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Committee on the Environment, Public Health and Food Safety

15.9.2006 PE 378.589v01-00

AMENDMENTS 51-207

Draft recommendation for second reading **(PE 371.746v01-00)**
Guido Sacconi
The Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) No. .../... [on Persistent Organic Pollutants]

Council common position (7524/2006 – C6-0267/2006 – 2003/0256(COD))

Council common position	Amendments by Parliament

Amendment by Philippe Busquin + Caroline Lucas, Carl Schlyter, Hiltrud Breyer + Dan Jørgensen + Ria Oomen-Ruijten

Amendment 51
RECITAL 1

(1) This Regulation should ensure a high level of protection of human health and the environment ***as well as*** the free movement of substances, on their own, in preparations and in articles, while enhancing competitiveness and innovation.	(1) This regulation should ensure a high level of protection of human health and the environment***,*** the free movement of substances, on their own, in preparations and in articles, ***increased transparency and the promotion of non-animal testing***, while enhancing competitiveness and innovation.

Or. en

Justification

In line with Amendment 1 adopted in First Reading.

Linked to amendment of Article 1(1). These two objectives of this Regulation from the

Commission Explanatory Memorandum have been deleted by the Council and should be re-instated in view of the importance of both increased transparency and the promotion of non-animal testing in this Regulation for all stakeholders and European citizens. (Busquin + Jørgensen + Oomen-Ruijten)

The Council added this recital to state the objectives of REACH, but forgot the objectives of increased transparency and the promotion of non-animal testing, as stated in the Explanatory Memorandum of the Commission proposal. (Lucas, Schlyter and Breyer)

Amendment by Amalia Sartori + Chris Davies + Alessandro Foglietta, Adriana Poli Bortone

Amendment 52
RECITAL 4 A (new)

(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 that they should be compatible with the free-trade principles in force under WTO provisions.

Or. en

Justification

Successful First Reading amendment intended to promote the competitiveness of the European industry. (Davies)

Intended to preserve the competitiveness of the products of European undertakings against imports from third countries. Retabling of Amendment 416 from first reading. (Foglietta & Poli Bortone)

Amendment by Frédérique Ries, Chris Davies

Amendment 53
RECITAL 7

(7) To preserve the integrity of the internal market and to ensure a high level of protection for human health, especially the health of workers, and the environment, it is	(7) To preserve the integrity of the internal market and to ensure a high level of protection for human health, especially the health of workers ***and that of vulnerable***

necessary to ensure that ***manufacturing of*** substances in the Community ***complies*** with Community law, even if those substances are exported.	***populations***, and the environment, it is necessary to ensure that ***all*** substances ***that are manufactured or placed on the market*** in the Community ***comply*** with Community law, even if those substances are exported.

Or. en

Justification

The standard of protection of people's health must be set to include both those most exposed (workers) and those most vulnerable. Re-tabling of original Parliament amendment 6.

Amendment by Carl Schlyter, Caroline Lucas, Hiltrud Breyer

Amendment 54
RECITAL 7

(7) To preserve the integrity of the internal market and to ensure a high level of protection for human health, especially the health of workers, ***and the environment***, it is necessary to ensure that manufacturing of substances in the Community complies with Community law, even if those substances are exported.	(7) To preserve the integrity of the internal market and to ensure a high level of protection for ***the environment and*** human health, especially the health of workers ***and that of vulnerable populations***, it is necessary to ensure that manufacturing of ***all*** substances in the Community complies with Community law, even if those substances are exported.

Or. en

(Amendment 6 - first reading)

Justification

The standard of protection of human health must be set to include those parts of the population that are particularly vulnerable to chemical exposure.

Amendment by Urszula Krupa

Amendment 55
RECITAL 7

(7) To preserve the integrity of the internal	(7) To preserve the integrity of the internal

market and to ensure a high level of protection for human health, especially the health of workers, ***and the environment***, it is necessary to ensure that manufacturing of substances in the Community complies with Community law, even if those substances are exported.	market and to ensure a high level of protection for ***the environment and*** human health, especially the health of workers ***and that of vulnerable populations,*** it is necessary to ensure that manufacturing of substances, ***or substances placed on the market,*** in the Community complies with Community law, even if those substances are exported.

Or. en

Justification

The standard of protection of human health must be set to include both those most exposed (workers) and those most vulnerable. EP amendment 6 is re-tabled.

Amendment by Carl Schlyter, Caroline Lucas, Hiltrud Breyer, Jonas Sjöstedt

Amendment 56
RECITAL 9

(9) The assessment of the operation of the four main legal instruments governing chemicals in the Community, i.e. Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations, Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations and Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of	(9) The assessment of the operation of the four main legal instruments governing chemicals in the Community, i.e. Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations, Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations and Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of

existing substances, identified a number of problems in the functioning of Community legislation on chemicals, resulting in disparities between the laws, regulations and administrative provisions in Member States directly affecting the functioning of the internal market in this field***,*** and ***the need to do more*** to protect public health and the environment in ***accordance with the precautionary principle.***

existing substances, identified a number of problems in the functioning of Community legislation on chemicals, resulting in disparities between the laws, regulations and administrative provisions in Member States directly affecting the functioning of the internal market in this field, and ***a failure*** to protect public health and the environment in ***a precautionary manner.***

Or. en

(Amendment 7 - first reading)

Justification

There should be recognition that REACH is filling the gaps in knowledge related to the protection of public health and the environment.

Amendment by Richard Seeber

Amendment 57
RECITAL 11

(11) To ensure workability and to maintain the incentives for waste recycling and recovery, wastes should not be regarded as substances, preparations or articles within the meaning of this Regulation.

(11) To ensure workability and to maintain the incentives for waste recycling and recovery, wastes ***and secondary raw materials*** should not be regarded as substances, preparations or articles within the meaning of this Regulation. ***Generating value ('valorisation') from wastes and materials used as secondary raw material or as a source of energy in recovery operations contributes to the EU objective of sustainable development, and this Regulation does not introduce requirements which reduce the incentives for such recycling and recovery.***

Or. de

Justification

This amendment corresponds to Amendment 424 adopted at first reading in combination with

Recital 11 of the common position. It is intended on the one hand to take into account the current discussions in the field of waste concerning secondary raw materials and, on the other hand, to provide additional incentives for recycling of waste in the interests of sustainable development.

Amendment by Françoise Grossetête, Anne Laperrouze, Vittorio Prodi + Ria Oomen-Ruijten

Amendment 58
RECITAL 11 A (new)

(11a) For reasons of resource efficiency and sustainability, secondary raw materials, derived by recycling from production, processing and end-of-life waste, should be exempted. Generating value ("valorisation") from materials used as secondary raw material contributes to the EU objective of sustainable development, and this Regulation must not introduce requirements which reduce the incentives for such recycling and recovery.

Or. en

Justification

Considering secondary raw materials in the scope of REACH could seriously hamper recycling and recovery and thereby increase the need for non-renewable resources. It should be made clear that recycling and resource efficiency is in no way discouraged by REACH. (Grossetête, Laperrouze & Prodi)

Amendment 424 from first reading. Incorporating secondary raw materials into the REACH system could substantially hamper the closure of materials cycles and consequently inevitably increase demand for primary resources. It is necessary to ensure that REACH in no way hampers recycling or resource efficiency. (Oomen-Ruijten)

Amendment by Dagmar Roth-Behrendt

Amendment 59
RECITAL 11 A (new)

(11a) For reasons of workability, wastes and materials used as secondary raw material or as a source of energy should be

exempted. Generating value ("valorisation") from wastes and materials used as secondary raw material or as a source of energy in recovery operations contributes to the European Union's objective of sustainable development, and this Regulation must not introduce requirements which reduce the incentives for such recycling and recovery.

Or. en

Justification

Reinstates amendment 424 as adopted in first reading.

Amendment by Urszula Krupa

Amendment 60
RECITAL 11 A (new)

(11a) The objective of the new system to be established by this Regulation is to deal with the most dangerous substances as a matter of priority. Hazard evaluation and risk assessment must also take into account the effects of substances on vulnerable populations.

Or. en

Justification

In order to protect future generations, the standard of protection of human health must include those most vulnerable to the health effects of man-made chemicals. This re-tables EP amendment 9.

Amendment by Carl Schlyter, Caroline Lucas, Hiltrud Breyer, Jonas Sjöstedt

Amendment 61
RECITAL 11 A (new)

(11a) The objective of the new system to be

established by this Regulation is to deal with the most dangerous substances as a matter of priority. Hazard evaluation and risk assessment must also take into account the effects of substances on foetal development and the health of women and children.

Or. en

(Amendment 9 - first reading)

Justification

In order to protect future generations, the standard of protection of human health must include those must vulnerable to the health effects of man-made chemicals.

Amendment by Guido Sacconi

Amendment 62
RECITAL 12

(12) An important objective of the new system to be established by this Regulation is to ***encourage and in certain cases to*** ensure that substances ***of high concern*** are ***eventually replaced*** by less dangerous substances or technologies where suitable economically and technically viable alternatives are available. This Regulation does not affect the application of Directives on worker protection and the environment, especially Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) and Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) under which	(12) An important objective of the new system to be established by this Regulation is to ensure that ***dangerous*** substances are ***substituted*** by less dangerous substances or technologies where suitable economically and technically viable alternatives are available. This Regulation does not affect the application of Directives on worker protection and the environment, especially Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) and Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) under which employers are required to eliminate dangerous substances, wherever technically

employers are required to eliminate dangerous substances, wherever technically possible, or to substitute dangerous substances with less dangerous substances.	possible, or to substitute dangerous substances with less dangerous substances.

Or. en

(Amendment 8 - first reading)

Justification

The principle of substitution ought to be an important element in REACH.

Amendment by Frédérique Ries, Chris Davies

Amendment 63
RECITAL 12 A (new)

	(12a) The objective of the new system to be established by this Regulation is to deal with the most dangerous substances as a matter of priority. Hazard evaluation and risk assessment must also take into account the effects of substances on vulnerable populations.

Or. en

Justification

In order to protect future generations, the standard of protection of people's health must be set to include those most vulnerable. This re-tables EP amendment 9.

Amendment by Guido Sacconi

Amendment 64
RECITAL 18

(18) The authorisation provisions ***should ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled. Authorisations*** for the	(18) The authorisation provisions ***provide for authorisations, of limited duration,*** for the placing on the market and use ***of substances of very high concern to*** be granted by the Commission ***where no***

placing on the market and use ***should*** be granted by the Commission ***only if*** the risks arising from their use are adequately controlled***, where this is possible, or the use can be justified for socio-economic reasons and no suitable alternatives are available, which are economically and technically viable***.	***suitable alternative substances or technologies exist, where the use of such substances can be justified on socio-economic grounds and where*** the risks arising from their use are adequately controlled.

Or. en

(Amendment 15 - first reading)

Justification

It is important for the principle of substitution to be linked to the granting of authorisation.

Amendment by Chris Davies, Lena Ek

Amendment 65
RECITAL 18

(18) The authorisation provisions should ensure the good functioning of the internal market ***while assuring that the risks from substances of very high concern are properly controlled***. Authorisations for the placing on the market and use should be granted by the Commission only if the risks arising from their use are adequately controlled, where this is possible, ***or*** the use can be justified for socio-economic reasons and no suitable alternatives are available, which are economically and technically viable.	(18) The authorisation provisions should ensure the good functioning of the internal market. Authorisations for the placing on the market and use should be granted by the Commission only if the risks arising from their use are adequately controlled, where this is possible, ***and*** the use can be justified for socio-economic reasons and no suitable alternatives are available, which are economically and technically viable.

Or. en

Justification

This amendment clarifies that the eventual replacement of dangerous chemicals is the aim of authorisation. Linked to the amendment to Article 52. EP amendment 15 is re-tabled.

Amendment by Carl Schlyter, Caroline Lucas, Hiltrud Breyer, Jonas Sjöstedt

Amendment 66
RECITAL 31

(31) The Member States, the Agency and all interested parties should take full account of the results of the RIPs, in particular with regard to the registration of substances which occur in nature.	(31) The Member States, the Agency and all interested parties should take full account of the results of the RIPs, in particular with regard to the registration of substances which occur in nature, ***given that the complex and variable composition of substances which occur in nature might require an adaptation of the information requirements***.

Or. en

(New amendment - Rule 62(2)(c)

Justification

It should be specified that the particular nature of natural substances might require an adaptation of the information requirements.

Amendment by Anders Wijkman, Frieda Brepoels, Erna Hennicot-Schoepges, Péter Olajos, Avril Doyle + Amalia Sartori + Ria Oomen-Ruijten + Alessandro Foglietta, Adriana Poli Bortone + Chris Davies + Lena Ek

Amendment 67
RECITAL 35 A (new)

	(35a) In the light of the particular circumstances of SMEs, Member States should adopt measures to provide special assistance to such enterprises for conducting the tests needed to collect the information required under this Regulation.

Or. en

Justification

It is important to take the needs of SMEs into account by providing special support to them. (Wijkman & others + Oomen-Ruijten)

Corresponds with Amendment 21 adopted in first reading.(Oomen-Ruijten)

It is important to provide the appropriate assistance measures, particularly to SMEs, to facilitate the implementation of this regulation. Amendment 363 at first reading. (Foglietta & Poli Bortone)

Successful First Reading amendment. (Davies)

SMEs require special assistance. Identical to first reading amendment 363. (Ek)

Amendment by Lena Ek + Chris Davies + Ria Oomen-Ruijten + Alessandro Foglietta, Adriana Poli Bortone

Amendment 68
RECITAL 35 B (new)

(35b) In order to help companies, and in particular SMEs, to comply with the requirements of this Regulation, Member States, in cooperation with the Commission, should put in place a comprehensive support network.

Or. en

Justification

SMEs require special assistance. Identical to first reading amendment 22.(Ek)

Successful First Reading amendment. (Davies)

Corresponds to amendment 22 adopted in first reading. Self explanatory. (Oomen-Ruijten)

Reinstates Amendment 22 at first reading in order to help SMEs to cope with the challenge of implementing the regulation. (Foglietta & Poli Bortone)

Amendment by Amalia Sartori + Frieda Brepoels, Anders Wijkman + Caroline Lucas, Carl Schlyter, Hiltrud Breyer, Jonas Sjöstedt + Alessandro Foglietta, Adriana Poli Bortone

Amendment 69
RECITAL 43 A (new)

(43a) In order to promote non-animal testing, the Commission, Member States and industry should allocate more resources to the development, validation and acceptance of non-animal tests. Part of the fees paid to the Agency should be allocated for that purpose.

Or. en

Justification

In order to achieve the objective of this Regulation to promote non-animal testing, it is necessary to make available more resources for the development, validation and acceptance of non-animal test methods that can be used to meet the information requirements of this Regulation. Amendment first reading 25. (Brepoels & Wijkman)

The use of non-animal tests is preferable from both an ethical and a scientific view. To promote non-animal testing to meet the information requirements of this Regulation, it is necessary to make available more resources for the development, validation and acceptance of non-animal test methods. (Lucas & others)

Efforts to phase out tests on animals can be effective only by means of research into and development of alternative methodologies. Reinstates Amendment 25 at first reading. (Foglietta & Poli Bortone)

Amendment by Amalia Sartori

Amendment 71
RECITAL 46 A (new)

(46a) If the owner of a study involving tests on vertebrate animals or another study that may prevent animal testing fails to make the study available to the Agency and/or other potential registrants, he should not be able to register his substance.

Or. en

Justification

Amendment 28 in first reading.

Amendment by Amalia Sartori

Amendment 72
RECITAL 50 A (new)

(50a) If a potential registrant and/or participant in a SIEF fails to pay his share of the cost of a study involving tests on vertebrate animals or another study that may prevent animal testing, he should not be able to register his substance.

Or. en

Justification

Amendment 27 in first reading.

Amendment by Chris Davies + Amalia Sartori

Amendment 73
RECITAL 51 A (new)

(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.

Or. en

Justification

Successful First Reading amendment 34. Communication of non-registration is important to inform downstream users about the withdrawal of certain substances from the market. (Davies)

Amendment by Ria Oomen-Ruijten, Vittorio Prodi + Chris Davies + Marie-Noëlle Lienemann, Anne Ferreira

Amendment 74
RECITAL 51 A (new)

(51a) Risk Communication is a vital part of the process of informing and advising people about how they can manage potential risks and so use a substance or preparation safely and effectively. Risk communication requires an understanding by the manufacturer of the information needs of users, and the subsequent provision of that information, advice and help to support the safe use of the substance or preparation by the end user. The development of an appropriate risk-based communication system, including the provision of complementary information using, for example, websites and educational campaigns, should be pursued to satisfy the right of consumers to know about the substances and preparations they use. This will further enhance the safe use of, and confidence in, substances and preparations. Such a system will be valuable to consumer organisations in setting a framework that will address the true concerns of consumers through REACH and to industry in building consumer confidence in the use of substances and preparations containing chemicals.

Or. en

Justification

Corresponds to Amendment 30 First Reading.

An appropriate and consistent communication system based on risk will provide consumers with the necessary information and advice to enable them to manage their risk safely and effectively when using a substance or preparation. (Oomen-Ruijten & Prodi)

Successful First Reading amendment. (Davies)

Linked to the amendment to Recital 21. An appropriate and consistent communication system

based on risk will provide consumers with the necessary information and advice to enable them to manage safely and effectively the risks involved in using a substance or preparation.

Tabling of Amendment 30 at first reading. (Lienemann & Ferreira)

Amendment by Gyula Hegyi, Dorette Corbey, Anne Ferreira, Dan Jørgensen, Åsa Westlund + Lena Ek + Urszula Krupa

Amendment 75
RECITAL 54

(54) The requirements for undertaking chemical safety assessments by downstream users should also be prescribed in detail to allow them to meet their obligations. ***These requirements should only apply above a total quantity of 1 tonne of substance or preparation.*** In any case, however, the downstream users should consider the use and identify and apply appropriate risk management measures. Downstream users ***should*** report ***certain basic information on use to the Agency***.	(54) The requirements for undertaking chemical safety assessments by downstream users should also be prescribed in detail to allow them to meet their obligations. In any case, however, the downstream users should consider the use and identify and apply appropriate risk management measures. Downstream users ***must*** report ***the risks as highlighted in the chemical safety assessment by the most effective and relevant means possible for the user of the substance or preparation at a given point in the supply chain/life cycle and provide advice on safe use for consumers.***

Or. en

Justification

This amendment ensures a fast and efficient flow of information in the supply chain and safe handling of articles for consumers and users, including those using substances in the workplace. The relevant part of EP amendment 33 is re-tabled.

Amendment by Carl Schlyter, Caroline Lucas, Hiltrud Breyer, Jonas Sjöstedt

Amendment 76
RECITAL 54

(54) The requirements for undertaking chemical safety assessments by downstream users should also be prescribed in detail to allow them to meet their obligations. ***These requirements should only apply above a total quantity of 1 tonne of substance or***	(54) The requirements for undertaking chemical safety assessments by downstream users should also be prescribed in detail to allow them to meet their obligations. In any case the downstream users should consider the use and identify and apply appropriate

preparation. In any case***, however,*** the downstream users should consider the use and identify and apply appropriate risk management measures. Downstream users should report certain basic information on use to the Agency.	risk management measures. ***Downstream users should report the risks as highlighted in the chemical safety assessment by the most effective and relevant means possible for the user of the substance or preparation at a given point in the supply chain/life cycle and provide advice on safe use for consumers.*** Downstream users should report certain basic information on use to the Agency.

Or. en

(New amendment - Rule 62(2)(c), and amendment 33 - first reading)

(Linked to paragraph 36(4)(c))

Justification

A threshold for the chemical safety report (CSR) of downstream users would create a perverse incentive for manufacturers to exclude uses below 1 tonne from their CSR, as it would not result in any obligations for downstream users. This creates a serious loophole with regard to safety information for small uses.

This amendment furthermore reflects the duty of downstream users to inform the supply chain as well as consumers.

Amendment by Caroline Lucas, Carl Schlyter, Hiltrud Breyer, Jonas Sjöstedt + Frieda Brepoels, Anders Wijkman + Dan Jørgensen

Amendment 77
RECITAL 58 A (new)

	(58a) To prevent animal testing and save costs, the European Centre for the Validation of Alternative Methods (ECVAM) should be consulted on testing proposals that include vertebrate animal tests.

Or. en

(Amendment 37 - first reading)

Justification

ECVAM is the EU's leading institution on alternative test methods. As new alternative test methods are constantly being developed, ECVAM should be consulted on testing proposals on vertebrate animals to ensure that the latest knowledge is made use of. (Lucas & others)

In view of ongoing developments in the field of alternative test methods, the Agency should consult experts with up-to-date knowledge, experience and information on alternative tests. Amendment first reading 37. (Brepoels & Wijkman + Jørgensen)

Amendment by Guido Sacconi

Amendment 78
RECITAL 63

(63) To ensure a sufficiently high level of protection for human health, ***including having regard to relevant human population groups and possibly to certain*** vulnerable ***sub-***populations, and the environment, substances of very high concern should***, in accordance with the*** precautionary ***principle, be subject to careful attention. Authorisation should be granted where natural or legal persons applying for an authorisation demonstrate to the granting authority that the risks to human health and the environment arising from the use of the substance are adequately controlled. Otherwise, uses may still be authorised if it can be shown that the socio-economic benefits from the use of the substance outweigh the risks connected with its use and there are no suitable alternative substances or technologies that are economically and technically viable. Taking into account the good functioning of*** the internal market it is appropriate that the Commission should be the granting authority.	(63) To ensure a sufficiently high level of protection for human health***, in particular that of*** vulnerable populations, and the environment, substances ***with properties*** of very high concern should ***be treated*** in a precautionary ***manner and should only be authorised if enterprises using them demonstrate to the granting authority that there are no suitable alternative substances or technologies, that the benefits to society deriving from the use of the substance outweigh the risks connected with its use and that the risks are adequately controlled. The granting authority should then verify that these requirements are met through an authorisation procedure on the basis of applications by enterprises. Since authorisations should ensure a high level of protection throughout*** the internal market, it is appropriate that the Commission should be the granting authority.

Or. en

(Amendment 41 - first reading)

Justification

Very high-risk substances shall be replaced, whenever possible, with other, safer, ones and, when used, the socio-economic benefits shall be taken into account and the risk 'adequately controlled'.

Specific attention needs to be paid to vulnerable populations in authorisation.

Amendment by Chris Davies + Lena Ek

Amendment 79
RECITAL 63

(63) To ensure a sufficiently high level of protection for human health, including having regard to relevant human population groups and possibly to certain vulnerable sub-populations, and the environment, substances of very high concern should, in accordance with the precautionary principle, be subject to careful attention. Authorisation should be granted where natural or legal persons applying for an authorisation demonstrate to the granting authority that ***the risks to human health and the environment arising from the use of the substance are adequately controlled. Otherwise, uses may still be authorized if it can be shown that the socio-economic benefits from the use of the substance outweigh the risks connected with its use and there are no suitable alternative substances or technologies that are economically and technically viable.*** Taking into account the good functioning of the internal market it is appropriate that the Commission should be the granting authority.	(63) To ensure a sufficiently high level of protection for human health, including having regard to relevant human population groups and possibly to certain vulnerable sub-populations, and the environment, substances of very high concern should, in accordance with the precautionary principle, be subject to careful attention. Authorisation should be granted where natural or legal persons applying for an authorisation demonstrate to the granting authority that ***there are no suitable alternative substances or technologies, that the benefits to society deriving from the use of the substance outweigh the risks connected with its use and that the risks are adequately controlled***. Taking into account the good functioning of the internal market it is appropriate that the Commission should be the granting authority.

Or. en

Justification

Proactive companies investing in safer solutions are currently disadvantaged on the market.

The availability of suitable safer alternatives should always be looked at first, thus improving the competitiveness, innovation and replacement of dangerous chemicals. The relevant part of EP amendment 41 is re-tabled.

Amendment by Frédérique Ries, Chris Davies

Amendment 80
RECITAL 63

(63) To ensure a sufficiently high level of protection for human health, ***including having regard to relevant human population groups and possibly to certain vulnerable sub-populations***, and the environment, substances of very high concern should, ***in accordance with the precautionary principle, be subject to careful attention***. ***Authorisation should be granted where natural or legal persons applying for an authorization*** demonstrate to the granting authority that ***the risks to human health and the environment arising from the use of the substance are adequately controlled. Otherwise, uses may still be authorized if it can be shown that the socio-economic benefits from the use of the substance outweigh the risks connected with its use and there are no suitable alternative substances or technologies that are economically and technically viable.*** Taking into account the good functioning of the internal market it is appropriate that the Commission should be the granting authority.	(63) To ensure a sufficiently high level of protection for human health***, in particular that of vulnerable populations,*** and the environment, substances ***with properties*** of very high concern should ***be treated in a precautionary manner and should only be authorised if enterprises using them*** demonstrate to the granting authority that ***there are no suitable alternative substances or technologies, that the benefits to society deriving from the use of the substance outweigh the risks connected with its use and that the risks are adequately controlled.*** Taking into account the good functioning of the internal market it is appropriate that the Commission should be the granting authority. The granting authority should then verify that these requirements are met through an authorisation procedure on the basis of applications by enterprises. Since authorisations should ensure a high level of protection throughout the internal market, it is appropriate that the Commission should be the granting authority**.**

Or. en

Justification

To ensure a sufficiently high level of protection for human health requires setting the protection at the level that suffices for vulnerable populations. The Council's version is distinctly weaker that this amendment, which re-tables the original EP amendment 41.

Amendment by Guido Sacconi + Anders Wijkman, Frieda Brepoels, Erna Hennicot-

Schoepges, Péter Olajos, Avril Doyle + Chris Davies

Amendment 81
RECITAL 64

(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.	***deleted***

Or. en

Justification

Deletes a new provision in the common position, since one single procedure should be used for the authorisation of substances of high concern. (Sacconi)

For substances, substitution should always be the first option, taking social economic aspects and adequate control into account. The Council focuses to a too large degree upon adequate control. It is not advisable to start to try to develop "safe" threshold levels for continued use of substances that can lead to cancer and change the DNA. (Wijkman & others)

The European Parliament should be involved in any decision to agree 'acceptable death limits' from chemicals that cause cancer and/or damage DNA. Such a change to the definition of 'adequate control' would allow almost all substances of high concern to claim 'adequate control', thereby fundamentally undermining REACH and the European Parliament's view. (Davies)

Amendment by Ria Oomen-Ruijten, Vittorio Prodi + Marie-Noëlle Lienemann, Anne Ferreira

Amendment 82
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.	(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.

Or. en

Justification

Corresponds to Amendment 45 First Reading. (Oomen-Ruijten & Prodi)

Linked to the amendment to Recital 84. Tabling of Amendment 45 at first reading. (Lienemann & Ferreira)

Amendment by Frieda Brepoels, Anders Wijkman + Chris Davies

Amendment 83
RECITAL 88 A (new)

(88a) In line with the objective to promote non-animal testing, part of the fee should be allocated to the development of non-animal test methods.

Or. en

Justification

In order to achieve the objective of this Regulation to promote non-animal testing, it is necessary to make available more resources through the Agency for the development of non-animal test methods that can be used to meet the information requirements of this Regulation, also in view of the current lack of resources, the fact that companies have much to gain from alternative methods in terms of costs and accuracy, and that much research still needs to be done that companies are unable or unwilling to fund. Amendment first reading 47. (Brepoels & Wijkman)

Reducing non-animal tests. Successful first reading amendment. Development of non-animal testing methods has been often delayed by the refusal of companies to contribute towards the costs, even though the alternatives may prove cheaper and more accurate. (Davies)

Amendment by Caroline Lucas, Carl Schlyter, Hiltrud Breyer + Dan Jørgensen

Amendment 84
RECITAL 92

(92) It is necessary to ensure close cooperation between the Agency and the competent authorities working within the Member States so that the scientific opinions of the Committee for Risk Assessment ***and*** the Committee for Socio-economic Analysis are based on the broadest possible scientific and technical expertise appropriate which is available within the Community. To the same end, these Committees should be able to rely on additional particular expertise.	(92) It is necessary to ensure close cooperation between the Agency and the competent authorities working within the Member States so that the scientific opinions of the Committee for Risk Assessment***,*** the Committee for Socio-economic Analysis ***and the Committee for Alternative Test Methods*** are based on the broadest possible scientific and technical expertise appropriate which is available within the Community. To the same end, these Committees should be able to rely on additional particular expertise.

Or. en

(New amendment to achieve coherence with amendment 27 of the rapporteur (Lucas & others))

Justification

Linked to amendment 27 of the rapporteur to ensure coherence. If such a new committee is established at the Agency, it should also be mentioned here, as the provisions in this recital are equally relevant to the work of the Committee for Alternative Test Methods. (Lucas & others)

Amendment by Dagmar Roth-Behrendt

Amendment 85
RECITAL 92 A (new)

	(92a) In order to promote non-animal testing, the Agency should have the task of developing and implementing a policy to ensure the appropriate use of non-animal methods to generate data for risk assessment to meet the requirements of this Regulation. To this end, the Agency should cooperate closely with existing structures such as the European Centre for the Validation of Alternative Methods (ECVAM) and its Scientific Advisory Committee (ESAC), and the European Partnership for Alternative Approaches to animal testing (EPAA), in order to access the broadest possible relevant scientific and

technical expertise which is available within the Community.

Or. en

Justification

Based on amendment 361 as adopted in first reading. The wording of the amendment is revised to facilitate the acceptance in Council. In addition, recent developments as the installation of the European Partnership for Alternative Approaches to Animal Testing (EPAA) are taken into account in order to avoid double structures. Linked with amendment on Article 76 by the same author.

Amendment by Philippe Busquin

Amendment 86
RECITAL 104

(104) Regular reports by the Member States and the Agency on the operation of this Regulation will be an indispensable means of monitoring the implementation of chemicals legislation as well as trends in this field. Conclusions drawn from findings in the reports will be useful and practical tools for reviewing the Regulation and, where necessary, for formulating proposals for amendments.	(104) Regular reports by the Member States and the Agency on the operation of this Regulation will be an indispensable means of monitoring the implementation of chemicals legislation as well as trends in this field. Conclusions drawn from findings in the reports will be useful and practical tools for reviewing the Regulation and, where necessary, for formulating proposals for amendments. ***To this end, the Commission should undertake an ex post impact assessment of the Regulation after the first five years of its implementation, to assess whether the targets initially set have been met and whether the functioning of, and competition within, the internal market has been preserved.***

Or. en

Justification

Considering the importance of the regulatory system REACH sets up, it is necessary to evaluate the results achieved in the first years of implementation in order to check whether the initial targets can be met, and if not, to make the necessary adjustments. Amendment 51 first reading.

Amendment by Carl Schlyter, Caroline Lucas, Hiltrud Breyer

Amendment 87
RECITAL 104 A (new)

(104a) In its opinion of 10 March 2006 on the appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies, the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) pointed to major gaps in the knowledge necessary for risk assessment, including nanoparticle characterisation, the detection and measurement of nanoparticles, the dose-response, fate and persistence of nanoparticles in humans and in the environment, and all aspects of toxicology and environmental toxicology related to nanoparticles. It concluded that current risk assessment methodologies require some modifications in order to deal with the hazards associated with nanotechnology, and in particular that existing toxicological and ecotoxicological methods may not be sufficient to address all of the issues arising with nanoparticles. The provisions of this Regulation should ensure an adequate safety evaluation of nanoparticles as a precondition for their manufacture and placing on the market.

Or. en

(New amendment - Rule 62(2)(d) to take account of the opinion of SCENIHR of 10 March 2006)

Justification

The major gaps in the knowledge for risk assessment of nanoparticles, as stated by SCENIHR, as well as their conclusions stating a need for modifications of existing methods, need to be stated explicitly. This has consequences for the safety assessment of nanoparticles, and should lead to specific provisions as well as a specific review of nanoparticles in the context of this regulation.

Amendment by Cristina Gutiérrez-Cortines

Amendment 88
RECITAL 112 A (new)

(112a) Naturally occurring substances that are reproduced through a manufacturing process should be deemed to be identical to their naturally occurring equivalent provided the degree of purity, the nature of impurities and their toxicity profile are similar.

Or. en

Justification

For reasons of workability this recital clarifies that natural substances and equivalent synthetic substances should be treated as equal as they are chemically and physically the same. It makes no difference – particularly not for protecting health or the environment, whether for example limestone (i.e. calcium carbonate) comes from natural sources or has been manufactured through a chemical process. The manufacturing process itself is covered under other legislation.

Amendment by Anja Weisgerber

Amendment 89
RECITAL 113 A (new)

(113a) The Commission should submit by ...* a proposal providing for a common list of ingredients authorised for tobacco products, in accordance with Article 12 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].

**** Six months after entry into force of this Regulation.***

[1] OJ L 194, 18.7.2001, p. 26.

Or. en

Justification

Additives in tobacco products have already for some years been subject to a registration and authorisation procedure laid down in the tobacco framework directive, 2001/37/EC. The Commission was required to submit by the end of 2004 a proposal for a common list of permitted constituents of tobacco products on the basis of information provided by Member States. The Commission still has not submitted this list. The Commission is now called upon at long last to urge the Member States to fully implement the tobacco products directive and also comply with the obligations imposed on them by Parliament and the Council in that directive.

Amendment by Alessandro Foglietta, Adriana Poli Bortone

Amendment 90
RECITAL 114 A (new)

(114a) To help consumers to use substances and preparations in a safe and sustainable manner, manufacturers must make available, by means of a label on the packing of each unit placed on the market for sale to consumers, information based on risk and identifying the risks associated with their recommended use or with the foreseeable situations in which they might be improperly used. The labelling of the packaging will also be complemented, if appropriate, by the use of other means of communication, such as websites, to provide more detailed information on safety and the use of the substance or preparation.

Directives 1999/45/EC and 67/548/EEC will be amended accordingly.

Or. it

Justification

The development of an appropriate and consistent communication system based on risk will provide consumers with the necessary information and advice to enable them to use chemicals and preparations containing them safely and effectively.

Amendment by Caroline Lucas, Carl Schlyter, Hiltrud Breyer + Dan Jørgensen + Ria Oomen-Ruijten

Amendment 91
ARTICLE 1, PARAGRAPH 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.	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.

Or. en

(New amendment to achieve coherence with the modification of the corresponding recital (Lucas & others))

Justification

Linked to the amendment of Recital 1 by the same authors. (Lucas & others)

Linked to Amendment of Recital 1. These two objectives of this Regulation from the Commission Explanatory Memorandum have been deleted by the Council and should be re-instated in view of the importance of both increased transparency and the promotion of non-animal testing in this Regulation for all stakeholders and European citizens. (Jørgensen + Oomen-Ruijten)

Amendment by Chris Davies

Amendment 92
ARTICLE 1, PARAGRAPH 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.	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***, transparent decision-taking and the promotion of non-animal testing*** while enhancing competitiveness and innovation.

Or. en

Justification

These two objectives of the Regulation were deleted by the Council and should be re-instated.

Amendment by Amalia Sartori + Ria Oomen-Ruijten, Vittorio Prodi + Chris Davies + Marie-Noëlle Lienemann, Anne Ferreira

Amendment 93
ARTICLE 1, PARAGRAPH 3

3. This Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle.	3. This Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment, ***under normal or reasonably foreseeable conditions of use.*** Its provisions are underpinned by the precautionary principle.

Or. en

Justification

Corresponds to Amendment 60 First Reading.

It is consistent with the definition of "safe product" as defined in the General Product Safety Directive (2001/95/EC) and is necessary to define the frame and the limits to which the subject of this Regulation applies. (Oomen-Ruijten & Prodi)

Successful First Reading amendment. (Davies)

This is consistent with the definition of 'safe product' given in the Directive on product safety (2001/95/EC) and is necessary in order to define the framework and limits of the application of the subject of this regulation.

Tabling of Amendment 60 adopted at first reading (Lienemann & Ferreira)

Amendment by Johannes Blokland, Jens-Peter Bonde

Amendment 94
ARTICLE 1, PARAGRAPH 3 A (new)

	3a. This Regulation shall not prevent individual Member States from

maintaining or introducing stricter protection measures.

Or. en

Justification

The present differences between member states regarding an control of chemicals pollution levels makes it necessary to give the member states the opportunity to keep and introduce more restrictive measures to ensure high level of protection of human health and the environment. This is done to fulfil article 95, paragraph 3, 152, paragraph 1, and article 153, paragraph 2 in the Treaty.

If the regulation is implemented without this guarantee some member states will get a lower level of protection than they have today.

Amendment by Chris Davies + Amalia Sartori

Amendment 95
ARTICLE 1, PARAGRAPH 3 A (new)

3a. The implementation and operation of the provisions of this Regulation may under no circumstances involve an increase in the bureaucratic and administrative burden on small and medium-sized enterprises.

Or. en

Justification

Successful First Reading amendment 63 seeking to avoid unnecessary red-tape for enterprises, particularly SMEs. (Davies)

Amendment by Anders Wijkman, Frieda Brepoels, Erna Hennicot-Schoepges, Péter Olajos, Avril Doyle

Amendment 96
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 or her to prevent, limit or remedy such effects, preferably through a substitution plan. Producers and downstream users shall select a substance for production and use on the basis of the safest substances available. When alternatives are not available they shall continue to work towards substituting substances with adverse effects upon human health or the environment.

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.

Or. en

Justification

A general duty of care principle is needed. Amendment 364 from first reading. Slightly reworded to be more in coherence with the amendments referring to substitution.

Amendment by Lena Ek

Amendment 97
ARTICLE 1, PARAGRAPHS 3 A AND 3 B (new)

3a. Any manufacturer, importer or downstream user:

(a) 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:

(i) make every effort that may reasonably be required of him to prevent, limit or remedy such effects, and

(ii) describe, document and notify in an appropriate and transparent fashion the risks stemming from the production, use and disposal of each substance;

(b) 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:

(i) 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, and

(ii) describe, document and notify in an appropriate and transparent fashion the risks stemming from the production, use and disposal of each substance.

3b. Producers and downstream users shall select a substance for production and use on the basis of the safest substances available.

Or. en

Justification

Important parts of amendment 364 from first reading are re-tabled. The Duty of care is a critical part of the European Parliament's first reading and should therefore be re-tabled. However, the amendment has been re-drafted so that it is clearer and easier to understand.

Amendment by Lena Ek + Alessandro Foglietta, Adriana Poli Bortone + Amalia Sartori

Amendment 98
ARTICLE 1, PARAGRAPH 3 C (new)

3c. In implementing this Regulation, the European Union shall establish mechanisms for providing aid and support to small and medium-sized enterprises.

Or. en

Justification

SMEs are financially and technically weaker than big companies and require special support. Identical to first reading amendment 64. (Ek)

It is important that the operative part of the REACH Regulation should likewise 48take account of the particular character of SMEs, which require additional assistance in order to comply with the REACH Regulation. Amendment 64 at first reading. (Foglietta & Poli Bortone)

Amendment 64 in first reading. (Sartori)

Amendment by Marie-Noëlle Lienemann

Amendment 99
ARTICLE 2, PARAGRAPH 1, POINT C A (new)

(ca) substances in batteries other than those exempted pursuant to Article 4(2) and 3 of [Directive 2006/xx/EC];

Or. en

Justification

The aim is to maintain consistency with the directive on batteries and accumulators, which has recognised that in principle the substances cadmium and mercury are harmful.

Amendment by Georgs Andrejevs, Mojca Drčar Murko, Holger Krahmer, Anne Laperrouze, Marios Matsakis, Vittorio Prodi + Ria Oomen-Ruijten

Amendment 100
ARTICLE 2, PARAGRAPH 1, POINT C A (new)

(ca) substances in batteries within the scope of Directive 91/157/EEC (as amended by Directives 91/86/EC and 98/101/EC);

Or. en

Justification

A directive on batteries has just been adopted and will come into force soon. Therefore, there is no need for REACH to cover it. We need to avoid double legislation. (Andrejevs & others + Krahmer & Laperrouze)

Corresponds to Amendment 464 adopted in First Reading.

Following the agreement on the revision of the batteries directive reached in the conciliation committee, the main purpose of the batteries directive is now to ban the marketing of batteries containing dangerous substances (Article 1(1) of the batteries directive). So far the focus has been only on the heavy metals mercury, cadmium and lead. With this new objective of the batteries directive, it will in future be possible for all aspects of risks associated with substances, risks in handling and possibilities of substitution to be regulated by means of further revisions of the batteries directive when necessary, in the case of all battery constituents.
The exception applies only to the use of substances in batteries, not their production. The production of current and future battery constituents will in any case be subject to the forthcoming REACH Regulation. That means that manufacturers (and importers) of battery constituents (which may be the battery industry itself) will in any case be required to register these substances under REACH and assess them with reference to their intrinsic properties, so that no lacunae arise here. The actual risks associated with use will then be assessed under the batteries directive. Insofar as the substances are put to use other than in batteries, the REACH Regulation will apply in full. (Oomen-Ruijten)

Amendment by Ria Oomen-Ruijten + Françoise Grossetête

Amendment 101
ARTICLE 2, PARAGRAPH 1, POINT D A (new)

(da) aircraft, provided such exemption is necessary to ensure compliance with the essential requirements for airworthiness and safety of passengers in civil aviation laid down by Regulation (EC) No 1592/2002 of the European Parliament and of the Council of 15 July 2002 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency[1].

[1] OJ L 240, 7.9.2002, p. 1. Regulation as amended by Commission Regulation (EC) No 1701/2003 (OJ L 243, 27.9.2003, p. 5).

Or. en

Justification

The proposed exemptions for aircraft would only be granted if it could be demonstrated that this is necessary ensuring compliance with community safety requirements in civil aviation.

Amendment by Ria Oomen-Ruijten

Amendment 102
ARTICLE 2, PARAGRAPH 2

2. ***Waste*** as defined ***in*** Directive 2006/12/EC of the European Parliament and of the Council ***is not a substance, preparation or article within the meaning of Article 3 of this Regulation.***	***2. This Regulation shall not apply to waste*** as defined ***by*** Directive 2006/12/EC of the European Parliament and of the Council.

Or. en

Justification

Partly reinstates Amendment 55 adopted in First Reading subsequently. Much waste is important raw material for several industries. The inclusion of waste in REACH could represent a serious threat to the recycling sector.

Amendment by Urszula Krupa + Carl Schlyter, Caroline Lucas, Hiltrud Breyer, Jonas Sjöstedt

Amendment 103
ARTICLE 2, PARAGRAPH 3

3. Member States may allow for exemptions from the Regulation in specific cases for certain substances, on their own, in a preparation or in an article, where necessary in the interests of defence.	***deleted***

Or. en

Justification

This paragraph contradicts the idea of having a level playing field. When Member States can decide on their own exemptions it would lead to a distortion of the internal market. Furthermore, it is equally important to protect workers and the environment from produced substances in the defence sector as with any other substance. (Krupa)

There is no justification for such a vague and broad exemption. Workers, consumers and the environment should also be protected against hazardous substances used in the defence sector. (Schlyter & others)

Amendment by Philippe Busquin, Vittorio Prodi + Chris Davies

Amendment 104
ARTICLE 2, PARAGRAPH 4

4. This Regulation shall apply without prejudice to Community workplace and environmental legislation, including Council Directive 89/391/EEC 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 of 24 September 1996 concerning integrated pollution prevention and control; Directive 98/24/EC, Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy and Directive	4. This Regulation shall apply without prejudice to Community workplace and environmental legislation, including Council Directive 89/391/EEC 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 of 24 September 1996 concerning integrated pollution prevention and control; Directive 98/24/EC, Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy and Directive

2004/37/EC.	2004/37/EC, ***and without prejudice to Regulation (EC) No 1592/2002 where this is necessary to establish and maintain a high uniform level of civil aviation safety in Europe.***

Or. en

Justification

The words "without prejudice to" must be understood as meaning "shall not affect" Community legislation. In other words, the implementation of REACH shall not prevent the achievement of objectives laid down by the Community legislation that is referred to in provision. In that respect, it must be noted that the main objective pursued by the EC Regulation 1592/2002 is to establish and maintain a high uniform level of civil aviation ***safety*** *in Europe. In implementing REACH, the Commission and Member States' national competent authorities shall take account of the obligation incumbent to aircraft manufacturers to comply with safety standards established by the EASA, in particular with regard to suitable alternatives and maintenance constraints. (Busquin & Prodi)*

The words "without prejudice to" must be understood as meaning "shall not affect" Community legislation. In implementing REACH account must be taken of the obligation incumbent to aircraft manufacturers to comply with safety standards established by the European Aviation Safety Agency, in particular with regard to suitable alternatives and maintenance constraints. This amendment should be read in parallel with the proposed amendment to Article 59§8. (Davies)

Amendment by Anders Wijkman

Amendment 105
ARTICLE 2, PARAGRAPH 4

4. This Regulation shall apply without prejudice to Community workplace and environmental legislation, including Council Directive 89/391/EEC ***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 of 24 September 1996 concerning integrated pollution prevention and control;*** Directive 98/24/EC, Directive 2000/60/EC ***of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy and***	4. This Regulation shall apply without prejudice to Community workplace and environmental legislation, ***and to more stringent national provisions implementing such legislation,*** including***:*** ***(a)*** Council Directive 89/391/EEC***,*** ***(b) Council Directive 90/394/EEC,*** ***(c) Council*** Directive 98/24/EC, ***(d) Council Directive 96/61/EC,*** ***(e) Council*** Directive 2000/60/EC***,*** ***(f)*** Directive 2004/37/EC.

Directive 2004/37/EC.

Or. en

Justification

Sweden among others has more stringent requirements for workers' safety and to clarify the possibility to keep these more stringent requirements the proposed wording is suggested.

Amendment by Dan Jørgensen, Åsa Westlund

Amendment 106
ARTICLE 2, PARAGRAPH 4

4. This Regulation shall apply without prejudice to Community workplace and environmental legislation, including Council Directive 89/391/EEC ***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 ***of 24 September 1996 concerning integrated pollution prevention and control; Directive 98/24/EC,*** Directive 2000/60/EC ***of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy and Directive 2004/37/EC***.	4. This Regulation shall apply without prejudice to Community workplace and environmental legislation, ***and to more stringent national provisions implementing such legislation*****,** including: ***(a)*** Council Directive 89/391/EEC ***(b) Council Directive 90/394/EEC*** ***(c) Council Directive 98/24/EC*** ***(d)*** Council Directive 96/61/EC ***(e) Council*** Directive 2000/60/EC.

Or. en

Justification

These EC-directives on workplace legislation is based on Article 137 in the Rome Treaty. Article 137 says that implemented minimum directives shall not stop any member state to keep or create stronger workplace or environmental legislation.

Amendment by Chris Davies + Caroline Lucas, Carl Schlyter, Hiltrud Breyer, Jonas Sjöstedt + Dagmar Roth-Behrendt

Amendment 107
ARTICLE 2, PARAGRAPH 4 A (new)

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 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)

Or. en

Justification

Successful First Reading amendment 65. Ensures that relevant provisions of the Cosmetics Directive, intended to curb animal testing, will still apply under this Regulation. (Davies)

Cosmetic products and ingredients are covered by Council Directive 76/768/EEC. Article 4a of Directive 2003/15/EC of the European Parliament and of the Council, amending Directive 76/768/EEC, prohibits animal testing of cosmetic ingredients in the Community after 11 March 2009 and restricts the marketing in the Community of cosmetic products that have been tested on animals. This amendment ensures that the provisions of Directive 76/768/EEC as amended will apply under this Regulation. (Lucas & others)

Partly reinstates amendment 65 as adopted in first reading. The 7th amendment to the Cosmetic Directive aims at stepwise removing animal testing from the Cosmetic sector. This

should not be undermined by REACH. (Roth-Behrendt)

Amendment by Ria Oomen-Ruijten

Amendment 108
ARTICLE 2, PARAGRAPH 5, POINTS (B) A, (B) B AND (B) C (new)

(ba) in medical devices within the scope of Directives 90/385/EEC, 93/42/EEC or 98/79/EC;

(bb) in plant protection products within the scope of Directive 91/414/EEC;

(bc) in biocidal products within the scope of Directive 98/8/EC;

Or. en

Justification

Corresponds to Amendment 466 adopted in First Reading.

It improves and completes the Council position and reflects the first readings vote.

Amendment by Philippe Busquin

Amendment 109
ARTICLE 2, PARAGRAPH 5, POINT (B) A (new)

(ba) in aircraft for the purposes of complying with the essential requirements for airworthiness and safety of passengers in civil aviation laid down by Regulation (EC) No 1592/2002 of the European Parliament and of the Council of 15 July 2002 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency.

Or. en

Justification

The proposed exemptions for aircraft would only be granted if it could be demonstrated that it is necessary ensuring compliance with Community safety requirements in civil aviation.

Amendment by Mojca Drčar Murko + Holger Krahmer + Dagmar Roth-Behrendt

Amendment 110
ARTICLE 2, PARAGRAPH 5, POINT (B) A (new)

(ba) in medical devices within the scope of Directives 90/385/EEC, 93/42/EEC or 98/79/EC;

Or. en

Justification

Given the existence of the specific directives and its risk assessment or management tools medical devices should be granted exemption from REACH. This view was shared by a majority in the EP First Reading. (Drčar Murko)

Partly reinstates amendment 466 as adopted in first reading. (Roth-Behrendt)

Amendment by Dagmar Roth-Behrendt + Ria Oomen-Ruijten

Amendment 111
ARTICLE 2, PARAGRAPH 5, POINT (B) A (new)

(ba) in batteries within the scope of Directive [2006/…/EC].

Or. en

Justification

Partly reinstates amendment 464 as adopted in first reading. Other than the amendment adopted in first reading, this amendment excludes the recently revised batteries directive not from the entire scope of the Regulation. This should open the way to a compromise with Council. (Roth-Behrendt)

Following the agreement on the revision of the batteries directive reached in the conciliation committee, the main purpose of the batteries directive is now to ban the marketing of batteries containing dangerous substances (Article 1(1) of the batteries directive). So far the focus has been only on the heavy metals mercury, cadmium and lead. With this new objective of the batteries directive, it will in future be possible for all aspects of risks associated with substances, risks in handling and possibilities of substitution to be regulated by means of

further revisions of the batteries directive when necessary, in the case of all battery constituents.
The exception applies only to the use of substances in batteries, not their production. The production of current and future battery constituents will in any case be subject to the forthcoming REACH Regulation. That means that manufacturers (and importers) of battery constituents (which may be the battery industry itself) will in any case be required to register these substances under REACH and assess them with reference to their intrinsic properties, so that no lacunae arise here. The actual risks associated with use will then be assessed under the batteries directive. Insofar as the substances are put to use other than in batteries, the REACH Regulation will apply in full. (Oomen-Ruijten)

Amendment by Richard Seeber

Amendment 112
ARTICLE 3, PARAGRAPH 2

2. Preparation: means a mixture or solution composed of two or more substances;	2. Preparation: means a mixture or solution composed of two or more substances; ***special preparations (such as alloys) are preparations which may be assessed on the basis of their own specific properties;***

Or. de

Justification

This amendment corresponds to Amendment 67 adopted at first reading. It is necessary in order to incorporate into the actual body of the text the intention expressed in Recital 27 of the common position and take greater account of the properties of special preparations (such as alloys, but possibly also including glass).

Amendment by Carl Schlyter, Caroline Lucas, Hiltrud Breyer, Jonas Sjöstedt

Amendment 113
ARTICLE 3, POINT 3

3. Article: means ***an*** object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition;	3. Article: means ***a man-made*** object ***composed of one or more parts, each composed of one or more homogeneous materials that contain substance(s) and/or preparation(s),*** which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition;

Or. en

(Combination of amendment 479/rev and 352 - first reading, and new amendment, Rule 62(2(d) –the final report of RIP 3.8. on the requirements of substances in articles, adopted 26 May 2006, represents a new fact)

Justification

The definition of an article should refer explicitly to it being made of one or more parts, each composed of one or more homogenous materials, which in turn can contain substances or preparations, particularly with regard to the 0,1% threshold in Article 7(2). This is needed to counter RIP 3.8.. The threshold should apply to substances within homogenous materials in an article, and not to the whole article, in line with other Community legislation (e.g. RoHS). Otherwise, Article 7(2) would be almost meaningless and create an uneven playing field between EU manufacturers and importers.

Amendment by Urszula Krupa + Gyula Hegyi, Dorette Corbey, Anne Ferreira, Dan Jørgensen, Åsa Westlund

Amendment 114
ARTICLE 3, POINT 3

3. Article: means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition;	3. Article: means an object ***composed of homogeneous material*** which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition;

Or. en

Justification

This amendment ensures compliance with existing EU legislation (Dir. 76/769/EEC on Restrictions, Dir. 2000/53/EC on End of Life Vehicles, and RoHS). Furthermore, the Council text would harm EU industry as it would cause competitive disadvantages to EU-producers of complex articles in relation to importers of complex articles.

Amendment by Carl Schlyter, Caroline Lucas, Hiltrud Breyer

Amendment 115
ARTICLE 3, POINT 5 A (new)

5a. Nanoparticle: means an engineered substance with one or more dimensions of 100 nanometers or less;

Or. en

(New amendment - Rule 62(2)(d) to take account of the modified Opinion of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) of 10 March 2006 on "The appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies")

Justification

Linked to amendments by the same authors to Articles 14, 56, 57 and Annex III. A definition of nanoparticles is necessary to clarify the scope of the newly introduced provisions on nanoparticles.

Amendment by Ria Oomen-Ruijten

Amendment 116
ARTICLE 3, POINT 22

22. Scientific research and development: means any scientific experimentation, analysis or chemical research carried out under controlled conditions ***in a volume less than 1 tonne per year*** ;	22. Scientific research and development: means any scientific experimentation, analysis or chemical research carried out under controlled conditions;

Or. en

Justification

Corresponds to Amendment 75 adopted in First Reading.

The ceiling of one tonne unduly restricts freedom in the area of science and research.

Amendment by Lena Ek

Amendment 117
ARTICLE 3, POINT 23 A (new)

23a. Unsupported use: means a use by downstream users which the registrant

	advises against by providing scientifically based arguments against the safety of this use;

Or. en

Justification

Arguments should be provided to justify why a use is not supported. Corresponds to first reading amendments 76-77.

Amendment by Ria Oomen-Ruijten

Amendment 118
ARTICLE 3, POINT 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;	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***.

Or. en

Justification

There must be an obligation for the producer and the suppliers to communicate to the down stream user which uses are supported or not; otherwise the down stream user does not know if he would have to register himself.

Amendment by Lena Ek + Amalia Sartori

Amendment 119
ARTICLE 3, POINT 29

29. Per year means per calendar year unless stated otherwise.	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;

Or. en

Justification

Market fluctuations should be taken into account to prevent them from affecting the terms of registration, evaluation and authorisation (existing substances). Identical to first reading amendment 78. (Ek)

Amendment by Carl Schlyter, Caroline Lucas, Hiltrud Breyer, Jonas Sjöstedt + Frédérique Ries, Chris Davies + Urszula Krupa

Amendment 120
ARTICLE 3, POINT 30 A (new)

30a. Vulnerable populations means susceptible humans including neonates, infants, children, pregnant women, nursing mothers, the infirm and immuno-compromised, elderly persons, those with individual genetic susceptibilities and other identified groups of concern.

Or. en

(Amendment 80 - first reading)

Justification

The Council wording of Article 3 has no definition of the term vulnerable populations although is used in the text. A definition is essential to ensure that susceptible populations are identified and that measures can be taken accordingly to reduce the risks to and exposures of these populations. (Schlyter & others)

The Council wording of Article 3 has no definition of the term 'vulnerable populations' which is used in the text. The EP amendment adopted at 1st reading (Am. 80) specifies the meaning of this term, and this amendment simply retables the Parliament's definition. (Ries, Davies)

The Council wording of Article 3 has no definition of the term 'vulnerable populations' although it is used in the text. EP amendment 80 providing this definition is re-tabled. (Krupa)

Amendment by Ria Oomen-Ruijten

Amendment 121
ARTICLE 3, POINT 35

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;	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.***

Or. en

Justification

Corresponds to Amendment 376 adopted in First Reading.

The definition clarifies that risk management is an important part of the exposure scenario, as laid down in ANNEX I. It clarifies further that several uses and processes can also be described by use and exposure categories.

Amendment by Ria Oomen-Ruijten

Amendment 122
ARTICLE 3, POINT 36

36. Use and exposure category: means ***an exposure scenario covering a wide range of processes or uses;***	36. Use and exposure category means ***the main use categories (e.g. industrial use, professional use, consumer use) and the significant routes of exposure (e.g. oral, dermal, inhalation, environmental) and patterns of exposure (e.g. frequent, accidental, occasional, continuous).***

Or. en

Justification

Corresponds to Amendment 377 adopted in First Reading.

This definition describes the structure of use and exposure categories, as laid down in ANNEX VI, NO. 6.

Amendment by Richard Seeber

Amendment 123
ARTICLE 3, PARAGRAPHS 36 a AND 36 b (NEW)

36a. Use categories: means a classification of uses distinguishing the following: industrial use, professional use and consumer use;

36b. Exposure categories: means a classification of exposures in accordance with the relevant routes of exposure of human beings, the routes of emission into the environment and the duration and frequency of exposure;

Or. de

Justification

This amendment corresponds to Amendments 434 and 435 adopted at first reading. It makes it clearer, as a complement to Article 3(36) of the common position, what is meant by use category and exposure category. This clear definition in the body of the regulation itself could on the one hand be necessary for pre-registration, so that downstream users can easily decide whether the previous supplier is also registering the intended use. On the other hand a clear and simple definition is also needed for the exposure assessment and for communication in the supply chain by means of an extended safety data sheet and, more particularly, is essential for downstream users.

Amendment by Cristina Gutiérrez-Cortines

Amendment 124
ARTICLE 3, POINT 39 A (new)

39a. Mineral means a combination of inorganic constituents as found in the earth's crust, with a characteristic set of

chemical compositions, crystalline forms and physico-chemical properties.

Or. en

Justification

Reinstates am. 676 adopted in first reading.

Amendment by Ria Oomen-Ruijten

Amendment 125
ARTICLE 6, PARAGRAPH 1

1. Save where this Regulation provides otherwise any manufacturer or importer of a substance, either on its own or in one or more preparation(s), in quantities of 1 tonne or more per year shall submit a registration to the Agency.	1. Save where this Regulation provides otherwise, any manufacturer or importer of a substance, either on its own or in one or more preparation(s), in quantities of 1 tonne or more per year shall submit a registration to the Agency. ***Instead of the submission of several registrations for each substance of a certain preparation the manufacturer or importer of the preparation may alternatively submit a registration for the preparation; in this case the substance-related requirements apply to the preparation.***

Or. en

Justification

Preparations are indispensable for the production of specific products. Since there are often more than 10 single substances in one preparation, it should be possible in individual cases, to register the preparation as a whole. It has only little sense first to test and register all the unknown single substances (with extensive animal testing), only in order to consolidate all the information to one single evaluation for the preparation afterwards. The new wording allows that animal testing could be reduced significantly. Often companies already have the information and data for the preparation but not for each single substance in the preparations.

Amendment by Cristina Gutiérrez-Cortines

Amendment 126
ARTICLE 6, PARAGRAPH 1

1. Save where this Regulation provides otherwise, any manufacturer or importer of a substance***, either*** on its own ***or in one or more preparation(s),*** in quantities of 1 tonne or more per year shall submit a registration to the Agency.	1. Save where this Regulation provides otherwise, any manufacturer or importer of a substance on its own in quantities of 1 tonne or more per year shall submit a registration to the Agency. ***Save where this Regulation provides otherwise, any manufacturer or importer of a substance in one or more preparation(s), in quantities of 1 tonne or more per year shall submit a registration to the Agency if not already registered pursuant to the first subparagraph.***

Or. en

Justification

This amendment is intended to find a compromise with Council, partly reinstating the resulting text in first reading.

Current wording leads to confusion among producers and importers of preparations concerning their obligations. It is not clear whether there is an obligation to submit registrations for the substances in their preparations, irrespective of whether the substances on their own have already been registered and vice versa. For sake of legal certainty this clarification is needed.

Amendment by Holger Krahmer

Amendment 127
ARTICLE 6, PARAGRAPH 3

3. Any manufacturer or importer of a polymer shall submit a ***registration*** to the Agency for the monomer substance(s) or any other substance(s)***, that have*** not ***already been*** registered by an actor ***up*** the supply chain, if both the following conditions are met:	3. Any manufacturer or importer of a polymer shall submit a ***notification*** to the Agency for the ***non-registered*** monomer substance(s) not registered by an ***upstream*** actor ***in*** the supply chain ***or other non-registered substance(s), except where such monomer substances are formed during synthesis and cannot be isolated,*** if both the

	following conditions are met:
(a) the polymer consists of 2 % weight by weight (w/w) or more of such monomer substance(s) or other substance(s***) in the form of monomeric units and chemically bound substance(s)***;	(a) the polymer consists of 2% weight by weight (W/W) or more of such monomer substances or other substance(s);
(b) the total quantity of such monomer substance(s) or other substance(s) makes up 1 tonne or more per year.	(b) the total quantity of such monomer substance(s) or other substance(s) makes up 1 tonne or more per year.
	A notification for such monomer/substance shall include the following information in the format specified by the Agency in accordance with Article 110:
	(i) the identity and contact details of the producer or importer;
	(ii) the identity of the monomer/substance as specified in section 2 of Annex VI;
	(iii) the classification of the substance;
	(iv) a brief description of the use of the polymer;
	A registration under this title shall be made for the non-registered monomer substance manufactured or imported in quantities of more than 1000 tonnes per year. This registration shall include the information specified in Annex VII in addition to the information required above.
	Non-registered monomer substances or other non-registered substances are substances that have not been registered by the manufacturer who supplies such substances to the polymer manufacturer.
	However, where non-registered monomer substances or other substances were registered by the original manufacturer or by a designated representative thereof, the polymer manufacturer may make use of this registration provided that the registrant has indicated that it is used in the manufacture of polymers.

Or. en

Justification

Re-tabling of Amendment 433 / 584 (first reading). Importers/manufacturers of polymers do not place monomer substances or other substances used to make polymers on the EU market. The purpose of monomers is to react with other monomers to form polymers. As a result, monomers no longer exist in the end-product, i.e. the polymer. Polymers, which are temporarily exempted from REACH, are recognised as being generally safe, posing limited risks to human health and the environment.

Requiring full registration of reacted monomers, or of substances that no longer exist in polymers, is therefore disproportionate to the potential risks that these monomers may present to health or the environment. To ensure proportionality and consistency with provisions on Substances in Articles, a notification of the monomer substances used to make polymers should be submitted to the Agency. The Agency may, in turn, require manufacturers or importers of polymers to submit a registration for any residual monomers or monomers that have only incompletely reacted to form the polymer if they present a risk to health and/or the environment.

In addition, and consistent with the underlying tonnage/exposure philosophy of REACH, where the 1000 tonne threshold is exceeded, manufacturers and importers should register monomer substances used to make polymers in accordance with the set conditions.

Amendment by Chris Davies, Holger Krahmer, Anne Laperrouze, Vittorio Prodi

Amendment 128
ARTICLE 6, PARAGRAPH 3

3. Any manufacturer or importer of a polymer shall submit a ***registration*** to the Agency for the monomer substance(s) or any other substance(s), that have not already been registered ***by an actor up the supply chain***, if both the following conditions are met:	3. Any manufacturer or importer of a polymer shall submit a ***notification*** to the Agency for monomer substance(s) or any other substance(s), that have not already been ***notified or*** registered, if both the following conditions are met:
(a) the polymer consists of 2 % weight by weight (w/w) or more of such monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s);	(a) the polymer consists of 2% weight by weight (w/w) or more of such monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s);
(b) the total quantity of such monomer substance(s) or other substance(s) makes up 1 tonne or more per year.	(b) the total quantity of such monomer substance(s) or other substance(s) makes up 1 tonne or more per year.

A notification for such monomer substance(s) or other substances shall include the following information in the format specified by the Agency in accordance with Article 110 :

(i) the identity and contact details of the polymer producer or importer;

(ii) the identity of the monomer substance(s) or other substances as specified in section 2 of Annex VI;

(iii) the classification of the substance;

(iv) a brief description of the use of the polymer(s);

(v) an indication of whether the substance is present as an impurity in the polymer at a concentration level of 0.1 % or greater weight by weight .

3a. The Agency may take decisions requiring producers or importers of polymers to submit a registration for any monomer substance(s) or other substance(s) notified in accordance with Article 6 paragraph 3, if all the following conditions are met:

(a) the monomer substance or other substance is present in the form of an impurity following the polymer forming reaction;

(b) such impurity is present above a concentration of 0.1% weight by weight (w/w);

(c) the Agency has grounds for suspecting that the impurity is released from the polymer, and that the release presents a risk to human health or the environment.

Or. en

Justification

(In view of a compromise with the Council)

The purpose of monomers is to react with other monomers to form polymers. Once reacted,

monomers no longer exist in the polymer. Requiring full registration of reacted monomers is disproportionate to the potential risks that these monomers may present to health and environment. To ensure proportionality and consistency with Article 7, a notification of the monomers used to make polymers should be submitted to the Agency. The Agency may then require manufacturers or importers of polymers to submit a registration for any residual monomers if they present a risk to health or the environment.

Amendment by Ria Oomen-Ruijten

Amendment 129
ARTICLE 6, PARAGRAPH 3

3. Any manufacturer or importer of a polymer shall submit a registration to the Agency for the monomer substance(s) or any other substance(s), that have not already been registered by an actor up the supply chain, if both the following conditions are met:	3. Any manufacturer or importer of a polymer shall submit a registration to the Agency for the monomer substance(s) or any other substance(s) that have not already been registered by an actor up the supply chain, ***except where such monomer substances formed during synthesis cannot be isolated,*** if both the following conditions are met:
a) the polymer consists of 2% weight by weight (w/w) or more of such monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s);	(a) the polymer consists of 2% weight by weight (w/w) or more of such monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s);
b) the total quantity of such monomer substance(s) or other substance(s) makes up 1 tonne or more per year.	(b) the total quantity of such monomer substance(s) or other substance(s) makes up 1 tonne or more per year.
	A notification for such monomer (s) or other substance(s) shall include the following information in the format specified by the Agency in accordance with Article 110:
	(i) the identity and contact details of the producer or importer;
	(ii) the identity of the monomer/substance as specified in section 2 of Annex VI;
	(iii) the classification of the substance;
	(iv) a brief description of the use of the polymer.
	A registration under this Title shall be made for the non-registered monomer(s) or other substance(s) manufactured or

imported in quantities of more than 1000 tonnes per year. This registration shall include the information specified in Annex VII in addition to the information required above.

Or. en

Justification

In line with Amendments 584 & 433 adopted in First Reading.

Polymers, which are temporarily exempted from REACH, are recognised as being generally safe.

Requiring full registration of reacted monomers, is therefore disproportionate to the potential risks that these monomers may present to health or the environment once they have been converted into polymers. To ensure proportionality and consistency with provisions on Substances in Articles, a notification of the monomer substances used to make polymers should be submitted to the Agency.

In addition, and consistent with the underlying tonnage/exposure philosophy of REACH, where the 1000 tonne threshold is exceeded, manufacturers and importers should register monomer substances used to make polymers in accordance with the set conditions.
Further, some monomers are formed in the production process and immediately continue to react. Registration is thus impossible except at an indefensibly high cost.

Amendment by Lena Ek + Anders Wijkman, Frieda Brepoels, Erna Hennicot-Schoepges, Péter Olajos, Avril Doyle +Gyula Hegyi, Dorette Corbey, Anne Ferreira, Dan Jørgensen, Åsa Westlund

Amendment 130
ARTICLE 7

1. Any producer or importer of articles shall submit a registration to the Agency for any substance contained in those articles, if both the following conditions are met:	1. Any producer or importer of articles shall submit a registration to the Agency for any substance contained in those articles, if both the following conditions are met:
(a) the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year;	(a) the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year;
(b) the substance is intended to be released under normal or reasonably foreseeable conditions of use.	(b) the substance is intended to be released under normal or reasonably foreseeable conditions of use.

A submission for registration shall be accompanied by the fee required in accordance with Title IX.	A submission for registration shall be accompanied by the fee required in accordance with Title IX.
2. Any producer or importer of articles shall notify the Agency, in accordance with paragraph 4 of this Article, if a substance meets the criteria in Article 56 and is identified in accordance with Article 58(1)***, if both the following conditions are met***:	2. Any producer or importer of articles shall notify the Agency, in accordance with paragraph 4 of this Article, if a substance meets the criteria in Article 56 and is identified in accordance with Article 58(1) ***where***:
(a) the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year;	***Deleted***
(b) the substance is present in those articles above a concentration of 0.1 % weight by weight (w/w).	(b) the substance is present in those articles above a concentration of 0.1 % weight by weight (w/w) ***in a homogenous part of an article;***
	(ba) substance specific concentration limits below the 0.1% limit may be adopted in accordance with the procedure referred to in Article 130(3);
	(bb) the producer or importer cannot exclude any exposure of the public or the environment to the substance during the full life-cycle of the article.
3. Paragraph 2 shall not apply where the producer or importer can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal. In such cases, the producer or importer shall supply appropriate instructions to the recipient of the article in accordance with Article 32(4).	***Deleted***
4. The information to be notified shall include the following:	4. The information to be notified shall include the following:
(a) the identity and contact details of the producer or importer as specified in section 1 of Annex VI, with the exception of their own use sites;	(a) the identity and contact details of the producer or importer as specified in section 1 of Annex VI, with the exception of their own use sites;
(b) the registration number(s) referred to in Article 20(1), if available;	(b) the registration number(s) referred to in Article 20(1), if available;
(c) the identity of the substance as specified in sections 2.1 to 2.3.4 of Annex VI;	(c) the identity of the substance as specified in sections 2.1 to 2.3.4 of Annex VI;

(d) the classification of the substance(s) as specified in sections 4.1 and 4.2 of Annex VI;	(d) the classification of the substance(s) as specified in sections 4.1 and 4.2 of Annex VI;
(e) a brief description of the use(s) of the substance(s) in the article as specified in section 3.5 of Annex VI and of the uses of the article(s);	(e) a brief description of the use(s) of the substance(s) in the article as specified in section 3.5 of Annex VI and of the uses of the article(s);
5. The Agency may take decisions requiring producers or importers of articles to submit a registration, in accordance with this Title, for any substance in those articles, if all the following conditions are met:	5. The Agency may take decisions requiring producers or importers of articles to submit a registration, in accordance with this Title, for any substance in those articles, if all the following conditions are met:
(a) the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year;	***Deleted***
(b) the Agency has grounds for suspecting that:	(b) the Agency has grounds for suspecting that:
(i) the substance is released from the articles, and	(i) the substance is released from the articles, and
(ii) the release of the substance from the articles presents a risk to human health or the environment;	(ii) the release of the substance from the articles the substance presents a risk to human health or the environment;
(c) the substance is not subject to paragraph 1.	(c) the substance is not subject to paragraph 1.
A submission for registration shall be accompanied by the fee in accordance with Title IX.	A submission for registration shall be accompanied by the fee in accordance with Title IX.
6. Paragraphs 1 to 5 shall not apply to substances that have already been registered for that use.	6. Paragraphs 1 to 5 shall not apply to substances that have already been registered for that use ***if the use volume in the articles is in the same or a lower tonnage band than the registered volume.***
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).	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).
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).	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).

Or. en

Justification

This amendment is a compromise between EP and Council and is in line with the compromise package on substances in articles agreed by a majority of political groups (first reading amendment 357). It simplifies the work for producers and importers.

This amendment helps to protect the competitiveness of EU producers of articles by providing the same level playing field within the framework of the WTO agreements. It will also provide a high level protection for consumer. (Ek)

It is very important to ensure that not only the whole car is viewed as an article, but also the steering wheel to give an example. If the definition of articles is not clarified, almost no information will be made available for articles. Amendment 357 from first reading. (Wijkman & others)

This amendment is a compromise between EP and Council and is in line with the compromise package on substances in articles agreed by a majority of political groups (EP amendment 357). It simplifies the work for producers and importers.

This amendment helps to protect the competitiveness of EU producers of articles by providing the same level playing field within the framework of the WTO agreements. It will also provide a high level protection for consumers. (Hegyi & others)

Amendment by Carl Schlyter, Caroline Lucas, Hiltrud Breyer, Jonas Sjöstedt

Amendment 131
ARTICLE 7

1. Any producer or importer of articles shall submit a registration to the Agency for any substance contained in those articles, if both the following conditions are met:	1. Any producer or importer of articles shall submit a registration to the Agency for any substance contained in those articles, if both the following conditions are met:
(a) the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year;	(a) the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year;
(b) the substance is intended to be released under normal or reasonably foreseeable conditions of use.	(b) the substance is intended to be released under normal or reasonably foreseeable conditions of use.
A submission for registration shall be accompanied by the fee required in accordance with Title IX.	A submission for registration shall be accompanied by the fee required in accordance with Title IX.
2. Any producer or importer of articles shall notify the Agency, in accordance with paragraph 4 of this Article, if a substance meets the criteria in Article 56 and is	2. Any producer or importer of articles shall notify the Agency, in accordance with paragraph 4 of this Article, if a substance meets the criteria in Article 56 and is

identified in accordance with Article 58(1)***, if both the following conditions are met***:	identified in accordance with Article 58(1) ***where***:
(a) the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year;	***deleted***
(b) the substance is present in those articles above a concentration of 0.1 % weight by weight (w/w).	(b) the substance is present in those articles above a concentration of 0.1 % weight by weight (w/w) ***in a homogeneous material;***
	(ba) the producer or importer cannot exclude any exposure of the public or the environment to the substance during the full life-cycle of the article.
3. Paragraph 2 shall not apply where the producer or importer can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal. In such cases, the producer or importer shall supply appropriate instructions to the recipient of the article in accordance with Article 32(4).	***deleted***
4. The information to be notified shall include the following:	4. The information to be notified shall include the following:
(a) the identity and contact details of the producer or importer as specified in section 1 of Annex VI, with the exception of their own use sites;	(a) the identity and contact details of the producer or importer as specified in section 1 of Annex VI, with the exception of their own use sites;
(b) the registration number(s) referred to in Article 20(1), if available;	(b) the registration number(s) referred to in Article 20(1), if available;
(c) the identity of the substance as specified in sections 2.1 to 2.3.4 of Annex VI;	(c) the identity of the substance as specified in sections 2.1 to 2.3.4 of Annex VI;
(d) the classification of the substance(s) as specified in sections 4.1 and 4.2 of Annex VI;	(d) the classification of the substance(s) as specified in sections 4.1 and 4.2 of Annex VI;
(e) a brief description of the use(s) of the substance(s) in the article as specified in section 3.5 of Annex VI and of the uses of the article(s);	(e) a brief description of the use(s) of the substance(s) in the article as specified in section 3.5 of Annex VI and of the uses of the article(s);
(f) the tonnage range of the substance(s), such as 1-10 tonnes, 10-100 tonnes and so on.	(f) the tonnage range of the substance(s), such as 1-10 tonnes, 10-100 tonnes and so on.
5. The Agency may take decisions requiring producers or importers of articles to submit a	5. The Agency may take decisions requiring producers or importers of articles to submit a

registration, in accordance with this Title, for any substance in those articles, if all the following conditions are met:	registration, in accordance with this Title, for any substance in those articles, if all the following conditions are met:
(a) the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year;	***deleted***
(b) the Agency has grounds for suspecting that:	(b) the Agency has grounds for suspecting that:
(i) the substance is released from the articles, and	(i) the substance is released from the articles, and
(ii) the release of the substance from the articles presents a risk to human health or the environment;	(ii) the release of the substance from the articles presents a risk to human health or the environment;
(c) the substance is not subject to paragraph 1.	(c) the substance is not subject to paragraph 1.
A submission for registration shall be accompanied by the fee required in accordance with Title IX.	A submission for registration shall be accompanied by the fee required in accordance with Title IX.
6. Paragraphs 1 to 5 shall not apply to substances that have already been registered for that use.	6. Paragraphs 1 to 5 shall not apply to substances that have already been registered for that use ***by an actor up the supply chain.***
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).	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).
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).	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).

Or. en

Justification

The use of substances of very high concern in articles should be notified as soon as it exceeds 0,1%, no matter the total quantity, or when exposure cannot be excluded, to facilitate calculations and to provide a high level of protection.

The addition "in a homogeneous material" is needed to counter RIP 3.8., otherwise the whole article would be almost meaningless and create an uneven playing field between EU manufacturers and importers. The threshold should apply to homogenous materials in an

article, and not to the whole article, in line with other Community legislation (e.g. RoHS, ELV).

The derogation from the notification requirement of substances in articles in the Council text only refers to exposure during use and disposal, whereas the derogation adopted by Parliament (see Art. 7 (2)(ba) refers to the full lifecycle. Exposure from manufacture should be included as well.

The Agency should be able to require a registration as soon as it has ground for suspecting a risk, irrespective of the total quantity, to avoid cumbersome calculations and to provide a high level of protection.

If the reference to "an actor up the supply chain" is not added, importers would not need to inform the agency anymore about the presence of substances of very high concern in their article as soon as anyone else has registered such a use. As a result, the agency would have no information about the presence of such substances in imported articles, even if present in high concentrations. However, such information may be essential for authorisation or restriction purposes with a view to protect human health and the environment.

Amendment by Ria Oomen-Ruijten

Amendment 132
ARTICLE 7, PARAGRAPH 1 A (new)

1a. Paragraph 1(a) shall not apply to substances which are ingredients added to tobacco products within the meaning of Article 2(1) and 2(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.

Or. en

Justification

Corresponds to Amendment 88 adopted in First Reading

As well the exposure scenario as the noxious effects resulting from tobacco additives do not justify any exemptions from the obligation to register these substances.

Amendment by Anja Weisgerber

Amendment 133
ARTICLE 7, PARAGRAPH 1 A (new)

	1a. Paragraph 1(a) shall not apply to substances which are ingredients added to cigarettes within the meaning of Article 4 of Directive 95/59/EC on taxes other than turnover taxes which affect the consumption of manufactured tobacco.

Or. en

Justification

Compromise amendment between amendment no. 88 of Parliament's first reading and the Council's common position.

Amendment by Dagmar Roth-Behrendt

Amendment 134
ARTICLE 7, PARAGRAPH 7

7. ***From [42 months after entry into force of this regulation] paragraphs*** 2, 3 and 4 ***of this Article*** shall apply 6 months after a substance is identified in accordance with Article 58(1).	7. ***Paragraphs 1 and 5 shall apply 3 months after the deadline specified in Article 23(3).*** ***Paragraphs*** 2,3 and 4 shall apply 6 months after a substance is identified in accordance with Article 58(1) ***on condition that 3 months have past from the deadline specified in Article 23(3)***.

Or. en

Justification

Reinstates the compliance dates of the Commission's initial proposal. Linked to amendment on Article 23 by the same author.

Amendment by Holger Krahmer

Amendment 135
ARTICLE 7, PARAGRAPH 7

7. ***From [42 month after entry into force of this regulation] paragraphs*** 2, 3 and 4 of this Article shall apply 6 months after a substance is identified in accordance with Article 58(1).	7. ***Paragraphs 1 and 5 shall apply 3 months after the deadline specified in article 23(3).*** ***Paragraphs*** 2, 3 and 4 of this Article shall apply 6 months after a substance is identified in accordance with Article 58(1) ***provided that 6 months have elapsed from the deadline specified in article 23(3)***.

Or. en

Justification

To help smooth putting into practice of provisions regarding substances in articles and to limit potential disruptions in the supply chain, the producer's responsibility should not be shifted down the supply chain i.e. to downstream users. Downstream users can at the same time be producers of articles; the majority of them are SMEs. In the interest of the workability of article 7, article producers should have the possibility, as foreseen in article 7(6), to base their registrations/notifications upon earlier registrations thereby avoiding a transfer of obligation from the producer of the substance to the downstream user.

Amendment by Ria Oomen-Ruijten

Amendment 136
ARTICLE 7, PARAGRAPH 7

7. From ***[42 month after entry into force of this regulation]*** paragraphs 2, 3 and 4 of this Article shall apply ***6*** months after a substance is identified in accordance with Article 58(1).	***7.*** From ***…**** paragraphs 2, 3 and 4 of this Article shall apply ***18*** months after a substance is identified in accordance with Art. 58 (1).

Or. en

Justification

Retailers and mail order companies order their goods up to 18 months before importation. Already when orders are placed, the importer of an article should be able to provide the supplier with a positive list of substances that must be handled with care or avoided during production. The candidate list – together with Annex XIV to REACH - will serve as this positive list. If the deadline in Art. 7 (7) is too short and does not take the actual buying cycles into account, the importer will not only face legal uncertainty but also will not be able to influence the production procedures accordingly. The deadline therefore needs to be extended.

Amendment by Ria Oomen-Ruijten + Chris Davies

Amendment 137
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.

Or. en

Justification

REACH represents a huge organisational challenge for importers of articles. The Council proposal foresees several sector specific guidelines; however, the sector specific guidelines for producers and importers of articles, on which the EP agreed in 1st plenary reading, are no longer mentioned. Project 3.8 (initially supposed to replace the guidelines for the consumer goods sector) has not produced a workable result. Nonetheless the sector depends on professional and knowledgeable help– just as the different authorities involved in the import procedures. Guidelines drafted by the agency would provide a uniform level of support for companies and authorities in all EU Member States and likewise for non-European companies who may lack a thorough knowledge of the REACH legislation. (Oomen-Ruijten)

Successful first reading amendment ensuring the leading role of the Agency in providing guidelines. (Davies)

Amendment by Ria Oomen-Ruijten

Amendment 138
ARTICLE 8 A (new)

Article 8a

Transfer and splitting of registrations and 'collective registrations'

1. The legal entitlement acquired through registration shall be both transferable and divisible. The party acquiring such an entitlement shall take over the rights and obligations of the original registrant. Where a registration is split, the Agency shall assign a new registration number to the new holder.

2. Where a manufacturer is a subsidiary of another legal person (termed the 'parent company'), the parent company may undertake and maintain a registration on behalf of the subsidiary. Conversely, a subsidiary may also undertake and maintain a registration for its parent company or for other subsidiaries. In such cases registration shall be required once only. The legal person designated for collective registration purposes shall be responsible for performance of duties under this Regulation.

3. Paragraph 2 shall also apply where the registered office of the parent company or the subsidiary is not located in the European Union. The legal person designated for collective registration purposes must have his registered office in the Union.

Or. en

Justification

Corresponds to Amendments 593,594,595 & 596 adopted in First Reading.

1. If a registrant no longer wishes to make use of his registration it must be possible for him to transfer the rights arising from the registration. The divisibility of rights arising from a registration is necessary in cases in which only part of a firm is transferred to a new owner. Since each manufacturer or importer must have a registration number as evidence of registration status, in such cases the Agency must assign a new registration number to the new owner.

2. Within conglomerates products are delivered from changing production plants to downstream users within the European Union who may belong to different subsidiaries. The delivery of products within a conglomerate is often coordinated by a unit which may be part of either the parent company or a subsidiary. The proposed group registration would be an appropriate way of reducing costs and bureaucracy.

Amendment by Ria Oomen-Ruijten

Amendment 139
ARTICLE 9, PARAGRAPH 2

2. For the purpose of paragraph 1, the manufacturer or importer or producer of articles shall notify the Agency of the following information:	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;	(a) the identity of the manufacturer or importer as specified in section 1 of Annex IV;
(b) the identity of the substance, as specified in section 2 of Annex VI;	(b) the identity of the substance, as specified in section 2 of Annex IV;
(c) the classification of the substance as specified in section 4 of Annex VI, if any;	(c) the classification of the substance as specified in section 4 of Annex IV, if any;
(d) the estimated quantity as specified in section 3.1 of Annex VI;	(d) the estimated quantity as specified in section 3.1 of Annex IV;
(e) the list of customers ***referred*** to ***in paragraph 1, including their names and addresses.***	(e) ***if relevant,*** the list of customers to ***which the substance is being supplied***.
The notification shall be accompanied by the fee required in accordance with Title IX.	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	The period set out in paragraph 1 shall begin at receipt of the notification at the Agency.

Or. en

Justification

The obligation for notification of substances, which are manufactured or important for R + D, should only apply if they are placed on the market. This would apply with the current EU chemical legislation. Otherwise, also R + D activities inside a company would have to be notified which leads to unnecessary bureaucracy and therefore to an unnecessary burden for R + D activities.

Amendment by Ria Oomen-Ruijten

Amendment 140
ARTICLE 9, PARAGRAPH 7

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***	7. The Agency may extend the five-year exemption period by a further maximum of ***ten*** years upon request ***of the manufacturer or importer,*** if the manufacturer or importer can demonstrate that such an extension is

human or veterinary use, for a further maximum of 10 years, upon request if the manufacturer or importer can demonstrate that such an extension is justified by the research and development programme.	justified by the research and development programme.

Or. en

Justification

The obligation for notification of substances, which are manufactured or important for R + D, should only apply if they are placed on the market. This would apply with the current EU chemical legislation. Otherwise, also R + D activities inside a company would have to be notified which leads to unnecessary bureaucracy and therefore to an unnecessary burden for R + D activities.

Amendment by Ria Oomen-Ruijten

Amendment 141
ARTICLE 9, PARAGRAPH 9

9. The Agency and the competent authorities of the respective Member States shall always keep confidential the information submitted in accordance with ***paragraphs*** 1 ***to 8***.	9. The Agency and the competent authorities of the respective Member State(s) shall always keep confidential the information submitted in accordance with ***paragraph 1. The Agency shall not release this information to any other competent authority.***

Or. en

Justification

The obligation for notification of substances, which are manufactured or important for R + D, should only apply if they are placed on the market. This would apply with the current EU chemical legislation. Otherwise, also R + D activities inside a company would have to be notified which leads to unnecessary bureaucracy and therefore to an unnecessary burden for R + D activities.

Amendment by Caroline Lucas, Carl Schlyter, Hiltrud Breyer, Jonas Sjöstedt

Amendment 142
ARTICLE 10, PARAGRAPH (A), POINT (VIII) A (new)

	(viiia) a statement as to whether or not information has been generated by testing on vertebrate animals, including which tests on vertebrate animals have been carried out and the number of animals used;

Or. en

(EP amendment 96 - first reading)

Justification

Information should be made available on the animal tests that have been carried out and the number of animals used.

Amendment by Carl Schlyter, Caroline Lucas, Hiltrud Breyer, Jonas Sjöstedt

Amendment 143
ARTICLE 10, PARAGRAPH (A), POINT (XI)

(xi) a request as to which of the information in Article 118(2) the manufacturer or importer considers should not be made available on the Internet in accordance with Article 76(2)(d), including a justification as to why publication ***could*** be harmful for his or any other concerned party's commercial interests;	(xi) a request as to which of the information in Article 118(2) the manufacturer or importer considers should not be made available on the Internet in accordance with Article 76(2)(d), including a justification as to why publication ***would*** be harmful for his or any other concerned party's commercial interests;

Or. en

(New amendment - Rule 62(2)(c))

Justification

A request for confidentiality should only be possible if public availability would be harmful to commercial interests, not just potentially so, to avoid any abuse of this clause.

Amendment by Ria Oomen-Ruijten

Amendment 144
ARTICLE 10, PARAGRAPH (A) A (new)

aa) Information required under the first paragraph and generated and checked under other EU, OECD or equivalent legislation and/or chemical programmes may be submitted and shall be presumed to meet the requirements of this Article.

Or. en

Justification

Corresponds to Amendment 575/600 adopted in First Reading.

Data already collected or reports already compiled on a substance under other EU or international programmes or legislation should be permitted and presented as such, without the need for modification and/or unnecessary redrafting or re-testing. Examples of such programmes are: the OECD programme for the production of internationally agreed Screening Information Data Sets (SIDS), the International Chemical Council Association High Production Volume (ICCA/HPV) assessments of chemicals, the Human and Environmental Risk Assessment Project (HERA) of chemicals used in the home for laundry and household cleaning, the monographs of the European Toxicology & Ecotoxicology Centre (ECETOC) on individual chemicals, or the EPA HPV Challenge.

Amendment by Lena Ek + Ria Oomen-Ruijten

Amendment 145
ARTICLE 10, PARAGRAPH (B) A (new)

(ba) Priority shall be given to in vitro methods and the use of (quantitative) structure activity relationships ((Q)SARs). To this end, the Commission shall make available to companies a list of tests, databases and approved models.

Or. en

Justification

In vitro methods limit unnecessary animal testing. Identical to first reading amendment 106. (Ek)

Corresponds with Amendment 106 adopted in First Reading.

In Vitro methods limit unnecessary animal testing. (Oomen-Ruijten)

Amendment by Chris Davies

Amendment 146
ARTICLE 11, PARAGRAPH 3, INTRODUCTORY PART

3. A manufacturer or importer may submit the information referred to in Article 10(a)(iv), (vi), (vii) or (ix) separately if:	3. A manufacturer or importer may***, without prejudice to Title III,*** submit the information referred to in Article 10(a)(iv), (vi), (vii) or (ix) separately if:

Or. en

Justification

To reduce duplication of animal testing companies opting out of joint submission of data must still be required to share data from animal testing. The data sharing requirements under Title III should apply irrespective of whether data is submitted jointly or separately.

Amendment by Caroline Lucas, Carl Schlyter, Hiltrud Breyer, Jonas Sjöstedt

Amendment 147
ARTICLE 11, PARAGRAPH 3, INTRODUCTORY PART

3. A manufacturer or importer may submit the information referred to in Article 10(a)(iv), (vi), (vii) or (ix) separately if:	3. A manufacturer or importer may***, except for matters requiring data from animal tests,*** submit the information referred to in Article 10(a)(iv), (vi), (vii) or (ix) separately if:

Or. en

(Amendment 379 relevant part - first reading)

Justification

It needs to specified explicitly that there is no opting out from the sharing of data from animal testing.

Amendment by Chris Davies

Amendment 148
ARTICLE 12, PARAGRAPH 2 A (new)

2a. Priority shall be given to in vitro methods, the use of (quantitative) structure activity relationships ((Q)SARs) and toxicogenomics. To this end, the Agency shall make available to companies a list of tests, databases and approved models.

Or. en

Justification

Intended to reduce unnecessary animal testing by ensuring that companies, particularly SMEs, are made aware of information already available. Successful First Reading amendment (106 and part of 549).

Amendment by Caroline Lucas, Carl Schlyter, Hiltrud Breyer

Amendment 149
ARTICLE 12, PARAGRAPH 2 A (new)

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.

Or. en

(Amendment 106 - first reading)

Justification

In light of the ethical and scientific concerns linked to animal tests, priority should be given to alternative strategies. The Agency should give all necessary information to companies.

Amendment by Ria Oomen-Ruijten

Amendment 150
ARTICLE 12, PARAGRAPH 2 A (new)

2a. For phase-in substances, the quantity per year shall be determined on the basis of the average quantity manufactured or imported in the preceding three years before the submission of the registration dossier.

Or. en

Justification

Corresponds to Amendment 611 adopted in First Reading.

Exceptional undulations in production volumes could increase information requirements significantly whenever a tonnage threshold is exceeded. It is therefore necessary to permit a degree of flexibility for low tonnage substances, particularly while sourcing. A 3 year average would ensure that more extensive registration requirements would only apply whenever a registrant has consistently exceeded a given tonnage threshold.

Amendment by Marie-Noëlle Lienemann, Anne Ferreira

Amendment 151
ARTICLE 13, PARAGRAPH 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, provided that the conditions set out in Annex IX 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 implement risk management measures as specified in Annex XI, section 3.	1. Information on intrinsic properties of substances***, in particular for human toxicity, shall*** be generated ***whenever possible*** by means other than ***vertebrate*** tests, in particular through the use of qualitative or quantitative structure-activity relationship models or from information from structurally related substances, provided that the conditions set out in Annex IX 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 implement risk management measures as specified in Annex XI, section 3.

Or. en

Justification

In addition to the ethical questions linked to vertebrate animal testing, there are numerous scientific problems with the validity of such animal tests for humans. Information about the properties of substances should therefore not only make use of alternative means such as QSARs, but also of the new and promising means of testing chemicals by assessing their effects via the reactions of marker genes.

(amendment 549 of the EP 1st reading)

Amendment by Caroline Lucas, Carl Schlyter, Hiltrud Breyer, Jonas Sjöstedt

Amendment 152
ARTICLE 13, PARAGRAPH 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.	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.

Or. en

(Amendment 549 - first reading)

Justification

In addition to the ethical questions linked to vertebrate animal testing, there are numerous scientific problems with the validity of such animal tests for humans. Information about the properties of substances should therefore not only make use of alternative means such as QSARs, but also of the new and promising means of testing chemicals by assessing their effects via the reaction of marker genes.

Amendment by Guido Sacconi

Amendment 153
ARTICLE 13, PARAGRAPH 2

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.	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.
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.	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.

Or. en

Justification

The amendment is needed to align the text to the provisions of the new "commitology" Decision, and in particular to replace the ordinary "regulatory committee" procedure with the "regulatory committee with scrutiny", since the measures concerned are measures of general scope designed to amend non-essential elements of the draft legislation.

Amendment by Ria Oomen-Ruijten

Amendment 154
ARTICLE 13, PARAGRAPH 3

3. ***Ecotoxicological and toxicological tests and analyses*** shall be carried out in compliance with the principles of good laboratory practice provided for in Directive ***2004/10/EC or other international standards recognised as being equivalent by the Commission or the Agency*** and with the provisions of Directive 86/609/EEC***, if applicable***.	3. ***New laboratory tests involving vertebrate animals*** shall be carried out in compliance with the principles of good laboratory practice provided for in Directive ***87/18/EEC*** and with the provisions of Directive 86/609/EEC.

Or. en

Justification

Corresponds to Amendment 375 adopted in First Reading.

The Good Laboratory Practice (GLP) System is a management system for certification of laboratories and documentation. It does not concern the test methods or the quality of test results. However, GLP is extremely expensive and would lead to disproportional testing costs, especially for lower volume substances without improving the results. Therefore, GLP should only be applied to vertebrate tests.

Amendment by Ria Oomen-Ruijten

Amendment 155
ARTICLE 13, PARAGRAPH 4

4. If a substance has already been registered, a new registrant shall be entitled to refer to ***the study summaries or robust study summaries,*** for the same substance submitted earlier, provided that he can show that the substance that he is now registering is the same as the one previously registered, including the degree of purity and the nature of impurities, and that the previous registrant(s) ***have given permission to refer to the full study reports for the purpose of registration. A new registrant shall not refer to such studies in order to provide the information required in section 2 of Annex VI***.	4. If a substance has already been registered, a new registrant shall be entitled to refer to ***studies and test reports, hereinafter "studies",*** for the same substance submitted earlier, provided that he can show that the substance that he is now registering is the same as the one previously registered, including the degree of purity and the nature of impurities, and that ***he submits a letter of access from*** the previous registrant(s).

Or. en

Justification

Corresponds to Amendment 615 adopted in First Reading.

Access must be guaranteed to data on tests not carried out on animals, as is already provided for in connection with tests carried out on animals. Related to the protection of property rights of the owners of the studies.

Amendment by Lena Ek + Carl Schlyter, Caroline Lucas, Hiltrud Breyer, Jonas Sjöstedt

Amendment 156
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.

Or. en

Justification

The intention of amendment 110 from the first reading was to secure basic safety data also for low volume chemicals. This should apply for all chemicals subject to registration. (Ek)

The industry and the institutions do not tire to stress the need for a "risk-based approach" of REACH. Risk is the combination of hazard and exposure. However, an assessment of a) hazard and b) exposure is only required in the chemical safety report. To limit the safety assessments to substances above 10 tonnes would exclude two-thirds of the substances from both those assessments. As a consequence, it would be near impossible to identify the appropriate risk management measures to protect workers or consumers against hazardous substances. A data graveyard serves nobody. (Schlyter & others)

Amendment by Evangelia Tzampazi + Gyula Hegyi, Dorette Corbey, Anne Ferreira, Dan Jørgensen, Åsa Westlund + Anders Wijkman, Frieda Brepoels, Erna Hennicot-Schoepges, Péter Olajos, Avril Doyle + Urszula Krupa

Amendment 157
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 if the registrant manufactures or imports such a substance in quantities of ***1 tonne*** or more per year.

Or. en

Justification

REACH should not be a data graveyard. The chemical safety assessment is essential for a risk-based system and risk management, simply recommending safe handling for users of the chemical. This amendment ensures that risk management will be available for substances above 1 tpa and chemicals of very high concern will be identified. The relevant part of EP amendment 110 is re-tabled. (Tzampazi + Hegyi & others + Krupa)

Data is needed to ensure that a simplified risk assessment via assessment of the chemical safety report can be done. The relevant part of EP amendment 110 is re-tabled. (Wijkman & others)

Amendment by Carl Schlyter, Caroline Lucas, Hiltrud Breyer

Amendment 158
ARTICLE 14, PARAGRAPH 2, SUBPARAGRAPH 1 A (new)

This paragraph shall not apply to nanoparticles.

Or. en

(New amendment - Rule 62(2)(d) to take account of the modified Opinion of SCENIHR of 10 March 2006))

Justification

Due to their very small size, nanoparticles have a far bigger surface area in relation to their mass than normal particles. The surface area in turn determines reactivity, which is of key importance to assess toxicity. According to SCENIHR, the focus on production expressed as mass rather than particle size may severely underestimate the potential contribution of nanoparticles to overall risk posed by the substance. Threshold levels to derogate from the requirement of chemical safety reports on the basis of mass or concentration should therefore not apply to engineered nanoparticles.

Amendment by Dagmar Roth-Behrendt + Anne Laperrouze, Vittorio Prodi + Cristina Gutiérrez-Cortines + Ria Oomen-Ruijten

Amendment 159
ARTICLE 14, PARAGRAPH 2 A (new)

2a. A chemical safety assessment and chemical safety report in accordance with paragraph 1 does not need to be performed for substances classified as dangerous according to Directive 67/548/ECC, or PBT or vBvP substances, which are present in massive preparations exempted from labelling according to Directive 1999/45/EC, article 12(2) and 67/548/EC Annex VI article 9(3).

Or. en

Justification

Reinstates amendments 422 and 960 as adopted in first reading. The risk for human health or the environment from substances bound in massive preparations is very limited and, accordingly, no labelling is required by existing legislation. Therefore, the obligation to perform chemical safety assessments and -reports can be dispensed under the same conditions as the labelling. (Roth-Behrendt)

Certain preparations, such as mixtures of rubber, are exempt from labelling pursuant to Directive 1999/45/EC, Article 12(2), because they do not present any danger to the environment or human health through inhalation, ingestion or contact with the skin.

Incorporating the proposed amendment into Article 14 would harmonise the provisions of REACH with Recital 28, with the provisions of Directive 1999/45/EC and with the regulation itself, which does not require a chemical safety assessment for substances in preparations which are not dangerous. (Laperrouze & Prodi)

This amendment reinstates amendments 422 and 960 tabled to the plenary and approved in first reading.

CSA of a dangerous substance in preparations is not required by REACH when the preparation is not classified as dangerous. Additionally Recital 28 indicates that these provisions should equally apply to preparations that are solid mixtures of substances until a specific shape is given to such a preparation that transforms it into an article.

Some massive preparations are exempted from labelling according to directive 1999/45/EC Art.12.2 exempt massive preparation because they don't pose any danger to the environment or human health. (Gutierrez-Cortines + Oomen-Ruijten)

Amendment by Carl Schlyter, Caroline Lucas, Hiltrud Breyer

Amendment 160
ARTICLE 14, PARAGRAPH 4, INTRODUCTORY PART

4. ***If***, as a result of carrying out steps (a) to (d) of paragraph 3, the manufacturer or importer concludes that the substance meets the criteria for classification as dangerous in accordance with Directive 67/548/EEC or is assessed to be a PBT or vPvB, the chemical safety assessment shall include the following additional steps:	4. ***For nanoparticles, or if***, as a result of carrying out steps (a) to (d) of paragraph 3, the manufacturer or importer concludes that the substance meets the criteria for classification as dangerous in accordance with Directive 67/548/EEC or is assessed to be a PBT or vPvB, the chemical safety assessment shall include the following additional steps:

Or. en

(New amendment - Rule 62(2)(d) to take account of the modified Opinion of SCENIHR of 10 March 2006)

Justification

According to SCENIHR, "in view of the specific characteristics demonstrated for nanoparticles and nanoparticle formulations, the assays usually performed for determining toxicity of products may not be sufficient to detect all possible adverse effects of nanoparticles". It is therefore not appropriate to rely solely on standard testing to determine hazard as a precondition to do an exposure assessment. Exposure assessment should be done for all engineered nanoparticles, irrespective of the results of standard toxicity testing.

Amendment by Dagmar Roth-Behrendt

Amendment 161
ARTICLE 15

1. Active substances ***and co-formulants*** manufactured or imported for use in plant protection products ***only*** and included either in Annex I to Directive 91/414/EEC or in Regulation (EEC) No 3600/92, Regulation (EC) No 703/2001, Regulation (EC) No 1490/2002, Decision 2003/565/EC and for any substance for which a Commission Decision on the completeness of the dossier has been taken pursuant to Article 6 of Directive 91/414/EEC shall be regarded as being registered and the registration as completed for manufacture or import for the use as a plant protection product and therefore as fulfilling the requirements of Chapters 1 and 5 of this Title.	1. Active substances ***to the extent that they are*** manufactured or imported for use in plant protection products and included either in Annex I to Directive 91/414/EEC or in Regulation (EEC) No 3600/92, Regulation (EC) No 703/2001, Regulation (EC) No 1490/2002, Decision 2003/565/EC and for any substance for which a Commission Decision on the completeness of the dossier has been taken pursuant to Article 6 of Directive 91/414/EEC ***and co-formulants to the extent that they are manufactured or imported for use in plant protection products authorized by Directive 91/414/EEC*** shall be regarded as being registered and the registration as completed for manufacture or import for the use as a

plant protection product and therefore as fulfilling the requirements of Chapters 1 and 5 of this Title.

2. Active manufactured or imported for use in biocidal products ***only*** and included either in Annexes I, IA or IB to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market or in Commission Regulation (EC) No 2032/2003 of 4 November 2003 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC, until the date of the decision referred to in the second subparagraph of Article 16(2) of Directive 98/8/EC, shall be regarded as being registered and the registration as completed for manufacture or import for the use in a biocidal product and therefore as fulfilling the requirements of Chapters 1 and 5 of this Title.	2. Active substances ***to the extent that they are*** manufactured or imported for use in biocidal products and included either in Annexes I, IA or IB to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market or in Commission Regulation (EC) No 2032/2003 of 4 November 2003 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC, until the date of the decision referred to in the second subparagraph of Article 16(2) of Directive 98/8/EC, shall be regarded as being registered and the registration as completed for manufacture or import for the use in a biocidal product and therefore as fulfilling the requirements of Chapters 1 and 5 of this Title.

Or. en

Justification

The amendment makes a necessary clarification to the Council's Common Position. Substances should be considered as registered as far as the use as plant protection product or biocide is concerned. Other uses have to be registered. (see amendment 466 as adopted in first reading which excludes substances to the extend that they are used in plant protection products and biocides inter alia from the registration chapter).

Amendment by Anne Laperrouze

Amendment 162
ARTICLE 17, PARAGRAPH 3, SUBPARAGRAPH 1

3. Paragraph 2 shall apply only to on-site isolated intermediates if the manufacturer confirms that the substance is only manufactured and used under strictly controlled conditions in that it is rigorously contained by technical means during its whole lifecycle. Control and procedural	3. Paragraph 2 shall apply only to on-site isolated intermediates if the manufacturer confirms that the substance is only manufactured and used under strictly controlled conditions in that it is rigorously contained by technical means during its whole lifecycle ***or that he has implemented***

technologies shall be used to minimise emission and any resulting exposure.	***the appropriate risk management measures identified on the basis of an assessment of risks to health and the environment***. Control and procedural technologies shall be used to minimise emission and any resulting exposure.

Or. fr

Justification

It is just as possible to control the risks associated with a manufacturing or use procedure by means of rigorous confinement as it is by implementing appropriate measures to manage risks identified on the basis of an assessment of risks to health and the environment.

Amendment by María Sornosa Martínez

Amendment 163
ARTICLE 19, PARAGRAPH 2, POINT (C)

(c) he disagrees with the lead registrant on the selection of this information.	(c) he disagrees with the lead registrant on the selection of this information. ***The Agency shall assess this explanation and take a decision on whether or not to accept it. In the event of non-acceptance, the undertaking shall be required to submit the data jointly.***

Or. es

Justification

As currently formulated, the criteria which manufacturers and importers may submit concerning separate information are very vague and difficult to justify and assess. Although subsequent articles make the Agency responsible for assessing this type of justification, it is not indicated what action should be taken if the justification is inadequate.

Amendment by Amalia Sartori

Amendment 164
ARTICLE 22, PARAGRAPH 1, POINT C)

c) changes in ***the annual or total*** quantities	c) changes in ***the*** quantities ***calculated on***

manufactured or imported by him if these result in a change of tonnage band, including cessation of manufacture or import;	***the basis of the average production volumes for the last three years*** manufactured or imported by him if these result in a change of tonnage band, including cessation of manufacture or import;

Or. en

Amendment by Dagmar Roth-Behrendt + Holger Krahmer

Amendment 165
ARTICLE 23

1. Article 5, Article 6, ***Article 7(1)*** and Article 21 shall not apply until …* to the following substances :	1. Article 5, Article 6 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 …**;	(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 ...**;	(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 …*.	(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)*** 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	2. Article 5, Article 6 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 …*.

after …*.

3. Article 5, Article 6, ***Article 7(1)*** 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. Article 5, Article 6 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 after the entry into force of this Regulation	* 3 years after the entry into force of this Regulation
** Date of entry into force of this Regulation	** Date of entry into force of this Regulation

Or. en

Justification

Reinstates the compliance dates of the Commission's initial proposal. Linked to amendment on Article 7 by the same author. (Roth-Behrendt)

The proposed modification to article 23 aims at bringing coherence with the proposed deadline for implementing article 7 and does not challenge the principle of a stepwise entry into force of REACH for phase-in substances. (Krahmer)

Amendment by Ria Oomen-Ruijten

Amendment 166
ARTICLE 23, PARAGRAPH 1, INTRODUCTORY PART

1. Article 5, Article 6, Article 7(1) and Article 21 shall not apply until....* to the following substances :	1. Article 5, Article 6, Article 7(1)***, Article 14, Article 17, Article 18*** and Article 21 shall not apply until....* to the following substances :

Or. en

Justification

Adds Transition periods for the registration of intermediates and for performing a Chemical Safety Assessment (CSA).

Amendment by Carl Schlyter, Caroline Lucas, Hiltrud Breyer, Jonas Sjöstedt + Urszula Krupa + Evangelia Tzampazi + Gyula Hegyi, Dorette Corbey, Anne Ferreira, Dan Jørgensen,

Åsa Westlund

Amendment 167
ARTICLE 23, PARAGRAPH 2

2. Article 5, Article 6, Article 7(1) 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 date of entry into force of this Regulation.	2. Article 5, Article 6, Article 7(1) and Article 21 shall not apply until ...* to ***phase-in substances classified as very toxic to aquatic organisms that 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 1 tonne or more per year per manufacturer or per importer; or 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 date of entry into force of this Regulation.

Or. en

(Amendment 374 - first reading)

Justification

Additional risk-based prioritisation: substances - in quantities below 100 tonnes - that are toxic to aquatic organisms and that may cause long-term adverse effects should be added to the second phase of registration. Otherwise, it would take up to 11 years until these hazardous substances would be registered. (Schlyter & others)

This amendment increases risk-based prioritisation in the registration process and improves coherence with existing legislation. Amendment 374 is re-tabled. (Krupa + Tzampazi + Hegyi & others)

Amendment by Ria Oomen-Ruijten

Amendment 168
ARTICLE 25, PARAGRAPH -1 (new)

	-1. Manufacturers or importers shall share between them and make available the information specified in Article 10(a) (vi) and (vii) for the purposes of registration, so

that the duplication of studies is avoided.

In circumstances (other than in matters requiring data from animal testing) where:

(a) the costs of sharing the information would be disproportionate;

(b) the data is not relevant for a substance; or

(c) the information is commercially confidential and the registrant justifiably considers that it may suffer loss of business as a result of requirements to share the information concerned,

the registrant shall submit to the Agency a justification for not sharing the information in part or in whole.

At the request of another potential registrant, and on payment of a fee, the Agency shall consider whether a justification is well-founded. SMEs shall pay only a reduced fee. If the Agency finds that a justification is not well-founded, the exception from sharing shall not be allowed to the original registrant, and the costs of the Agency related to its consideration shall be borne by him. In such cases, the fee paid shall be reimbursed.

No justification shall be required in respect of not sharing physicochemical information specified in section 5 of Annexes VII and VIII.

Or. en

Justification

Corresponds to Amendment 379 adopted in First Reading.

Makes consistency with Article 11, Paragraph 3 of the Common Position. This amendment intends to make the costs of data sharing more practical; Data-sharing stays mandatory unless the burden for the parties involved is disproportionate.

Amendment by Ria Oomen-Ruijten

Amendment 169
ARTICLE 25, PARAGRAPH 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***.	3**.** Any summaries or robust study summaries of studies ***relating to both animal and to non-animal tests*** submitted in the framework of a registration at least ***15*** years previously ***may*** be ***made freely available by the Agency to any other registrants or potential registrants***.

Or. en

Justification

Corresponds to Amendment 383 adopted in First Reading.

Makes REACH consistent with other EU regulations (like the biocidal product regulation).

Amendment by Amalia Sartori + Alessandro Foglietta, Adriana Poli Bortone

Amendment 170
ARTICLE 25 A (new)

	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.

Or. en

Justification

This is intended to protect downstream users from dangers arising from unregistered uses of a substance (Am. 121 at first reading). (Foglietta & Poli Bortone)

Amendment by Ria Oomen-Ruijten

Amendment 171
ARTICLE 27, PARAGRAPH 1

1. ***Where a substance has previously been registered less than 10 years earlier as referred to in Article 26(3), the potential registrant:***	1. ***In the case of substances previously registered less than 15 years the potential registrant shall ask the previous registrant(s) for*** the information he requires with respect to Article 10(a)(vi) and (vii) in order to register.
(a) shall, in the case of information involving tests on vertebrate animals, and	
(b) may, in the case of information not involving tests on vertebrate animals,	
request from the previous registrant(s) the information he requires with respect to Article 10(a)(vi) and (vii) in order to register.	

Or. en

Justification

Makes REACH consistent with other EU regulations (like the biocidal product regulation. According to Directive 67/548/EC for the notification of new substances, expensive studies have even unlimited protection of property rights.

Amendment by Lena Ek + Amalia Sartori

Amendment 172
ARTICLE 27, PARAGRAPH 5 A (new)

	5a. If the potential registrant fails to pay his share of the cost of a study involving tests on vertebrate animals or another study that may prevent animal testing, he shall not be able to register his substance.

Or. en

Justification

Registrants who do not pay should not be entitle to register. Identical to first reading amendment 135. (Ek)

Amendment by Ria Oomen-Ruijten

Amendment 173
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. ***The previous registrant(s) shall have*** one month from the receipt of the information referred to in paragraph 5 ***to inform the potential registrant and the Agency of the cost incurred by him for the study concerned. At the request of the potential registrant, the Agency shall take the decision to make available to him the summaries or robust study summaries, as the case may be, of the studies concerned, or the results thereof, on receipt of proof that he has paid the previous registrant(s) a share of the cost shown by the latter, calculated by following cost sharing guidance adopted by the Agency in accordance with Article 76(3)(f).***

Or. en

Justification

This amendment protects the property rights of the data owner. In case of disagreement between data-owner and data requestor, the cost sharing should be based on agency guidelines.

Amendment by Johannes Blokland + Lena Ek + Alessandro Foglietta, Adriana Poli Bortone

Amendment 174
ARTICLE 28, PARAGRAPH 1, POINTS D) A AND D) B (new)

(da) a brief general description of identified uses; as a minimum initial information on use and exposure categories as specified in section 6 of Annex VI;

(db) a list of the uses he intends to support through registration.

Or. en

(Reinstatement of amendments 139 and 368 adopted in first reading)

Justification

A downstream user (DU) requires the following data of a substance he uses in his preparations:

- is the substance going to be registered,
- who will register the substance,
- when will it be registered
- which uses are identified

If the DU has no access to all of these data or only in a very late stage he may be confronted with a 'non-registration' or a 'not identified use' and therewith left with a too short time frame to make his supplier reconsider the registration or identified use, or run the cycle of reformulation (without the non-registered substance) (Blokland)

This is necessary to enable downstream users access to adequate pre-registration data, thus enabling them to fulfil their obligations under REACH on time. Minor changes from first reading amendments 368 and 139. (Ek)

The development of an appropriate and consistent communication system based on risk will provide consumers with the necessary information and advice to enable them to use chemicals and preparations containing them safely and effectively. (Am. 368; 139). (Foglietta & Poli Bortone)

Amendment by Ria Oomen-Ruijten

Amendment 175
ARTICLE 28, PARAGRAPH 1, POINT D) A (new)

(da) a brief general description of identified uses; as a minimum initial information on use and exposure categories as specified in section 6 of Annex VI;

Or. en

Justification

Corresponds to Amendment 368 adopted in First Reading.

Under REACH the Downstream users requires the data of a substance he uses in his preparations like who will register which substance and when it will be registered and which non-confidential uses are identified. If the downstream user has no access to all these data or only in a very late stage he may be confronted with a `non registration´ or a ´not identified use´ and therewith left with a too short time frame to make his supplier reconsider the registration or the incorporation of an additional identified use, to run the cycle of reformulation and the consequent customer approval.

Amendment by Avril Doyle

Amendment 176
ARTICLE 28, PARAGRAPH 3 A (new)

3a. The Agency shall:

(a) within one month of the expiry of the deadlines referred to in paragraph 2, make a list of the substances pre-registered in accordance with those paragraphs publicly available over the Internet. The list shall comprise only the names of the substances, including their EINECS and CAS number if available;

(b) if the same substance has been previously registered less than 10 years earlier, inform the potential registrant(s) without delay of the name(s) and address(es) of the previous registrant(s)

	and of the relevant summaries or robust study summaries of the studies, as the case may be, already submitted by them.
	The available studies must be shared with the potential registrant(s).

Or. en

Justification

Reintroduces amendment 142 from the First Reading.

Amendment by Lena Ek

Amendment 177
ARTICLE 28, PARAGRAPH 5

5. The Agency ***shall by …* publish on its website a list of the substances referred to in paragraph 1(a) and (d). That list shall comprise only the names of the substances, including their EINECS and CAS number if available and other identity codes.***	5. The Agency shall ***operate a register of substances containing the information specified in Article 28 (1).***
	5a. The Agency shall publish on its website the register of substances within one month after the expiry of the period laid down in Article 28 (2), indicating:
	(a) the name of the substance and, where applicable, the group of substances, including EINECS and CAS numbers, if available;
	(b) the name and address of the manufacturer or importer or, where appropriate, the name and address of the person representing him in accordance with Article 4 as specified in section 1 of Annex VI;
	(c) a general description of identified uses; as a minimum, initial information on use and exposure in accordance with Article 28.1 (e) and (f);
	(d) the first deadline for the registration of each substance in accordance with Article

23.

Or. en

Justification

This is necessary to enable downstream users access to adequate pre-registration data, thus enabling them to fulfil their obligations under REACH on time. Slight rewording of first reading amendment 371, taking into account the clarifying that the register should be made available by the Council.

Amendment by Ria Oomen-Ruijten

Amendment 178
ARTICLE 28, PARAGRAPH 5

5. The Agency shall ***by …* publish on its website a list of the substances referred to in paragraph 1(a) and (d). That list shall comprise only the names of the substances, including their EINECS and CAS number if available and other identity codes.***	5. The Agency shall ***operate a register of substances containing the information specified in Article 28 (1).***
	5a. The Agency shall publish all pre-registered substances in the register of substances within one month after the expiry of the period laid down in Article 28 (2), indicating: ***(a) the name of the substance and, where applicable, the group of substances, including EINECS and CAS numbers, if available;*** ***(b) the name and address of the manufacturer or importer or, where appropriate, the name and address of the person representing him in accordance with Article 4 as specified in section 1 of Annex VI;*** ***(c) a general description of identified uses; as a minimum, initial information on use and exposure in accordance with Article 28.1 (e) and (f);*** ***(d) the first deadline for the registration of each substance in accordance with Article 23.***

Or. en

Justification

Corresponds to Amendment 371 adopted in First Reading.

Under REACH the downstream users requires users access to adequate pre-registration data in order to be able to make his supplier reconsider the registration or the incorporation of an additional identified use in case the supplier has not pre-registered the substance for a certain use.

Amendment by Amalia Sartori + Chris Davies

Amendment 179
ARTICLE 28, PARAGRAPH 5

5. The Agency shall by … publish on its website a list of the substances referred to in paragraph 1(a) and (d). That list shall comprise only the names of the substances, including their EINECS and CAS number if available and other identity codes.	The Agency shall by … publish on its website a list of the substances referred to in paragraph 1(a) and (d). That list shall comprise only the names of the substances, including their EINECS and CAS number if available and other identity codes. ***If the same substance has been previously registered less than 10 years earlier, the Agency shall inform the potential registrant(s) without delay of the name(s) and address(es) of the previous registrant(s) and of the relevant summaries or robust study summaries of the studies, as the case may be, already submitted by them. The available studies must be shared with the potential registrant(s).***

Or. en

Justification

Successful first reading amendment 142 to ensure liberalisation of test data after 10 years. This gives sufficient time for companies to recoup their investment and provides SMEs with the access to tests data they need to survive. (Davies)

Amendment by Caroline Lucas, Carl Schlyter, Hiltrud Breyer, Jonas Sjöstedt + Frieda Brepoels, Anders Wijkman

Amendment 180
ARTICLE 28, PARAGRAPH 5

5. The Agency shall by ...* publish on its website a list of the substances referred to in paragraph 1(a) and (d). That list shall comprise ***only*** the names of the substances, ***including*** their EINECs and CAS number if available and other identity codes.	5. The Agency shall by ...* publish on its website a list of the substances referred to in paragraph 1(a) and (d). That list shall comprise the names of the substances, their EINECs and CAS number if available and other identity codes***, and the information made available under Article 28(1a) and (4a), and where applicable, the group of the substances.***

Or. en

(Amendment 371 relevant part - first reading)

Justification

Linked to amendments 14 and 16 of the rapporteur of Article 28(1a) and (4a). Existing data from animal tests and other information that could prevent animal experimentation should be published as early as possible in order to prevent duplicate animal testing and save costs for industry, particularly SMEs. (Lucas & others)

Linked to Amendments of Article 28(1a) and (4a). Conform EP Amendment 371, the chemical group to which a substance belongs as well as existing data from animal tests and other information that could prevent animal experimentation should be published as early as possible in order to prevent duplicate animal testing and save costs for industry, particularly SMEs. This would also allow for 'cross-SIEF' data sharing. (Brepoels & Wijkman)

Amendment by Chris Davies + Caroline Lucas, Carl Schlyter, Hiltrud Breyer

Amendment 181
ARTICLE 28, PARAGRAPH 5 A (new)

	5a. The Agency shall by ...* also publish on its website a list of phase-in substances already registered without pre-registration. That list shall comprise the names of the substances, their EINECs and CAS number if available and other identity codes, and,

where applicable, the group of the substances.

**** 19 months after the entry into force of this Regulation***

Or. en

Justification

Successful first reading amendment linked to the amendment of Article 28(5) intended to ensure data sharing and, where applicable, read-across from the grouping of substances in order to prevent duplicate animal testing and save costs for industry, particularly SMEs. (Davies)

Linked to the amendment by the same authors to Article 28(5). A list of phase-in substances that have been registered without pre-registration, and the chemical group to which such substances belong should also be published as early as possible to ensure data sharing and, where applicable, read-across from the grouping of substances in order to prevent duplicate animal testing and save costs for industry, particularly SMEs. (Lucas & others)

Amendment by Johannes Blokland

Amendment 182
ARTICLE 28 A (new)

Register of substances

1. The Agency shall operate a register of substances containing the information specified in Article 28.

2. The Agency shall publish all pre-registered substances in the register of substances within one month after the expiry of the period laid down in Article 28 (2), indicating:

(a) the name of the substance and, where applicable, the group of substances, including EINECS and CAS numbers, if available;

(b) where applicable, the name and address of the manufacturer or importer or the third party representative, provided that consent pursuant to Article 28 (1) (ba) has been given;

(c) a brief general description of identified uses in accordance with Article 28 (1) (ca);

(d) the first deadline for the registration of each substance in accordance with Article 23.

3. The Agency shall publish the name of the substance and, where applicable, the group of substances, including EINECS and CAS numbers, if available, in respect of which late notification has been requested, immediately following the receipt of such requests.

4. Within one month of the expiry of the late notification period pursuant to Article 28(2), the Agency shall update the register of substances to include those substances for which late pre-registrations have been received.

5. The Agency shall publish together with the publication of the register of substances, pursuant to paragraphs 1 and 4, a request to anyone who owns studies on vertebrate animals which are not publicly available to submit indications on the availability of such studies.

6. Anyone who owns such studies may send indications on the availability of such studies to the Agency, within six months of the publication of the register of substances, pursuant to paragraph 4, and the Agency shall include this information in the database in accordance with Article 28(5). Such studies shall be used in accordance with Article 30.

Or. en

(Partial reinstatement of amendment 371 adopted in first reading)

Justification

A downstream user (DU) requires the following data of a substance he uses in his preparations:

- *is the substance going to be registered,*

- *who will register the substance,*
- *when will it be registered*
- *which uses are identified*

If the DU has no access to all of these data or only in a very late stage he may be confronted with a 'non-registration' or a 'not identified use' and therewith left with a too short time frame to make his supplier reconsider the registration or identified use, or run the cycle of reformulation (without the non-registered substance)

Amendment by Chris Davies, Frédérique Ries + Ria Oomen-Ruijten + Richard Seeber

Amendment 183
ARTICLE 29, PARAGRAPH 1

1. All manufacturers ***and*** importers who have submitted information to the Agency in accordance with Article 26 for the same phase-in substance shall be participants in a substance information exchange forum (SIEF).	1. All manufacturers**,** importers ***and downstream users*** who have submitted information to the Agency in accordance with Article 26 for the same phase-in substance shall be participants in a substance information exchange forum (SIEF).

Or. en

Justification

Successful First Reading amendment. (Davies)

Downstream Users who have shared data should also overtly be recognised as having access to SIEF. This right is actually implicitly recognised in Art 28 paragraph 6, which states that manufacturers, importers and downstream users may submit information on substances "with the intention of being part of the substance information exchange forum…" It is further implicitly recognised in Art 30 paragraph 2 where "the Agency shall specify which registrant or downstream user shall perform the test" when SIEF participants cannot agree on which participant will conduct a test. (Oomen-Ruijten)

For downstream users who, pursuant to Art. 28(6) of the common position, provide necessary data for registration, comparable participation in SIEFs should be possible. In Article 30(2), likewise, downstream users are specifically mentioned in connection with registration. This amendment therefore serves only to achieve the necessary consistency of the text of the regulation and to correct an error which evidently occurred in making the numerous changes involved in producing the common position. (Seeber)

Amendment by Marie-Noëlle Lienemann, Anne Ferreira

Amendment 184
ARTICLE 29, PARAGRAPH 1

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).

Or. fr

Justification

'Formulators' must also have access to the SIEF so that they can share their data on risks and exposure.

Amendment by Caroline Lucas, Carl Schlyter, Hiltrud Breyer, Jonas Sjöstedt

Amendment 185
ARTICLE 30, PARAGRAPH 1, SUBPARAGRAPH 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 study not involving tests on vertebrate animals is available within the SIEF, a SIEF participant may request that study by … **.	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 on vertebrate animals is available, a participant of that SIEF shall request that study by …**. If a relevant study not involving tests on vertebrate animals is available within the SIEF, a SIEF participant may request that study by …**.

Or. en

(Modified reinstatement of the Commission text)

Justification

Linked to the amendment of Article 28(5) and 28(5a). In order to prevent duplication of animal testing and save costs for industry, particularly SMEs, SIEFs should also be required to consult the lists published by the Agency to ensure data sharing and, where applicable, read-across from the grouping of substances.

Amendment by Lena Ek + Amalia Sartori

Amendment 186
ARTICLE 30, PARAGRAPH 1, SUBPARAGRAPH 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 study not involving tests on vertebrate animals is available within the SIEF, a SIEF participant may request that study by …**.***	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 is available within the SIEF, a participant of that SIEF shall request that study by …**.

Or. en

Justification

*All tests (vertebrates and non-vertebrates) should be shared. Identical to first reading amendment 149****.***

Amendment by Ria Oomen-Ruijten

Amendment 187
ARTICLE 30, PARAGRAPH 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	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 ***within two months of the deadline set in Article 26(2)***. If a relevant study not involving tests on vertebrate animals is available within the SIEF, a SIEF participant may request that study ***within two months of the deadline set in Article 26(2)***.	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 not involving tests on vertebrate animals is available within the SIEF, a SIEF participant may request that study.
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 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.	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.

Or. en

Justification

It is not feasible for companies or others concerned to ask within 2 months after publication of the list with pre-registered substances the relevant studies of all other SIEF-participants. with phase-in-substances decisions concerning possible tests will be done only, when the applicable deadlines for registration of the substance is expired. Therefore it is not necessary to set a deadline.

Amendment by Chris Davies

Amendment 188
ARTICLE 30, PARAGRAPH 1, SUBPARAGRAPH 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 study not involving tests on vertebrate animals is available within the SIEF, a SIEF participant may request that study by …**.	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 on vertebrate animals is available, a participant of ***the*** SIEF shall request that study by …**. If a relevant study not involving tests on vertebrate animals is available within the SIEF, a SIEF participant may request that study by …**.

Or. en

Justification

Reducing duplication of animal tests. Linked to Amendments of Article 28(5) and (5a).

Amendment by Amalia Sartori + Lena Ek

Amendment 189
ARTICLE 30, PARAGRAPH 1 A (new)

	1a. Failure to make available vertebrate animal data or other information that could prevent animal testing to the Agency will result in potential registrants forfeiting their right to register the substance concerned.

Or. en

Justification

This requirement strengthens the principle of compulsory data sharing. Identical to first reading amendment 151. (Ek)

Amendment by Amalia Sartori + Lena Ek

Amendment 190
ARTICLE 30, PARAGRAPH 1 B (new)

1b. If the other participant(s) fail to pay their share of the cost, they shall not be able to register their substance.

Or. en

Justification

Registrants who do not pay should not be entitled to register. Identical to first reading amendment 152. (Ek)

Amendment by Frieda Brepoels, Anders Wijkman + Chris Davies

Amendment 191
ARTICLE 30, PARAGRAPH 2

2. If a relevant study involving tests is not available ***within the SIEF***, only one study shall be conducted per information requirement within each SIEF by one of its participants acting on behalf of the others. They shall take all reasonable steps to reach an agreement within a deadline set by the Agency as to who is to carry out the test on behalf of the other participants and to submit a summary or robust study summary to the Agency. If no agreement is reached, the Agency shall specify which registrant or downstream user shall perform the test. All participants of the SIEF who require a study shall contribute to the costs for the elaboration of the study with a share corresponding to the number of participating potential registrants. Those participants that do not carry out the study themselves shall have the right to receive the full study report within two weeks following payment to the participant that carried out the study.	2. If a relevant study involving tests is not available, only one study shall be conducted per information requirement within each SIEF by one of its participants acting on behalf of the others. They shall take all reasonable steps to reach an agreement within a deadline set by the Agency as to who is to carry out the test on behalf of the other participants and to submit a summary or robust study summary to the Agency. If no agreement is reached, the Agency shall specify which registrant or downstream user shall perform the test. All participants of the SIEF who require a study shall contribute to the costs for the elaboration of the study with a share corresponding to the number of participating potential registrants. Those participants that do not carry out the study themselves shall have the right to receive the full study report within two weeks following payment to the participant that carried out the study.

Or. en

Justification

Linked to Amendment of Article 30(1). (Brepoels & Wijkman)

Reducing duplication of animal tests. Linked to Amendment of Article 30(1). (Davies)

Amendment by Lena Ek

Amendment 192
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.	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) ***in a homogeneous part of the article***, 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.

Or. en

Justification

This clarifies the interpretation of the 0.1% threshold. Analogous to the corresponding part of amendment XX on paragraph 7(2)(b).

Amendment by Anders Wijkman, Frieda Brepoels, Erna Hennicot-Schoepges, Péter Olajos

Amendment 193
ARTICLE 33 A (new)

	1. Any manufacturer or importer of a substance listed in Annex XIII, 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 30 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.

Or. en

Justification

In order to ensure that downstream users or consumers obtain the necessary information about substances or articles containing such a substance, this article is needed. Only when the information is made available, is it possible to assess the effects of the substance on human health or the environment with respect to the operations and uses indicated in that request. Amendment 366 from the first reading.

Amendment by Anders Wijkman, Frieda Brepoels, Erna Hennicot-Schoepges, Péter Olajos

Amendment 194
ARTICLE 33 A (new)

1. Suppliers who incorporate into an article a substance or preparation and those who subsequently handle or further process that article shall on request pass on the following information to any recipient of

the article, without prejudice to Article 32(4). The same duty applies to importers of articles.

(i) safety data sheet(s) according to Article 31; and/or

(ii) if a safety data sheet is not established, any relevant information covered by Article 32(1) as a minimum.

2. Any producer or importer of an article shall upon request provide information on the substances present in an article produced or imported by him to a consumer.

Producers or importers shall, on request and within 30 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.

Or. en

Justification

Amendments 166 and 366 from first reading.

Amendment by Urszula Krupa + Gyula Hegyi, Dorette Corbey, Anne Ferreira, Dan Jørgensen, Åsa Westlund + Lena Ek

Amendment 195
ARTICLE 33 A (new)

1. Suppliers who incorporate into an article a substance or preparation and those who subsequently handle or further process that article shall on request pass on the following information to any recipient of the article, without prejudice to Article 32(4). The same duty applies to importers of articles.

(i) safety data sheet(s) according to Article 31; and/or

(ii) if a safety data sheet is not established, any relevant information covered by Article 32(1) as a minimum.

2. Any producer or importer of an article shall upon request provide information on the substances present in an article produced or imported by him to a consumer.

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.

Or. en

Justification

Manufacturers, retailers and consumers should be able to find out whether specific substances are contained in an article. The information will be provided solely ***on request,*** *which will render the process simple and manageable.*

It will not entail any extra burden on the system as retailers and consumers will only have the right to ask for information that is already being generated under REACH.

This amendment is an improved version of the compromise package on access to information/transparency agreed by a majority of political groups (EP amendment 366).

Amendment by Ria Oomen-Ruijten

Amendment 196
ARTICLE 36, PARAGRAPH 3

3. For registered substances, the manufacturer, importer or downstream user shall comply with the obligation laid down in Article 13 before he next supplies the substance on its own or in a preparation to the downstream user making the request referred to in paragraph 2, provided that the request was made at least one month before the supply, or within 1 month after the	3. For registered substances, the manufacturer, importer or downstream user shall comply with the obligation laid down in Article 13 before he next supplies the substance on its own or in a preparation to the downstream user making the request referred to in paragraph 2***, provided that this use is supported, and*** provided that the request was made at least one month before the supply, or within 1 month after the

request, whichever is the later.

For phase-in substances, the manufacturer, importer or downstream user shall comply with this request and with the obligations laid down in Article 13 before the relevant deadline in Article 21, provided that the downstream user makes his request at least 12 months before the deadline in question.

request, whichever is the later.

For phase-in substances, the manufacturer, importer or downstream user shall comply with this request and with the obligations laid down in Article 13 before the relevant deadline in Article 21, ***provided that this use is supported, and*** provided that the downstream user makes his request at least 12 months before the deadline in question.

Or. en

Justification

A producer or supplier only has to comply with the obligations of Art. 13 for the uses he actually supports. Otherwise he would have to consider all uses the downstream user is announcing, independent of the fact that he supports it or not.

Amendment by Carl Schlyter, Caroline Lucas, Hiltrud Breyer, Jonas Sjöstedt + Gyula Hegyi, Dorette Corbey, Anne Ferreira, Dan Jørgensen, Åsa Westlund + Lena Ek

Amendment 197
ARTICLE 36, PARAGRAPH 4, POINT (C)

(c) the downstream user uses the substance or preparation in a total quantity of less than 1 tonne per year;

deleted

Or. en

(New amendment - Rule 62(2)(c)), linked to recital 54)

Justification

As a result of the 1 tonne threshold introduced by Council, downstream users would only have to prepare a chemical safety report (CSR) for uses >1 tonne, if not covered by the CSR of the manufacturer. No such use threshold is foreseen for the CSR by manufacturers. This new clause would create a perverse incentive for manufacturers to exclude uses below 1 tonne from their CSR, as it would not result in any obligations for downstream users. This creates a serious loophole with regard to safety information for small uses. (Schlyter & others)

Establishing a 1 tpa threshold would create a serious loophole for many uses of chemicals. Deleting the threshold of 1 tpa ensures that the downstream users have the right to obtain the safety information from the manufacturers in order to handle the substance safely and

improve their products. (Hegyi & others + Ek)

Amendment by John Bowis, Ria Oomen-Ruijten

Amendment 198
ARTICLE 36, PARAGRAPH 8 A (new)

8a. Without prejudice to paragraphs 1 to 8 and without prejudice to Title IX, downstream users should avoid the use of substances of high concern, identified in accordance with the procedure laid down in Article 58, either on their own, in preparations or in articles destined for use by the general public, unless it can be demonstrated that:

a) the substance is present below a concentration limit of 0.1%, or

b) the use will not present unacceptable risks to human health or the environment, or

c) technically and economically feasible and validated alternatives which pose lower risks to humans or the environment in the intended use are not available.

Or. en

Amendment by Cristina Gutiérrez-Cortines

Amendment 199
ARTICLE 36, PARAGRAPH 8 A (new)

Without prejudice to paragraphs 1 to 8 and to Title IX, downstream users should aim to avoid the use of substances of high concern, identified in accordance with the procedure laid down in Article 58, either or their own, in preparations or in articles destined for use by the general public, unless it can be demonstrated that:

a) the substance is present below a concentration limit of 0.1% in line with

Articles 14(2) and 55(6) of this Regulation or

b) the use will not present unacceptable risks to human health or the environment as indicated by the Safety Data Sheet or

c) technically and economically viable alternatives which pose lower risks to humans or the environment are not available or

d) the substitute substance is in the hands of a single supplier.

Or. en

Justification

This amendment is proposed in order to find a compromise with Council on the substitution issue.

Amendment by Avril Doyle + Amalia Sartori

Amendment 200
ARTICLE 37 A (new)

Procedure for compulsory notification of information by SMEs

1. Where the downstream user is an SME, within the meaning of Article 3(34), the notification procedure provided for in Article 37 shall apply, with the exception of paragraphs 2(f) and 3, 4 and 5 thereof.

2. Further more detailed tests on vertebrates and non-vertebrates which prove necessary as a result of the Agency's assessment shall be identified where possible by the Agency from among existing tests.

3. If the tests referred to in the previous paragraph do not already exist, the Agency shall instruct the Member State in which the SME has its head office to carry out the tests. Results which are useful to the safety assessments shall be notified to the SME

following conclusion of the tests.

4. The Agency shall as soon as possible notify the applicant (SME) and the Member State in which it has its head office if the results of the tests are negative with a view to blocking the use of the substance which has been tested.

5. The downstream user SME shall be required to update the information reported under paragraph 1 as soon as any change occurs in this information.

6. A downstream user SME shall report to the Agency in the format specified by the Agency in accordance with Article 108 if his classification of a substance is different from that of his supplier.

7. Reporting in accordance with paragraphs 1 to 6 shall not be required in respect of a substance, on its own or in a preparation, used by the downstream user SME in quantities of less than one tonne per year.

Or. en

Justification

This specific procedure for SMES enables them to protect their industrial secrets for specific uses of chemical substances; by giving a special role to the Agency it limits unnecessary tests. (Doyle)

Amendment by Chris Davies + Frieda Brepoels + Caroline Lucas, Carl Schlyter, Hiltrud Breyer

Amendment 201
ARTICLE 39, PARAGRAPH 1

1. The Agency shall examine any testing proposal set out in a registration or a downstream user report for provision of the information specified in Annexes ***IX and*** X for a substance. Priority shall be given to registrations of substances which have or may have PBT, vPvB, sensitising and/or	1. The Agency shall examine any testing proposal set out in a registration or a downstream user report for provision of the information specified in Annexes ***VII to*** X ***which involves tests on vertebrate animals*** for a substance. Priority shall be given to registrations of substances which have or

carcinogenic, mutagenic or toxic for reproduction (CMR) properties, or substances classified as dangerous according to Directive 67/548/EEC above 100 tonnes per year with uses resulting in widespread and diffuse exposure.	may have PBT, vPvB, sensitising and/or carcinogenic, mutagenic or toxic for reproduction (CMR) properties, or substances classified as dangerous according to Directive 67/548/EEC above 100 tonnes per year with uses resulting in widespread and diffuse exposure.

Or. en

Justification

Promotion of non-animal testing. Successful First Reading amendment 175 intended to ensure that animal tests take place only when absolutely necessary. (Davies)

In order to prevent animal testing and save costs for industry, particularly SMEs, and as data from animal tests should only be provided if necessary for the safety assessment of a substance, any testing proposals for provision of the information specified in Annexes VII and VIII should also be examined by the Agency. Amendment first reading 175. (Brepoels + Lucas & others)

Amendment by Caroline Lucas, Carl Schlyter, Hiltrud Breyer, Jonas Sjöstedt

Amendment 202
ARTICLE 39, PARAGRAPH 2, INTRODUCTORY PART

2. On the basis of the examination under ***paragraph 1***, the Agency shall draft one of the following decisions and that decision shall be taken in accordance with the procedure laid down in Articles 49 and 50:	2. On the basis of the examination under ***paragraphs 1, 1a and 1b***, the Agency shall draft one of the following decisions and that decision shall be taken in accordance with the procedure laid down in Articles 49 and 50:

Or. en

(Modified reinstatement of the Commission text)

Justification

To ensure coherence with amendments 22 and 23 by the rapporteur.

Amendment by Gyula Hegyi, Dorette Corbey, Anne Ferreira, Dan Jørgensen, Åsa Westlund + Evangelia Tzampazi + Carl Schlyter, Caroline Lucas, Hiltrud Breyer, Jonas Sjöstedt + Urszula Krupa

Amendment 203
ARTICLE 40, PARAGRAPH 4

4. The registrant shall submit the information required to the Agency ***by the*** deadline set.	4. The registrant shall submit the information required to the Agency ***within a reasonable*** deadline ***to be*** set ***by the Agency. This deadline shall not exceed six months. The Agency shall withdraw the registration number if the registrant fails to submit the relevant information within the deadline set***.

Or. en

Justification

Council has failed to provide a clear deadline for submission of information as the Parliament has proposed in Amendment 180. (Hegyi & others + Tzampazi + Krupa)

A registrant might have passed the completeness check as stipulated in Article 20, but the information requirements might nevertheless not be fulfilled. Non-compliance with the information requirements should have clear consequences. Registrants should have no more than one chance within a maximum of six months to correct flawed registrations. This could ensure good quality and avoid never-ending disputes between the authorities and registrants. The wording is in line with the provisions for the completeness check in Article 20. (Schlyter & others)

Amendment by Guido Sacconi

Amendment 204
ARTICLE 40, PARAGRAPH 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)***.	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)***.

Or. en

Justification

The amendment is needed to align the text to the provisions of the new "commitology" Decision, and in particular to replace the ordinary "regulatory committee" procedure with the "regulatory committee with scrutiny", since the measures concerned are measures of general scope designed to amend non-essential elements of the draft legislation.

Amendment by Caroline Lucas, Carl Schlyter, Hiltrud Breyer

Amendment 205
ARTICLE 42, PARAGRAPH 2, POINTS (A) AND (B)

(a) by … for all registrations received by … containing proposals for testing in order to fulfil the information requirements in Annexes ***IX and*** X;	(a) by … for all registrations received by … containing proposals for testing in order to fulfil the information requirements in Annexes ***VII to*** X;
(b) by … for all registrations received by … containing proposals for testing in order to fulfil the information requirements in ***Annex IX only***;	(b) by … for all registrations received by … containing proposals for testing in order to fulfil the information requirements in ***Annexes VII to IX***;

Or. en

(Amendment 186 - first reading)

Justification

Linked to the amendment to Article 39(1) by the same authors. In order to prevent animal testing and save costs for industry, particularly SMEs, and as data from animal tests should only be provided if necessary for the safety assessment of a substance, any testing proposals for provision of the information specified in Annexes VII and VIII should also be examined by the Agency.

Amendment by Guido Sacconi

Amendment 206
ARTICLE 46, PARAGRAPH 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	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)***.	with the procedure referred to in Article ***132(3a)***.

Or. en

Justification

The amendment is needed to align the text to the provisions of the new "commitology" Decision, and in particular to replace the ordinary "regulatory committee" procedure with the "regulatory committee with scrutiny", since the measures concerned are measures of general scope designed to amend non-essential elements of the draft legislation.

Amendment by Caroline Lucas, Carl Schlyter, Hiltrud Breyer, Jonas Sjöstedt + Frieda Brepoels, Anders Wijkman + Philippe Busquin + Dan Jørgensen

Amendment 207
ARTICLE 49, PARAGRAPH 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.	1. The Agency shall notify any draft decision under Articles 39, 40 or 45 to the registrant(s) or downstream user(s) concerned, ***together with any comments by stakeholders and the European Centre for the Validation of Alternative Methods (ECVAM),*** 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.

Or. en

(Amendment 206 - first reading)

Justification

For reasons of transparency, the comments by ECVAM and other stakeholders should also be

published. (Lucas & others)

EP Amendment 206 - first reading. Linked to Amendments to Article 39(1), (1a) and (2). (Brepoels & Wijkman)