known to be dangerous; (b) the total tonnage band (i.e. 1-10 tonnes, 10-100 tonnes, 100-1 000 tonnes or over 1 000 tonnes) within which a particular substance has been registered; (c) the study summaries or robust study summaries of the information referred to in paragraph 1(e) and (f); (d) information, other than that listed in paragraph 1, contained in the safety data sheet; **(da) the trade name(s) of the substance;** **(b) the name in the IUPAC Nomenclature, for dangerous substances within the meaning of Directive 67/548/EEC;** **2a. In justified special cases the information in paragraph 1 may be exempted from the electronic public access, if the a party submitting the information proofed to the Agency that his commercial interests, or interests on scientific research and development are potentially harmed by such a publication.**	publicly available, free of charge, over the Internet in accordance with Article 76(2)(d) except where a party submitting the information submits a justification in accordance with Article 10(a)(xi), accepted as valid by the Agency, as to why such publication is potentially harmful for the commercial interests of the registrant or any other party concerned: (a) if essential to classification and labelling, the degree of purity of the substance and the identity of impurities and/or additives which are known to be dangerous; (b) the total tonnage band (i.e. 1-10 tonnes, 10-100 tonnes, 100-1 000 tonnes or over 1 000 tonnes) within which a particular substance has been registered; (c) the study summaries or robust study summaries of the information referred to in paragraph 1(e) and (f); (d) information, other than that listed in paragraph 1, contained in the safety data sheet; ***(da) the trade name(s) of the substance;*** ***(db) the name in the IUPAC Nomenclature for non-phase-in substances which are dangerous within the meaning of Directive 67/548/EEC for a period of <u>six</u> years;*** ***(dc) the name in the IUPAC Nomenclature for dangerous substances within the meaning of Directive 67/548/EEC that are only used as one or more of the following:*** ***(i) as an intermediate;*** ***(ii) in scientific research and development;*** ***(iii) in product and process orientated research and development.***

8.2 Technical issues

Council Common Position	EP amendment	Result of the 6th trilogue
Article 66.3 Until …* a Member State may maintain any existing ***and*** more stringent restrictions in relation to Annex XVII on the manufacture, placing on the market or use of a substance, provided that those restrictions have been notified according to the Treaty. The Commission shall compile and publish an inventory of these restrictions by ….** _____ * 6 years after entry into force of this Regulation ** 2 years after entry into force of this Regulation	Amendment 116 Until …*, a Member State may maintain any existing ***or*** more stringent restrictions ***as well as any implementing measures thereof*** in relation to Annex XVII on the manufacture, placing on the market or use of a substance, provided that those restrictions have been notified according to the Treaty. The Commission shall compile and publish an inventory of these restrictions by …**.	It was agreed that the concern behind this amendment should be addressed by modifiying Articles 136, 138 and 140 to read as below, and that Recital 73 should be modified as follows. In addition, it was agreed that the entry into force of the Regulation be specified by means of an accurate date. *Article 136* *Transitional measures regarding restrictions* 1. By…*, the Commission shall, if necessary, prepare a draft amendment to Annex XVII in accordance with either of the following: (a) any risk evaluation and recommended strategy for limiting risks that has been adopted at Community level in accordance with Article 11 of Regulation (EEC) No 793/93 as far as it includes proposals for restrictions in accordance with Title VIII of this Regulation but for which a decision under Directive 76/769/EEC has not yet been taken; (b) any proposal, which has been submitted to the relevant institutions but has not yet been adopted, concerning the introduction ***or the amendment*** of restrictions under Directive 76/769/EEC. 2. Until…*, any dossier referred to in Article 128(3) shall be submitted to the Commission. The Commission shall, if necessary, prepare a draft amendment to Annex XVII. ***3. Any amendment to the restrictions adopted under Directive 76/769/EEC from ** shall be incorporated in Annex XVII with effect from ***.***

		_____ * ~~18~~***36*** months after entry into force of this Regulation. ** ***Date of entry into force of this Regulation.*** *** ***24 months after entry into force of this Regulation.*** _____ *Article 138* *Repeals* Directive~~s 76/769/EEC and~~ 91/155/EEC shall be repealed. Directives 93/105/EC and 2000/21/EC and Regulations (EEC) No 793/93 and (EC) No 1488/94 shall be repealed with effect from ….*. Directive 93/67/EEC shall be repealed with effect from ….** ***Directive 76/769/EEC shall be repealed with effect from…***.*** References to the repealed acts shall be construed as references to this Regulation. _____ * 12 months after entry into force of this Regulation. ** 14 months after entry into force of this Regulation. *** 24 months after entry into force of this Regulation *Recital* (73) In order to accelerate the current system, the restriction procedure should be restructured and Directive 76/769/EEC, which has been substantially amended and adapted several times, should be replaced. In the interests of clarity and as a starting point for this

		new accelerated restriction procedure, ~~the *acquis* of the harmonised rules~~ ***all the restrictions developed under*** ~~under the Annex to~~ th***e***~~at~~ Directive should be ~~recast and taken over~~ ***incorporated into this Regulation.*** ~~This recast follows the rules set out within the Interinstitutional Agreement of 28 November 2001 on a more structured use of the recasting technique for legal texts concerning recasting techniques~~. ***Where appropriate, the application of Annex XVII should be facilitated by guidance developed by the Commission.*** ____ The Presidency suggests to modify Paragraph 1 of Article 140 as follows: *Article 140* *Entry into force and application* 1. This Regulation shall enter into force on ***1st of June, 2007*** ~~twentieth day following that of its publication in the Official Journal of the European Union~~. 2. Titles II, III, V, VI, VII, XI and XII as well as Articles 127 and 135 shall apply from …*. 3. Article 134 shall apply from …**. 4. Title VIII and Annex XVII shall apply from …***. ____ * 12 months after entry into force of this Regulation. ** 14 months after entry into force of this Regulation. *** ~~18~~***24*** months after entry into force of this Regulation ____
	EP amendments on the scope: AM 31, AM 99(ENVI), AM 100 (ENVI), AM 101 (ENVI), AM 102 (ENVI), AM 104 (ENVI), AM 108(ENVI), AM 109(ENVI),	It was agreed that the Commission will review the scope of the Regulation as regards the interface with other pieces of Community legislation. The proposed

	AM110 (ENVI), AM111(ENVI), AM112 (ENVI)	review is intended to respond to amendments on the scope. ***Article 137*** ***Review*** ***1(b). By …*, the Commission shall carry out a review to assess whether or not to amend the scope of this Regulation to avoid overlaps with other relevant Community provisions. On the basis of this review, the Commission may, if appropriate, present a legislative proposal.*** **** 5 years after entry into force of this Regulation.***
Annex XVII (Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles)	Amendment 172 ANNEX XVII, POINT 47 A, B, C, D, E (new) (Annex D, not included in this table)	It was agreed to update Annex XVII to indicate all amendments and technical adaptations introduced to Directive 76/769/EEC since adoption of the proposal for REACH Regulation. The updated Annex XVII IS AVAILABLE BUT NOT INCLUDED IN THIS DOCUMENT, more than 300 pages.

ANNEX B

Commission Statement on Alternative Methods:

As part of the Community's strategy to promote alternative test methods, the development of methods covering computer supported, in vitro and other methodologies, including refinement of current methods, has been a priority for decades. Between 1999 and 2002 (Fifth Framework Programme), the EU supported 43 research projects worth €65 million, several of which are still ongoing. In the current Research Framework Programme (Sixth Framework Programme: 2003-2006), the European Union is investing more than €90 million to develop robust, effective, non-animal testing methods that will withstand the requirements of international validation.

Research activities will continue in the forthcoming Seventh Framework Programme (2007-2013) through coordinated activities on alternative methods and strategies for safety testing focused on pharmaceuticals (under the Health theme) and industrial chemicals (under the Environment theme). Consideration has been given to which methods could make the most contribution to reducing animal testing within REACH, taking due account of the time needed to develop tests and the relevant registration deadlines in REACH. As a result, the Seventh Framework Programme includes development of methods that could directly support the reduction of animals used in testing within REACH. Involvement of stakeholders is being sought through initiatives such as the European Partnership for Alternative Approaches to Animal Testing, launched on November 7, 2005 by Commissioners Potocnik and Verheugen together with industry. By effectively pooling Commission and industry experience, expertise and resources, a common coordinated Partnership at EU level and across sectors will be more effective than historically fragmented initiatives in this area.

The validation of alternative testing methods has been a priority for the Commission since 1991. To this end, the Commission set up the European Centre for the Validation of Alternative Methods (ECVAM), a specific unit within the Joint Research Centre with the task of coordinating the validation of alternative test methods at the European Union level, and promoting the development, validation and international recognition of alternative test methods. The Commission will continue to validate appropriate methods and will consider the application of validated methods in Community legislation. Today, suitable methods are used in the context of the Community legislation on chemicals, to adapt the Annex V of Directive 67/548/EEC. The Commission recognises the importance of securing regulatory acceptance for such methods as

rapidly as possible and has adopted several validated alternative test methods in Annex V of 67/548/EEC ahead of their eventual international acceptance. The Commission will give a high priority to ensuring that the REACH testing regulation is adapted as soon as possible after appropriate validated methods become available.

The Commission will continue to be active in international fora, particularly the OECD where it contributes to the development of new standards for tests and with especial focus on newly validated methods as mentioned above.

The regulatory framework in which test methods are used is as important as the specific methods. Since its very beginning, the minimisation of animal testing has been a key element of the design of REACH and the Commission has consistently worked to improve this aspect of the proposal. This can be seen in terms of significant changes throughout the process such as adding the pre-registration phase as a result of feedback on the White Paper in 2001 and accepting a single pre-registration date as proposed in both Parliament's First Reading Opinion and the Council Common Position. Minimisation of animal testing is also apparent in the detailed legal text, including encouragement for grouping of substances, evaluation of testing proposals and use of read across Important work related to reducing the use of animals is on-going in the RIPs (REACH Implementation Projects) with the development of intelligent testing strategies. The Commission is committed to continuing this work after the adoption of REACH. For example the development and maintenance of guidelines and Agency procedures will offer further opportunities to address concerns over animal testing.

The Commission will also consider relevant aspects in the review of Directive 86/609/EEC, specifically in relation to the ways in which the development, validation and regulatory acceptance of alternative methods in accordance with the 'Three Rs' principle could be further promoted.

ANNEX C

Commission declaration on tobacco Additives in the context of the negotiations on REACH and addressing the EP amendments on tobacco additives

The REACH Regulation covers chemical ingredients to tobacco products like any other chemical substance. As such, they will need to be registered and be subject to evaluation, restriction or authorisation under the REACH system. Some of their effects in burnt form should be covered by any required chemical safety assessments.

Once the REACH system is in operation, it will be necessary to summarize and to take into account the information made available under REACH on tobacco ingredients in order to better benefit from the synergies with the on-going work in the context of Directive 2001/37/EC on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products.

In the context of Directive 2001/37/EC, the Commission is committed to promote:

- the development and application of a harmonised reporting format for tobacco ingredients in order to create a precondition for systematic assessment of tobacco ingredients. This could evolve, at a later stage, into the setting up of a European data bank on tobacco ingredients and their effects;

- the assessment of tests for toxicological and addictive effects from a public health perspective

- cooperation of independent tobacco laboratories within the EU in order to create the operational basis for a shared analysis and assessment of tobacco ingredients and/or smoke emissions by the Member States, and subsequent consideration on the form of a possible proposal for a common list of ingredients.

The Commission will also:

- participate in the process of developing guidelines on testing and measuring of the contents and emissions of tobacco products in the context of Framework Convention on Tobacco Control (FCTC), and

- consider co-financing research on toxicity and in particular addictiveness of tobacco ingredients and/or smoke emissions in the context of the research framework program.

By the next review of Directive 2001/37/EC, which will be based on the report on its implementation due for the end of 2007, the Commission will consider further development of the framework for the assessment of tobacco ingredients in the light of the experience gathered and impact assessments on different options.

The burden of proof on the health effects of the contents and emissions of tobacco products should fully lie with the industry, which should be responsible for the financing of the development, validation and carrying out of the appropriate toxicological and addictiveness tests. This process must be led by the public health authorities to ensure that all the methodologies developed properly address public health concerns.

On the basis of the principle established in the previous paragraph concerning the role of the industry in financing the tests, the Commission will examine the concrete options for raising adequate human and financial resources in order to fund any substantial work programme on evaluating ingredients and smoke emissions to properly assess the results from a health perspective.

The Commission is aware that the development and validation of methodologies and the evaluation of substances is a demanding task that will take several years.

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