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Committee on the Environment, Public Health and Food Safety

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*****II**

DRAFT RECOMMENDATION FOR SECOND READING

on the Council common position for adopting a regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC of the European Parliament and of the Council and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC
(7524/2006 – C6-0000/2006 – 2003/0256(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Guido Sacconi

Symbols for procedures

- * Consultation procedure
majority of the votes cast
- **I Cooperation procedure (first reading)
majority of the votes cast
- **II Cooperation procedure (second reading)
*majority of the votes cast, to approve the common position
majority of Parliament's component Members, to reject or amend
the common position*
- *** Assent procedure
*majority of Parliament's component Members except in cases
covered by Articles 105, 107, 161 and 300 of the EC Treaty and
Article 7 of the EU Treaty*
- ***I Codecision procedure (first reading)
majority of the votes cast
- ***II Codecision procedure (second reading)
*majority of the votes cast, to approve the common position
majority of Parliament's component Members, to reject or amend
the common position*
- ***III Codecision procedure (third reading)
majority of the votes cast, to approve the joint text

(The type of procedure depends on the legal basis proposed by the Commission.)

Amendments to a legislative text

In amendments by Parliament, amended text is highlighted in ***bold italics***. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). These suggested corrections are subject to the agreement of the departments concerned.

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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the Council common position for adopting a regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC of the European Parliament and of the Council and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (7524/2006 – C6-0000/2006 – 2003/0256(COD))

(Codecision procedure: second reading)

The European Parliament,

- having regard to the Council common position (7524/2006 – C6-0000/2006),
 - having regard to its position at first reading¹ on the Commission proposal to Parliament and the Council (COM(2003)0644)²,
 - having regard to Article 251(2) of the EC Treaty,
 - having regard to Rule 62 of its Rules of Procedure,
 - having regard to the recommendation for second reading of the Committee on the Environment, Public Health and Food Safety (A6-0000/2006),
1. Approves the common position as amended;
 2. Instructs its President to forward its position to the Council and Commission.

Council common position

Amendments by Parliament

Amendment 1 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***.

(14) Responsibility for the management of, ***and 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***

¹ Texts Adopted, 17.11.2005, P6_TA(2005)0434.

² OJ C ... / Not yet published in OJ.

procedures.

(Amendment 10 (modified) - first reading)

Justification

Preliminary to the introduction of "duty of care" in further amendments.

REACH should provide an opportunity to involve firms, including very small businesses, and not be an obstacle that excludes them.

Amendment 2

RECITAL 43 A (new)

(43a) Better coordination of resources at Community level will contribute to increasing the scientific knowledge indispensable for the development of alternative methods to that of experimentation on vertebrates. It is essential, for this purpose, that the Community continue and increase its efforts and take the measures necessary for the promotion of research and the development of new non-animal alternative methods, in particular within its Seventh Framework Programme for Research and Technological Development.

(Amendment 24 - first reading)

Justification

This recalls the Community's duty to promote alternative methods to that of animal experimentation, already introduced in Directive 2003/15/EC on cosmetics.

Amendment 3

RECITAL 58 A (new)

(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.

(Amendment 36 - first reading)

Justification

The High Production Volume (HPV) chemicals programme in the United States has proven the positive effect a stakeholder commenting period can have towards preventing animal tests and saving costs.

Amendment 4

RECITAL 92 A (new)

(92a) In order to promote non-animal testing, the Agency should have the task of developing and implementing a policy for 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. To this end, the Agency should include a Committee for Alternative Test Methods, consisting of experts from the European Centre for the Validation of Alternative Methods (ECVAM), animal welfare organisations and other relevant stakeholders, to ensure the broadest possible appropriate scientific and technical expertise which is available within the Community.

(Amendment 361 - first reading)

Justification

The objective of this Regulation to promote non-animal testing should be included in the mandate and work of the Agency to ensure its effective implementation. Therefore a Committee should be established in the Agency consisting of relevant experts to carry out the tasks related to the development of alternative test methods and their application.

Amendment 5

ARTICLE 1, PARAGRAPH 1

1. The purpose of this Regulation is to ensure a high level of protection of human

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health and the environment as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation.

health and the environment as well as the free circulation of substances on the internal market 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.***

(Amendment 59 and 419 - first reading)

Justification

In view of the considerable number of chemicals and uses which will not be covered by REACH provisions -including an estimated 70,000 substances produced at less than 1 tonne per annum - a general principle of Duty of care is needed to define the responsibility of industry for the safe handling and use of ALL chemicals. It is intended to apply to all substances (irrespective of production volume), implying that industry is expected not just to meet the specific obligations under REACH, but also to fulfil the basic social, economic and environmental responsibilities of entrepreneurship. These specific provisions will also ensure legal certainty for companies to fulfil their duty of care.

Amendment 6

ARTICLE 1, PARAGRAPHS 3 A, 3 B and 3 C (new)

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.

(Amendment 364 - first reading)

Justification

Introduces the principle of duty of care.

Amendment 7

ARTICLE 7, PARAGRAPH 7 A (new)

7a. The Agency shall provide guidelines to help the producers and importers of articles as well as the competent authorities.

(Amendment 88 (partially) - first reading)

Justification

Implementation of the provisions relating to the registration and notification of substances in articles would be easier if appropriate guidelines were established.

Amendment 8

ARTICLE 8 A (new)

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.

**** Two years after the entry into force of this Regulation.***

(Amendment 90 - first reading)

Justification

A mark to be stamped on articles would make it possible to identify and promote those involved in the production procedure who have complied with the requirements stemming from this Regulation.

Amendment 9

ARTICLE 13, PARAGRAPH 2, SUBPARAGRAPH 1 A (new)

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.

(Amendment 108 - first reading)

Justification

The test methods should be automatically updated when an alternative test method is validated by ECVAM.

Amendment 10
ARTICLE 14, PARAGRAPH 1, SUBPARAGRAPH 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.***

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.

For substances manufactured or imported in quantities of less than 10 tonnes per year, a chemical safety assessment shall be undertaken if the substance meets criterion (a) of Annex III.

(Amendment 110 + 387 (modified) - first reading)

Justification

It is unacceptable to limit safety assessments to substances above 10 tonnes. This would mean, firstly, that for two-thirds of the substances that fall under REACH, the data provided under registration would not be assessed with regard to its impacts on human health and the environment. And even when they are hazardous, there would be no requirement to provide exposure data. Without exposure information, it would be near impossible to identify the appropriate risk management measures to protect workers or consumers against hazardous substances. However, in view of the specific criteria established for substances between 1 and 10 tonnes, a chemical safety assessment for these substances will only be required when they are likely to be c/m/r.

Amendment 11
ARTICLE 14, PARAGRAPHS 7 A AND 7 B (new)

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.

(Amendment 112 - first reading)

Justification

Communication between the players in the production chain must not be limited to a mere exchange of information intended simply to comply with the directive. Throughout the whole supply chain, there must be a responsibility towards a form of interaction and communication between suppliers and upstream and downstream users.

Amendment 12
ARTICLE 23 A (new)

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 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.

(Amendment 121 - first reading)

Justification

Downstream users are concerned that some - and even, perhaps, a large number - substances will not be registered for economic reasons, which would have an adverse impact on their business. They are unable to make suitable preparations for such an eventuality because they would not know about it until the deadline for registration had passed. A provision requiring manufacturers and importers to give advance notice would enable them to negotiate with the manufacturer or importer. Downstream users might be willing to pay a higher price in order to avoid even higher reformulation costs, thus avoiding withdrawal of the substance.

Amendment 13

ARTICLE 27, PARAGRAPH 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.

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.

(Amendment 134 (partially) - first reading)

Justification

Establishes a mechanism for sharing in a fair way the original costs of tests irrespective of the number of registrants and the timing for subsequent registrations.

Amendment 14
ARTICLE 28, PARAGRAPH 1 A (new)

1a. Anyone in possession of studies or information on a substance derived through experiments on animals shall be required to forward such information to the Agency at the latest 18 months before the deadline laid down in Article 23(1).

(Amendment 140 - first reading)

Justification

Bringing forward the deadline for forwarding information derived from animal experimentation enables duplication of such experiments to be avoided and at the same time reduces the burden on businesses, particularly SMEs.

Amendment 15
ARTICLE 28, PARAGRAPH 2 A (new)

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.

(Amendment 369/rev. (partially) - first reading)

Justification

Allows six additional months for pre-registration of substances when requested by a

downstream user.

Amendment 16
ARTICLE 28, PARAGRAPH 4 A (new)

4a. Manufacturers and importers shall forward to the Agency any information in their possession deriving from experiments on vertebrate animals and other information that could prevent animal experimentation, in relation also to substances they have ceased to manufacture or import. Registrants who later make use of such information shall share the costs of creating such information in a manner that is proportional to each party's production volume. Anyone coming into possession of the results of studies or other information on a substance derived from experiments on vertebrate animals after the expiry of the deadline referred to in paragraph 1a, shall forward such information to the Agency.

(Amendment 143 - first reading)

Justification

This makes it clear that all information that could be useful in avoiding animal experimentation must be shared, avoiding duplication of such experiments and at the same time reducing the burden on businesses, particularly SMEs.

Amendment 17
ARTICLE 30, PARAGRAPH 1, SUBPARAGRAPH 2

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

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 ***and in proportion to each party's production volume***. This may be facilitated by following any *cost-sharing* guidance

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.

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.

(Amendment 150 (partially) - first reading)

Justification

Establishes a mechanism for sharing in a fair way the original costs of tests in analogy with the corresponding modifications to Article 27.

Amendment 18
ARTICLE 31, PARAGRAPH 1

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.

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 has been identified in accordance with Article 56(f).

(Amendment 157 revised - first reading)

Justification

With the help of Safety Data Sheets information about a substance shall be passed on in the supply chain according to the requirements of REACH. The scope of substances that require a safety data sheet needs to be expanded to include all substances of very high concern that are mentioned in Article 56 on authorisation.

Amendment 19
ARTICLE 31, PARAGRAPH 9 A (new)

9a. The Commission shall organise the development of technical guidelines setting minimum requirements for safety data sheets, to ensure the provision of clear and adequate information of optimal use to all actors up and down the supply chain.

(Amendment 162 - first reading)

Justification

Safety data sheets (SDS) can be a good tool to communicate information up and down the supply chain for both substances and preparations. However, SDS will achieve their purpose only if they are completed adequately. Thus, the Commission should develop technical guidance that provide minimum requirements on the completion of SDS.

Amendment 20
ARTICLE 32, PARAGRAPH 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. ***deleted***

Justification

All provisions relating to duty to communicate information on substances in articles should be grouped in a single article (see new Article 33a).

Amendment 21
ARTICLE 33 A (new)

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.

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.

(Amendments 166 and 366 - first reading)

Justification

Manufacturers, retailers and consumers should be able to find out whether specific substances are contained in an end product and, if necessary, to seek out and choose a safer alternative.

Information on hazardous (authorised) substances on their own, in preparations, and in articles must be distributed through the supply chain (upwards and downwards) to enable the

companies to take appropriate actions and to make informed decisions concerning the contents of their products. The downstream users' right to obtain information on such substances is crucial in order to rebuild consumer confidence and to regain goodwill.

Amendment 22
ARTICLE 39, PARAGRAPH 1 A (new)

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.

(Amendment 176 - first reading)

Justification

All relevant comments and information which could reduce animal testing should be taken into account.

Amendment 23
ARTICLE 39, PARAGRAPH 1 B (new)

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.

(Amendment 177 - first reading)

Justification

Given the rapid advances in the development of alternative tests, expert knowledge and experience should be provided to the competent authorities when evaluating testing proposals to prevent animal testing and save costs.

Amendment 24
ARTICLE 59, PARAGRAPH 1

1. The Commission shall be responsible for taking decisions on applications for authorisations in accordance with this Title.

1. The Commission shall be responsible for taking decisions on applications for authorisations in accordance with this Title. ***The precautionary principle shall apply when such decisions are taken.***

(Amendment 231 - first reading)

Justification

Reminds that such decisions should be taken based on the precautionary principle.

Amendment 25
ARTICLE 64

Obligation of ***holders of*** authorisations

Holders of an authorisation, as well as downstream users referred to in Article 55(2) including the substances in a preparation, shall include the authorisation number on the label before they place the substance or a preparation containing the substance on the market for an authorised use without prejudice to Directive 67/548/EEC and Directive 1999/45/EC. This shall be done without delay once the authorisation number has been made publicly available in accordance with Article 63(9).

Obligation of ***information on substances subject to*** authorisations

All substances, for use on their own, in preparations or in articles, that fulfil the conditions set out in Article 56 shall be labelled and accompanied, at all times, by a safety data sheet. The label shall include:

- (a) the name of the substance,***
- (b) attestation that the substance is included in Annex XIV, and***
- (c) each specific use for which the substance has been authorised.***

(Amendment 246 - first reading)

Justification

More comprehensive wording.

Amendment 26
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.

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(3). 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 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.

(Amendment 251 (partially) - first reading)

Justification

In the current Directive 76/769/EEC the European Parliament and the Council have a role in decisions on certain restrictions of chemicals such as prohibiting the use of phthalates in certain toys. This amendment aims to keep this procedure and not further increase the role of the Commission.

Amendment 27
ARTICLE 75, PARAGRAPH 1, POINT (D A) (new)

(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 intelligent stepwise risk assessment to meet the requirements of this Regulation, and the amount and distribution of funding for alternative test methods.

(Amendment 257 - first reading)

Justification

Linked to amendments of Recital 92. The objective of this Regulation to promote non-animal testing should be included in the mandate and work of the Agency to ensure its effective implementation. The development, validation, legal acceptance and use of alternative test methods is often hampered by a lack of strategic planning and coordination. Therefore the Agency should have a Committee consisting of experts in the field of alternative test methods with the mandate to develop and implement such strategic planning and to ensure that alternative test methods are used in intelligent, flexible risk assessment wherever possible to prevent animal testing and save costs. The Committee should also allocate funding for alternative test methods and produce a yearly report on the progress made to ensure transparency.

Amendment 28

ARTICLE 76, PARAGRAPH 2, POINT G A (new)

(ga) publishing on its website a list of substances that have been identified as

fulfilling the criteria referred to in Article 56, one year after the entry into force of this Regulation. This list shall be updated periodically;

(Amendment 263 letter gd - first reading)

Justification

The list of substances fulfilling the criteria for authorisation should be made public.

Amendment 29

ARTICLE 76, PARAGRAPH 3, POINT 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.

(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.

(Amendment 260 letter f) - first reading)

Justification

Parliament should also have the right to request opinions from the Agency, as it is the case for instance with EFSA.

Amendment 30

ARTICLE 76, PARAGRAPH 4, POINT D

(d) identifying enforcement strategies, as well as best practice in enforcement;

(d) identifying enforcement strategies, as well as best practice in enforcement, ***taking particular account of the specific problems for SMEs;***

(Amendment 262 letter d) - first reading)

Justification

Particular help should be given to SMEs for the enforcement of REACH.

Amendment 31

ARTICLE 78, PARAGRAPH 1

1. The Management Board shall be

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.

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.

(Amendment 267 (revised) - first reading)

Justification

This restates Parliament's traditional view as regards the composition of, and the arrangements for appointing, the Management Board, based on the EMEA model. The number of representatives from interested parties is increased from three to four in order to enable all the relevant sectors to be included.

Amendment 32
ARTICLE 78, PARAGRAPH 3

3. The duration of the term of office shall be four years. The term of office may be renewed once. However, for the first mandate, the Commission shall identify half of **its appointees**, and the Council shall identify 12 of its appointees, for whom this period shall be six years.

3. The duration of the term of office shall be four years. The term of office may be renewed once. However, for the first mandate, the Commission **and the European Parliament shall each identify half of their appointees** and the Council shall identify 12 of its appointees, for whom this period shall be six years.

(Amendment 360 revised - first reading)

Justification

Consequent to amendment to Article 78(1).

Amendment 33
ARTICLE 78, PARAGRAPH 3 A (new)

3a. The list drawn up by the Commission shall be forwarded to the European Parliament, together with the relevant background documents. Within three months of notification the European Parliament may submit its view for consideration to the Council, which shall then appoint the Management Board.

(Amendment 1037 - first reading)

Justification

The involvement of the European Parliament in the appointment of the Management Board should be facilitated.

Amendment 34
ARTICLE 79, PARAGRAPH 2 A (new)

2a. The elected Chairman shall introduce himself to the European Parliament.

(Amendment 269 - first reading)

Justification

With the aim of strengthening democracy and accountability the European Parliament should be given a possibility to get to know the Chairman and his programme.

Amendment 35
ARTICLE 82, PARAGRAPH 1

1. The Agency shall be managed by its Executive Director, ***who shall perform his duties in the interests of the Community, and independently of any specific interests.***

1. The Agency shall be managed by its Executive Director.

(Amendment 272 - first reading)

Justification

All the provisions relating to the independence of the component parts of the Agency's bodies

are brought together in a single article, in the interests of greater clarity (see the amendment to Article 87).

Amendment 36
ARTICLE 82, PARAGRAPH 2, POINT (J A) (new)

(ja) establishing and maintaining contact with the European Parliament and ensuring that a regular dialogue is held with that institution's relevant committees.

(Amendment 273 - first reading)

Justification

Restates the European Parliament's traditional view on relations with agencies.

Amendment 37
ARTICLE 82, PARAGRAPH 3 A (new)

3a. Once the general report and the programmes have been adopted 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.

(Amendment 276 - first reading)

Justification

Restates the European Parliament's traditional view on relations with agencies.

Amendment 38
ARTICLE 83, PARAGRAPH 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.

deleted

(Amendment 277 - first reading)

Justification

Linked to the amendment to Article 83, paragraph 2.

Amendment 39

ARTICLE 83, PARAGRAPH 2, SUBPARAGRAPH 1

2. The Executive Director of the Agency shall be appointed by the Management Board 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 decision by a two-thirds majority of all members with a right to vote.

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.***

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 Management Board shall take its decision by a two-thirds majority of all members with a right to vote.

(Amendment 278 - first reading)

Justification

This restates Parliament's traditional view (which was accepted by the Council in connection with the European Food Safety Authority and the Agency for the Evaluation of Medicinal Products) as regards the procedure for nominating executive directors.

Amendment 40

ARTICLE 84, PARAGRAPHS 1 TO 7

1. Each Member State ***may nominate***

1. Each Member State ***shall appoint one***

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. 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. 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).

3. Each Member State shall appoint one member to the Member State Committee.

4. The Committees shall aim to have a broad range of relevant expertise among their members. To this end each Committee may co-opt a maximum of five additional members chosen on the basis of their specific competence.

Members of the Committees shall be appointed for a term of three years which shall be renewable.

The members of the Management Board may not be members of the Committees. The members of each Committee may be accompanied by advisers on scientific, technical or regulatory matters.

The Executive Director or his representative and representatives of the Commission shall be entitled to attend all the meetings of the Committees and

member to the Committee for Risk Assessment. Members shall be appointed for their role and experience in performing the tasks specified in Article 76(3).

2. Each Member State *shall appoint one member to the Committee for Socio-economic Analysis. Members shall be appointed for their role and experience in performing the tasks specified in Article 76(3).*

3. Each Member State shall appoint one member to the Member State Committee.

4. The Committees shall aim to have a broad range of relevant expertise among their members. To this end each Committee may co-opt a maximum of five additional members chosen on the basis of their specific competence.

Members of the Committees shall be appointed for a term of three years which shall be renewable.

The members of the Management Board may not be members of the Committees. The members of each Committee may be accompanied by advisers on scientific, technical or regulatory matters.

The Executive Director or his representative and representatives of the Commission shall be entitled to attend all the meetings of the Committees and

working groups convened by the Agency or its committees as observers. Stakeholders may also *be invited to* attend meetings as observers, *as appropriate, at the request of the Committee members, or the Management Board.*

5. The members of each Committee *appointed following nomination by a Member State* shall ensure that there is appropriate co-ordination between the tasks of the Agency and the work of their Member State competent authority.

6. The members of the Committees shall be supported by the scientific and technical resources available to the Member States. To this end, Member States shall provide adequate scientific and technical resources to the members of the Committees that they have nominated. Each Member State competent authority shall facilitate the activities of the Committees and their working groups.

7. The Member States shall refrain from giving the members of the Committee for Risk Assessment or of the Committee for Socio-Economic Analysis, 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 independence of the Agency.

(Amendment 279 - first reading)

Justification

All Member States should be present in the committees. The presence of stakeholders at meetings of the committees should not be by invitation only. All the provisions relating to the independence of the component parts of the Agency's bodies are brought together in a single article, in the interests of greater clarity (see amendment to Article 87).

This clarifies the procedure for nominating the chairman of the Member State Committee.

Amendment 41 ARTICLE 85, PARAGRAPHS 1 TO 3

1. Each Member State shall appoint, for a

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 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 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.*

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. *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.*

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 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 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 attend meetings as observers.

Members of the Forum may not be members of the Management Board.

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.

(Amendment 280 - first reading)

Justification

The presence of stakeholders at meetings of the committees should not be by invitation only. All the provisions relating to the independence of the component parts of the Agency's bodies are brought together in a single article, in the interests of greater clarity (see amendment to Article 87).

Amendment 42
ARTICLE 86, PARAGRAPH 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.

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.

(Amendment 281 - first reading)

Justification

All the provisions relating to the independence of the component parts of the Agency's bodies are brought together in a single article, in the interests of greater clarity (cf. amendment to Article 87).

Amendment 43

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 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.***

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

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 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, ***the members*** of the Forum and any experts ***and scientific and technical advisers*** participating in the meeting shall declare

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**.

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**.

(Amendment 285 - first reading)

Justification

This restates Parliament's traditional view (which was accepted by the Council in connection with the European Food Safety Authority and the Agency for the Evaluation of Medicinal Products) as regards independence of members of committees and boards, their declaration of financial interests and indirect interests in the sector.

Amendment 44

ARTICLE 88, PARAGRAPH 3, SUBPARAGRAPH 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**.

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.

(Amendment 286 - first reading)

Justification

In view of the nature of the tasks to be performed by the Board of Appeal, a transparent procedure for the submission of applications should be introduced.

Amendment 45

ARTICLE 89, PARAGRAPHS 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.**

3. The members of the Board of Appeal may not perform any other duties in the Agency.

(Amendment 287 - first reading)

Justification

All the provisions relating to the independence of the component parts of the Agency's bodies are brought together in a single article in the interests of greater clarity. Even though the number of appeal cases may enable the members of the Board of Appeal to engage in other activities, their function will continue to be a full-time one.

Amendment 46
ARTICLE 90, PARAGRAPH 1

1. An appeal may be brought against decisions of the Agency taken pursuant to Article 9, Article 20, Article 27(6), Article 30(2) and (3) and Article 50.

1. An appeal may be brought against decisions of the Agency taken pursuant to Article 9, Article 20, Article 27(6), Article 30(2) and (3), Article 50 **and Article 59.**

(Amendment 288 - first reading)

Justification

For consistency authorisation decisions should also be subject to the Appeal process.

Amendment 47
ARTICLE 108

To ensure transparency, the Management Board shall, on the basis of a proposal by the Executive Director and in agreement with the Commission, adopt rules to ensure the availability to the public of regulatory, scientific or technical information concerning the safety of substances on their own, in preparations or in articles **which is not of a confidential nature.**

To ensure **maximum** transparency, the Management Board shall, on the basis of a proposal by the Executive Director and in agreement with the Commission, adopt rules **and set up a registry** to ensure the availability to the public of regulatory, scientific or technical information concerning the safety of substances on their own, in preparations or in articles, **pursuant to Regulation (EC) No**

1049/2001.

The internal rules of procedure of the Agency and of the Committees and working groups thereof shall be made available to the public via the Agency and on the Internet.

The applications for authorisation submitted, the stage reached in the procedure, interim decisions, authorisations and any other condition or restriction imposed shall be published on the Internet in a comprehensible form.

(Amendment 294 - first reading)

Justification

This restates Parliament's traditional view (which was accepted by the Council in connection with the Regulation governing the Agency for the Evaluation of Medicinal Products) as regards transparency and access to information.

Amendment 48

ARTICLE 127, PARAGRAPH 1 A (new)

1a. Paragraph 1 shall not affect the right of Member States to maintain or introduce more stringent protective measures in accordance with Community legislation on worker protection, if a chemical safety assessment has not been carried out in accordance with this Regulation for a use of a substance.

(Amendment 309 - first reading)

Justification

Provisions adopted pursuant to Article 137 of the Treaty establishing the European Community should not prevent Member States from maintaining or introducing more stringent protective measures. This includes provisions on worker protection. If a chemical safety assessment has been carried out for a substance, it may be assumed that the protection of workers is adequately ensured. It is therefore proposed that in other cases the right of Member States to adopt more stringent measures should not be restricted.

Amendment 49

Amendment by Parliament

Designation of the substance, of the groups of substances or of the preparation	Conditions of restriction
<p>47a. Toluene CAS No 108-88-3</p>	<p><i>May not be placed on the market or used as a substance or constituent of preparations in a concentration equal to or higher than 0,1 % by mass in adhesives and spray paints intended for sale to the general public.</i></p>
<p>47b. Trichlorobenzene CAS No 120-82-1</p>	<p><i>May not be placed on the market or used as a substance or constituent of preparations in a concentration equal to or higher than 0,1 % by mass for all uses except:</i></p> <ul style="list-style-type: none"> <i>— as an intermediate of synthesis, or</i> <i>— as a process solvent in closed chemical applications for chlorination reactions,</i> <p><i>or</i></p> <ul style="list-style-type: none"> <i>— in the manufacture of 1,3,5 — trinitro</i> <i>— 2,4,6 — triaminobenzene (TATB)</i>
<p>47c. Polycyclic-aromatic hydrocarbons (PAH)</p> <ol style="list-style-type: none"> 1. Benzo(a)pyrene (BaP) CAS No 50-32-8 2. Benzo(e)pyrene (BeP) CAS No 192-97-2 3. Benzo(a)anthracene (BaA) CAS No 56-55-3 4. Chrysen (CHR) CAS No 218-01-9 5. Benzo(b)fluoranthene (BbFA) CAS No 205-99-2 6. Benzo(j)fluoranthene (BjFA) CAS No 205-82-3 	<p><i>1. Extender oils may not be placed on the market and used for the production of tyres or parts of tyres, if they contain:</i></p> <ul style="list-style-type: none"> <i>— more than 1 mg/kg BaP, or</i> <i>— more than 10 mg/kg of the sum of all listed PAHs.</i> <p><i>These limits are regarded as kept, if the polycyclic aromatics (PCA) extract is less than 3 % by mass, as measured by the Institute of Petroleum standard IP346: 1998 (Determination of PCA in unused lubricating base oils and asphaltene free petroleum fractions — Dimethyl sulphoxide extraction refractive index method), provided that compliance with the limit values of BaP and of the listed PAHs, as well as the correlation of the measured values with the PCA extract, is</i></p>

7. Benzo(k)fluoranthene (BkFA)

CAS No 207-08-9

8. Dibenzo(a, h)anthracene (DBAhA)

CAS No 53-70-3

controlled by the manufacturer or importer every six months or after each major operational change, whichever is earlier.

2. Furthermore, the tyres and treads for retreading manufactured after 1 January 2010 may not be placed on the market if they contain extender oils exceeding the limits indicated in paragraph 1.

These limits are regarded as kept, if the vulcanised rubber compounds do not exceed the limit of 0,35 % Bay protons as measured and calculated by ISO 21461 (Rubber vulcanised — Determination of aromaticity of oil in vulcanised rubber compounds).

3. By way of derogation, paragraph 2 shall not apply to retreaded tyres if their tread does not contain extender oils exceeding the limits indicated in paragraph 1.

47d. The following phthalates (or other CAS- and EINECS numbers covering the substance):

bis (2-ethylhexyl) phthalate (DEHP)

CAS No 117-81-7 EINECS No 204-211-0

dibutyl phthalate (DBP)

CAS No 84-74-2 EINECS No 201-557-4

benzyl butyl phthalate (BBP)

CAS No 85-68-7 EINECS No 201-622-7

Shall not be used as substances or as constituents of preparations, at concentrations of greater than 0,1 % by mass of the plasticised material, in toys and childcare articles.

Such toys and childcare articles containing these phthalates in a concentration greater than the limit mentioned above shall not be placed on the market.

47e. The following phthalates (or other CAS- and EINECS numbers covering the substance):

di-“isononyl” phthalate (DINP)

CAS No 28553-12-0 and 68515-48-0

EINECS No 249-079-5 and 271-090-9

di-“isodecyl” phthalate (DIDP)

CAS No 26761-40-0 and 68515-49-1

Shall not be used as substances or as constituents of preparations, at concentrations of greater than 0,1 % by mass of the plasticised material, in toys and childcare articles which can be placed in the mouth by children.

Such toys and childcare articles containing these phthalates in a concentration greater than the limit mentioned above shall not be placed on

*Einecs No 247-977-1 and 271-091-4
di-n-octyl phthalate (DNOP) CAS No 117-
84-0 Einecs No 204-214-7*

the market.

*For the purposes of points 47d and 47e,
“childcare article” means any product
intended to facilitate sleep, relaxation,
hygiene, the feeding of children or
sucking on the part of children.*

*The Commission shall re-evaluate, by 16
January 2010 at the latest, the measures
provided for in relation to points 47d and
47e in the light of new scientific
information on such substances and their
substitutes, and if justified, these
measures shall be modified accordingly.*

Justification

*The list established in Annex XVII needs to be updated with the latest restriction measures
adopted by Council and Parliament.*

EXPLANATORY STATEMENT

The Council common position mirrors and in some respects enhances the healthy balance achieved by Parliament at first reading between the competitiveness of the European chemicals industry and protection of human health and the environment.

The rapporteur welcomes this approach and considers that agreement can be reached at second reading if the Council and Commission take a genuinely constructive stance in negotiations.

With a view to this, the rapporteur wishes to focus on a number of priorities relating to the purpose of the regulation which the Council failed properly to take into account. He reserves the right to raise further minor issues, if appropriate, following the discussions in committee.

The rapporteur therefore intends to retable a number of amendments which Parliament adopted by a large majority but which the Council did not see fit to include in its common position.

The principal aim is to strengthen the 'due diligence' principle for manufacturers and importers with a view to ensuring proper controls on substances placed on the market and adequate communication and information exchange in connection with the risks arising from their use.

A second batch of amendments on which the rapporteur intends to focus covers animal testing of substances. In particular, he intends to enhance the role of the European Centre for the Validation of Alternative Methods (ECVAM) and to foster the replacement of animal testing with an alternative method if the ECVAM acknowledges its scientific validity. Amendments on compulsory forwarding to the Agency of studies or information on substances obtained using animal testing and all those in respect of which this could be avoided, and on the establishment of a Committee for Alternative Test Methods, will also be retabled.

The rapporteur intends, furthermore, to retable a batch of amendments seeking to step up the exchange of information required for the purpose of assessing the health and environmental risks and effects of substances. In particular, this will reopen the possibility of establishing 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 REACH requirements.

The rapporteur also considers it essential to improve the Council common position by retabling amendments seeking to make the system more manageable, particularly in view of the problems small and medium-sized undertakings are likely to have in implementing it. Amendments providing for aid and support mechanisms for small and medium-sized undertakings and for the adoption of special assistance measures by Member States will therefore be retabled.

The rapporteur sees it as a priority to enhance Parliament's prerogatives and give it a more incisive role in the process of establishing the Agency and in monitoring the results obtained.

A few other amendments dealing with specific issues in respect of which, in the rapporteur's view, Parliament's position at first reading will significantly improve the common position

will also be retabled.

The draft recommendation does not include the amendments adopted at first reading on the authorisation of substances. The rapporteur believes that, compared to the common position, Parliament's position at first reading is more rigorous and more consistent with the main aim of the regulation - namely to replace highly problematic substances with safer alternative substances or technologies - and it should be revived. Furthermore, the gap between that position and the Council's position is not unbridgeable. A compromise on this important area is therefore possible and necessary. The rapporteur therefore intends, in cooperation with the other political groups, to assess the best way forward with a view to securing a broad agreement, the case for which can be argued with the Council and Commission.

The rapporteur nevertheless intends to retable the entire position adopted by Parliament at first reading in those areas where negotiations to reach an agreement were not initiated.