EUROPEAN PARLIAMENT

2004 *2009*

Committee on Petitions

2003/0256(COD)

18.7.2005

OPINION

of the Committee on Petitions

for the Committee on the Environment, Public Health and Food Safety

on the proposal for a regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) No …/… on Persistent Organic Pollutants
(COM(2003)0644 – C5-0530/2003 – 2003/0256(COD))

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SHORT JUSTIFICATION

1. Background

The current legislative system for chemicals has been largely unable to ensure an adequate level of protection of human health and the environment from the risks associated with the production and use of chemical substances. The lack of available knowledge about the properties of approximately 100.000 so-called existing substances, which were placed on the market prior to 1981 gives rise to concerns, in particular. Thus, there has been broad consensus on the need for a new EU regulatory framework, which would improve the protection of human health and the environment, while at the same time maintaining the competitiveness and enhancing the innovative capacity of the EU chemicals industry.

While the objectives of the new legislative framework have been endorsed by the major stakeholders during the extensive consultation process conducted by the Commission in the run-up to the publication of the proposal, there have been heated debates, mainly among technical experts and lobbyists, on how the legislation should be shaped in order to best achieve these goals. Yet, it will be the ordinary citizens, who will be primarily affected by the forthcoming legislation. If effective, the new legislation would undoubtedly have a direct impact on the health and quality of life of millions.

The Committee on Petitions has received petitions on this subject, in which concerns are raised in relation to different aspects of the Commission's proposal. Altogether, they were supported by more than 578.000 citizens, who signed the petitions. The Committee wishes to make their voices heard alongside the expert and technical debate and therefore decided to draw up the present opinion. It should enable the European Parliament to take the public's concerns into account during the legislative process.

According to the petitions received, two issues appear to be of particular importance to EU citizens, namely a reduction of exposure of wildlife and humans to dangerous chemicals on the one hand and the need to reduce animal testing of chemicals, as far as possible, on the other.

2. Exposure to hazardous substances

The petition

Petition 960/2004, which was signed by over 78.000 mainly female citizens, refers to certain hazardous chemicals, which are known to be capable of causing adverse effects on both wildlife and humans. Among today's most dangerous chemical pollutants are those that are persistent and are often also bioaccumulative and toxic. Vast amounts of these chemicals have been released into the environment, where they remain stable and accumulate over time in fatty tissues of animals and humans. There is increasing scientific evidence that some of them are linked to a broad range of adverse health impacts, including genetic and reproductive damage, cancers and neurological disorders. The greatest concern lies in the impact of

maternal exposures in pregnancy, as babies are affected due to the transfer of these chemicals across the placenta and via breast milk. The petitioners demand that the forthcoming legislation addresses these substances and effectively reduces exposure in order to protect the health of people and wildlife across Europe.

Recommendations

The Committee on Petitions has great sympathy for the petitioners' concerns. It considers that while the REACH legislation as proposed by the Commission would significantly improve chemicals safety overall, its provisions concerning the most dangerous substances, so called substances of very high concern, need to be strengthened in order to achieve the aim to give improved protection to human health and the environment. Under the proposed system (Article 57 paragraph 2), these substances could continue to be used, even if safer alternatives are available. Reflecting the petitioners' concerns, the Committee on Petitions proposes a set of amendments with a view to introducing the "substitution principle". Thus, the use of substances of very high concern should only be authorised for a limited time, if no safer alternatives are available and if the chemical in question serves an essential societal need. This would lead to a progressive phase-out of the most dangerous chemicals and spur innovation towards safer alternatives. A second set of amendments proposed by the Committee responds to the petitioners' call for special protection of particularly vulnerable parts of the population such as children and the elderly.

3. Animal testing

The petition

The authors of petition 841/2004, signed by half a million Europeans, agree that there is a need for a new regulatory framework to improve chemicals safety. However, they are concerned that REACH could lead to an increase in the numbers of animals used in toxicity testing. In their view, animal experiments are not only cruel and unethical but also unreliable as predictors of chemical toxicity to humans, since the results cannot simply be extrapolated from animals to humans. By contrast, non-animal testing techniques would offer a cheaper, faster, more humane and accurate way forward. Therefore, animal testing should be eliminated from the testing regime and replaced with non-animal alternatives. To this end, the timely development and validation of alternative testing methods should be prioritised.

Recommendations

The REACH proposal contains a number of provisions that have been developed with a view to limiting animals testing. They include the use of qualitative models and obligatory data sharing. However, the Committee believes that further measures should be introduced to promote non-animal testing. Firstly, it is of utmost importance that sufficient resources are allocated to the development and validation of alternative testing methods. Therefore, part of the fees to be paid for the registration of substances should be earmarked for this purpose.

Secondly, a committee for non-animal test methods should be set up within the newly established Chemicals Agency. This committee would be responsible for developing a strategy to replace animal-tests and for allocating the funds raised via fees. Finally, it is suggested that the European Centre for the Validation of Alternative Methods (ECVAM) should be consulted when testing proposals are considered that include vertebrate animal tests. This way, up-to-date expert knowledge on alternative methods is made available to the competent authorities, who evaluate the testing proposals, which may help avoid unnecessary animal tests.

AMENDMENTS

The Committee on Petitions calls on the Committee on the Environment, Public Health and Food Safety as the committee responsible, to incorporate the following amendments in its report:

Text proposed by the Commission[1]	Amendments by Parliament
Amendment 1 Recital 4	
(4) To preserve the integrity of the internal market and ensure a high level of protection for human health, especially the health of workers ***and the environment***, it is necessary to ensure that substances manufactured in the Community comply with Community law, even if they are exported.	(4) To preserve the integrity of the internal market and ensure a high level of protection for ***the environment and*** human health, especially the health of workers ***and that of vulnerable population groups,*** it is necessary to ensure that substances manufactured in the Community comply with Community law, even if they are exported.
Justification	
REACH should provide for special protection of those parts of the population that are particularly vulnerable to chemical exposure.	
Amendment 2 Recital 34 a (new)	
	(34a) An important objective of the new legislation is the promotion of non-animal

[1] Not yet published in OJ.

testing. The Commission, Member States and industry should therefore allocate sufficient resources to the development, validation and acceptance of non-animal tests. An appropriate part of the fees paid to the Agency for the registration of substances should be earmarked for that purpose.

Justification

The promotion of non-animal testing should be highlighted as an important objective of REACH. The allocation of sufficient resources to the development of alternative testing methods is a necessary measure to achieve this aim.

Amendment 3
Recital 47 a (new)

(47a) In order to prevent unnecessary animal tests, the European Centre for the Validation of Alternative Methods (ECVAM) should be consulted by the competent authorities in the course of the examination of testing proposals that include vertebrate animal tests.

Justification

The consultation of ECVAM would ensure that up-to-date expert knowledge on alternative methods is made available to the competent authorities who evaluate the testing proposals, which may help avoid unnecessary animal tests and save costs.

Amendment 4
Recital 52

(52) To ensure a sufficiently high level of protection for human health and the environment, substances with properties of very high concern should ***be treated in a precautionary manner which requires enterprises using them to demonstrate to the granting authority that the risks are adequately controlled. If this is not the case, uses may still*** be authorised if	(52) To ensure a sufficiently high level of protection for human health***, in particular the health of workers and vulnerable population groups,*** and the environment, substances with properties of very high concern should ***only*** be authorised if enterprises show that the benefits to society from the use of the substance ***significantly*** outweigh the risks connected with its use, ***if***

enterprises show that the benefits to society from the use of the substance outweigh the risks connected with its use ***and*** there are no suitable alternative substances or technologies. 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.	there are no suitable alternative substances or technologies ***and if 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.

Justification

Vulnerable populations should be protected in particular. The authorisation procedure will only ensure a high level of protection, if it provides for the substitution of substances of very high concern with safer alternatives. Thus, the use of substances of very high concern should only be authorised, if no safer alternatives are available, if the chemical in question serves an essential societal need and if adequate measures to control the risks are put in place.

Amendment 5
Article 3, point 29 a (new)

29a. Vulnerable population groups means susceptible humans including the new-born, infants, children, pregnant women, nursing mothers and elderly persons.

Justification

REACH should provide for special protection of those parts of the population that are particularly vulnerable to chemical exposure.

Amendment 6
Article 28, paragraph 1 a (new)

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

Justification

Mandatory sharing of vertebrate animal test data should be linked to penalties in case of refusal to share data in order to avoid duplicate animal testing.

Amendment 7
Article 39, paragraph 1 a (new)

	1a. The competent authority shall consult the European Centre for the Validation of Alternative Methods (ECVAM) on any testing proposal that includes tests on vertebrate animals.

Justification

The consultation of ECVAM would ensure that up-to-date expert knowledge on alternative methods is made available to the competent authorities, who evaluate the testing proposals, which may help avoid unnecessary animal tests and save costs.

Amendment 8
Article 39, paragraph 2, introductory part

2. On the basis of the examination under paragraph 1, the competent authority shall draft one of the following decisions and that decision shall be taken in accordance with the procedure laid down in Articles 48 and 49	2. On the basis of the examination under paragraph 1 ***and taking into account, where appropriate, the results of the consultation under paragraph 1a***, the competent authority shall draft one of the following decisions and that decision shall be taken in accordance with the procedure laid down in Articles 48 and 49:

Justification

This amendment is linked to the amendment of Article 39, paragraph 2, introductory part.

Amendment 9
Article 52

The aim of this Title is to ensure ***the good functioning of the internal market while assuring that the risks from substances of***	The aim of this Title is to ensure ***that substances of very high concern are replaced by safer alternative substances or***

very high concern are properly controlled or that these substances are replaced by suitable alternative substances or technologies.	***processes, where available. Where no such alternative is available, a substance shall be banned, unless it can be demonstrated that the benefits to society from its use significantly outweigh the risks. Where this is the case, the aim of this Title is to ensure that the risks are properly controlled and that the development of alternatives is encouraged.***

Justification

The authorisation procedure will only ensure a high level of protection, if it provides for the substitution of substances of very high concern with safer alternatives. Thus, the use of substances of very high concern should only be authorised, if no safer alternatives are available, if the chemical in question serves an essential societal need and if adequate measures to control the risks are put in place.

Amendment 10
Article 57, paragraph 2

2. An authorisation shall be granted if the risk to human health or the environment from the use of a substance arising from the intrinsic properties specified in Annex XIII is adequately controlled in accordance with Annex I, section 6, and as documented in the applicant's chemical safety report.	***deleted***
The Commission shall not consider the following:	
(a)risks to human health and the environment of emissions of the substance from an installation for which a permit was granted in accordance with Council Directive 96/61/EC 49 ;	
(b) risks to and via the aquatic environment of discharges of the substance from a point source governed by the requirement for prior regulation referred to in Article 11(3) and legislation adopted under Article 16 of Directive 2000/60/EC of the European Parliament and of the Council 50;	
(c) risks to human health arising from the	

use of a substance in a medical device regulated by Council Directive 90/385/EEC 51, Council Directive 93/42/EEC52 or Directive 98/79/EC of the European Parliament and of the Council.

Justification

The deletion of this Article is linked to the introduction of the substitution principle through the amendment to Article 52 and the amendment to Article 57, paragraph 3, introductory part, respectively. Unless this Article is deleted, substances of very high concern could continue to be used and released, even if there are no significant socio-economic benefits arising from their use and even if safer alternatives would be available.

Amendment 11
Article 57, paragraph 3, introductory part

3. ***If an authorisation cannot be granted under paragraph 2,*** an authorisation ***may*** be granted if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance ***and*** if there are no suitable alternative substances or technologies. This decision shall be taken after consideration of all of the following elements:	3**.** An authorisation ***shall only*** be granted if it is shown that socio-economic benefits ***significantly*** outweigh the risk to human health or the environment arising from the use of the substance, if there are no suitable alternative substances or technologies ***and if the risk from the use of a substance is adequately controlled in accordance with Annex I, section 6, and as documented in the applicant's chemical safety report.*** This decision shall be taken after consideration of all of the following elements:

Justification

The authorisation procedure will only ensure a high level of protection if it provides for the substitution of substances of very high concern with safer alternatives. Thus, the use of substances of very high concern should only be authorised if no safer alternatives are available, if the chemical in question serves an essential societal need and if adequate measures to control the risks are put in place.

Amendment 12
Article 57, paragraph 7, point (c) a (new)

	(ca) the duration for which the authorisation is granted;

Justification

Authorisations for the use of substances of very high concern should be time-limited in order to encourage research and innovation towards safer alternatives.

Amendment 13
Article 65, paragraph 1, subparagraph 1

1. When there is an unacceptable risk to ***human health or*** the environment arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Community-wide basis, Annex XVI shall be amended in accordance with the procedure referred to in Article 130(3) by adopting new restrictions, or amending current restrictions in Annex XVI, for the manufacture, use or placing on the market of substances on their own, in preparations or in articles, pursuant to the procedure set out in Articles 66 to 70.	1. When there is an unacceptable risk to the environment ***or human health, including the health of vulnerable population groups*****,** arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Community-wide basis, Annex XVI shall be amended in accordance with the procedure referred to in Article 130(3) by adopting new restrictions, or amending current restrictions in Annex XVI, for the manufacture, use or placing on the market of substances on their own, in preparations or in articles, pursuant to the procedure set out in Articles 66 to 70.

Justification

REACH should provide for special protection of those parts of the population that are particularly vulnerable to chemical exposure.

Amendment 14
Article 72, paragraph 1, point (d a) (new)

	(da) a Committee for Non-Animal Test Methods, which shall be responsible for developing a strategy for the gradual phase-out of animal tests and for allocating the funds, provided through registration fees, to the development and validation of non-animal test methods.

Justification

This committee should ensure strategic planning with a view to accelerating the development, validation and regulatory acceptance of non-animal test methods. It should also be responsible for allocating funds to the implementation of the strategic plan.

Amendment 15
Article 95, paragraph 1 a (new)

Part of the fee shall be allocated to the development of non-animal test methods.

Justification

Increased financial resources should be made available to promote the use of non-animal test methods.

PROCEDURE

Title	Proposal for a regulation of the European Parliament and of the Council on 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
References	COM(2003)0644 – C5-0530/2003 – 2003/0256(COD)
Committee responsible	ENVI
Committee asked for its opinion Date announced in plenary	PETI 9.6.2005
Enhanced cooperation	
Draftsman Date appointed	David Hammerstein Mintz 24.5.2005
Discussed in committee	15.6.2005
Date amendments adopted	13.7.2005
Result of final vote	for: 14 against: 1 abstentions: 0
Members present for the final vote	Robert Atkins, Inés Ayala Sender, Michael Cashman, Proinsias De Rossa, Janelly Fourtou, Elly de Groen-Kouwenhoven, David Hammerstein Mintz, Mairead McGuinness, Maria Matsouka, Manolis Mavrommatis, Marie Panayotopoulos-Cassiotou, Andreas Schwab
Substitutes present for the final vote	Marie-Hélène Descamps
Substitutes under Rule 178(2) present for the final vote	Albert Deß, Doris Pack