UNION EUROPEENNE DE L'ARTISANAT ET DES PETITES ET MOYENNES ENTREPRISES
EUROPÄISCHE UNION DES HANDWERKS UND DER KLEIN- UND MITTELBETRIEBE
EUROPEAN ASSOCIATON OF CRAFT, SMALL AND MEDIUM-SIZED ENTERPRISES
UNIONE EUROPEA DELL' ARTIGIANATO E DELLE PICCOLE E MEDIE IMPRESE

AMENDMENTS proposed by UEAPME TO The COUNCIL COMMON POSITION on REACH

Amendment 1 Recital 4 bis new	
	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.
It is of great importance to guarantee the competitiveness of European enterprises. **EP Amendments n 416**.	

Amendment 2 Recital 26 A new	
	In the light of the particular circumstances of small and medium-sized enterprises (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.
Self evident. SMEs require special assistance. **EP Amendment 363**.	

Amendment 3 Recital 26 B new	
	In order to help companies, and in particular SMEs, to comply with the requirements of this Regulation, the Member States, in cooperation with the Commission, should put in place a comprehensive support network.
Same as above for amendment to Recital 26 A new . **EP Amendment 22**.	

Amendment 4 Recital 34 BIS new	
	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.
Finding test data alternative to those on vertebrate would limit both animal testing and costs for tests. **EP Amendament 25**.	

Amendment 5 Recital 37 A new	
	In order to strengthen the competitiveness of Community industry and to ensure that this Regulation is applied as efficiently as possible, it is appropriate to make provision for the sharing of data between registrants on the basis of fair compensation.
In order to protect SMEs it is important that costs sharing is fair and proportional. **EP Amendment 26**.	

Amendment 6 Recital 39 A new	
	If a potential registrant and/or participant in a substance information exchange forum (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.
Data sharing is a fundamental precondition to the registration of substances. **EP Amendment 27**.	

Amendment 7 Recital 40 A new	
	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.
As amendment 6. **EP Amendment 28**.	

Amendment 8 Recital 46 A new	
	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.
The Communication of non-registration is important to inform downstream users about the withdrawal of certain substances from the market. **EP Amendment 34**.	

Amendment 9 **Article 1 Paragraph 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.	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.
The criteria laid down by this article can only be applied under normal and reasonably foreseable conditions of use. **EP Amendment 60**.	

Amendment 10 **Article 1 Paragraph 3 A new**	
	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.
There should be no unnecessary redt-ape for enterprises, and in particular for SMEs. **EP Amendment 63**.	

Amendment 11 **Articolo 1 Paragraph 3 B new**	
	In implementing this Regulation, the European Union shall establish mechanisms for providing aid and support to small and medium-sized enterprises.
SMEs are financially and technically weaker than big companies and require special support. **EP Amendment 64**.	

Amendment 12 **Article 3 point 23 A new**	
	26. **Unsupported*** use means a use by downstream users which the registrant advises against **by providing scientifically based arguments against the safety of this use;**
Arguments should be provided to justify why a use is not supported. **EP Amendment 76-77**.	

Amendment 13 Article 3 point 29	
Per year: means per calendar year unless stated otherwise	28. 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;**
Market fluctuations should be taken into account to prevent them from affecting the terms of registration, evaluation and authorisation (existing substances). **EP Amendment 78**.	

Amendment 14 Article 7 paragraph 8 A new	
	The Agency shall provide guidelines to help the producers and importers of articles as well as the competent authorities.
The Agency should have a leading role in providing guidelines. **EP Amendment 88-357**.	

Amendment 15 Article 10 paragraph c) new	
	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.
In vitro methods limit unnecessary animal testing. **EP Amendament 106**.	

Amendment 18 Article 22 paragraph 1 point c)	
changes in the annual or total quantities manufactured or imported by him if these result in a change of tonnage band, including cessation of manufacture or import	changes **in the quantities calculated on 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
Linked to **EP Amendment 78**.	

Amendment 19 Article 23 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 21(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 21(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 21(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.**
The Communication of non-registration is important to inform downstream users about the withdrawal of certain substances from the market. **EP Amendment 121**.	

Amendment 20 **Article 27 paragraph 5 A new**	
	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.
Registrants who do not pay should not be entitled to register. **EP Amendment 135**.	

Amendment 21 **Article 28 paragraph 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 alist 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. **(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).**

* 19 months after entry into force of this Regulation.

* 19 months after entry into force of this Regulation.

The liberalisation of test data after 10 years is a fair criteria. It provides a sufficient time-framework for companies to recoup their investment and provides SMEs with the access to tests data they need to survive. **EP Amendment 142**.

Amendment 22 **Article 30 paragraph 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 …*.** Within two weeks of the request, the owner of the study shall provide proof of its cost to the participant(s) requesting it. The participant(s) and the owner shall make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non discriminatory way. This may be facilitated by following any cost sharing guidance which is based on those principles and is adopted by the Agency in accordance with Article 76(2)(f). If they cannot reach such an agreement, the cost shall be shared equally. The owner shall give permission to refer to the full study report for the purpose of registration within two weeks of receipt of payment. Registrants are only required to share in the costs of information that they are required to submit to satisfy their registration requirements.	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 …**. Within two weeks of the request, the owner of the study shall provide proof of its cost to the participant(s) requesting it. The participant(s) and the owner shall make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non discriminatory way. This may be facilitated by following any cost sharing guidance which is based on those principles and is adopted by the Agency in accordance with Article 76(2)(f). If they cannot reach such an agreement, the cost shall be shared equally. The owner shall give permission to refer to the full study report for the purpose of registration within two weeks of receipt of payment. Registrants are only required to share in the costs of information that they are required to submit to satisfy their registration requirements.
All tests (vertebrates and non-vertebrates) should be shared. **EP Amendment 149**.	

Amendment 23 **Article 30 paragraph 1 A new**	
	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.
This requirement strengthens the principle of compulsory data sharing. **EP Amendment 151**.	

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

Amendment 24 Article 30 paragraph 1 B new	
	If the other participant(s) fail to pay their share of the cost, they shall not be able to register their substance.
Registrants who do not pay should not be entitled to register. **EP Amendment 152**.	

Amendment 25 Article 37 B new	
	Procedure for compulsory notification of information by SMEs **1. Where the downstream user is an SME, within the meaning of Article 3(29a), the notification procedure provided for in Article 35 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 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.**

This specific ad hoc procedure for SMES enables them to protect their industrial secret for specific uses of chemical substances; by giving a special role to the Agency it limits unnecessary tests. **EP Amendment 169**.	

For further information please contact:

Mr. Guido Lena
Director for Internal Affairs
UEAPME
R. Jacques de Lalaing, 4
B- 1040 Brussels
Tel: +32 2 230 7599
Fax: +32 2 230 7861
email: g.lena@ueapme.com
www.ueapme.com