



EUROPEAN COMMISSION

ENTERPRISE DIRECTORATE-GENERAL
ENVIRONMENT DIRECTORATE-GENERAL

REACH REGULATION PUBLIC INTERNET CONSULTATION

A - Contact details

(Please enter your contact details)

Name: Robert Feierl
Organisation : WKÖ - Wirtschaftskammer Österreich
Address : Wiedner Hauptstraße 63
Post/zip code : A-1045
City/Town : Vienna
Country : Austria
Telephone : +43 1 50105 4393
Fax : +43 1 50105 14393
E-mail: robert.feierl@wko.at

B - Confidentiality

- I would like my identity to be kept confidential**
(please leave this box blank if you agree that your name and organisation will be identified on the Commission's website for public access)

C - SME

- Are you a small or medium sized enterprise?** ([EC legal definition](#))
please specify the number of members:

D - Description of your primary activities

(please select only one of the following)

Industry

- Manufacturer**
 Importer
 Downstream user
 Distributor
 Trade association
 Other

NGO

- Environmental group**
 Animal welfare group
 Trade union
 Consumer organisation
 Other



EUROPEAN COMMISSION

ENTERPRISE DIRECTORATE-GENERAL
ENVIRONMENT DIRECTORATE-GENERAL

Public authorities

- EU Member State government
- Other national government
- International organisation
- National or regional authority

Other

- Academic or technical institute
- Worker in chemicals or downstream industry
- EU citizen
- Other

Please structure your response according to the following topic areas and provide comments or proposals for amendments to the legislation. Please comment on those topics that are relevant to you.

When finished, please send your document to the following address:
entr-env-ec-reach@cec.eu.int.

Thank you in advance for your contribution.

E - Topics :

1. Duty of care
2. Chemical safety assessment
3. Information flow
4. Registration procedure
5. Polymers
6. Intermediates
7. Data requirements
8. Data sharing/consortia formation
9. Procedures for downstream users
10. Evaluation procedure
11. Authorisation procedure
12. Restrictions procedure
13. The Agency
14. Other

The Austrian Federal Economic Chamber co-ordinates and represents the interests of the Austrian business community on a national and international level. Within the Austrian Federal Economic Chambers' system it functions as the national umbrella organisation for the 9 regional Chambers (one in each of Austria's federal regions) and 110 trade associations for different industries. Membership is compulsory and includes all Austrian companies in operation. The resultant membership, some **300,000** businesses draws from a diverse selection of business areas such as **trade and craft, commerce, industry, transportation, tourism, services industries, finance and insurance.**



EUROPEAN COMMISSION

ENTERPRISE DIRECTORATE-GENERAL
ENVIRONMENT DIRECTORATE-GENERAL

Public law (Wirtschaftskammergesetz) provides the legal foundation for the Austrian Federal Economic Chambers, supplying the legal framework for all Chambers, their co-operation, mandatory membership, and rules for setting membership fees. Although established by public law the Austrian Federal Economic Chambers are exclusively business driven.

Comments on the draft:

1. Duty of care:

Regarding the provisions concerning the general duty of care, it should be investigated further, how the general duty of care could be allocated in the suitable intensity to the different actors in relation to their possibilities to influence the risk assessment and the risk management procedures.

2. Chemical safety assessment:

In accordance with the legislation in the field of occupational health and safety the safety assessment should be limited to the current or intended use of a substance or preparation with a certain exposure category.

The safety data sheet for a substance or a preparation shall serve as the basis for the risk assessment.

The assessment of single substances in preparations on the basis of the chemical safety report (CSR) is not feasible - especially for down stream users (SME) - in terms of workload and proper expertise. Furthermore the assessment of single substances will in most cases not reflect the proper risk of a preparation and thus might result in the wrong safety management measures.

The use of exposure categories (a model that was already submitted to the commission in a joint action of the Austrian Ministers for Environment and Economy) as indicated in the White Paper, will simplify the chemical safety assessment especially for the down stream users.

However, to administrate the production and exchange of this additional information paper for substances might be too great an effort for SME.

3. Information flow:

The lot of information which, according to the proposal, has to be communicated up and down the supply chain is extensive and **redundant** as the Safety Data Sheet already contains most of the information. Most SME outsource already now the preparation of SDS as they have not enough resources to deal with these issues themselves.

From our experience it will be impossible for all actors in the supply chain - especially SME - to cope with all these information procedures and to deal with the immense amount of information that has to be available or communicated (Pt. 4 - 6). Downstream user will be completely lost if they receive safety data sheets along with chemical safety reports of the constituent substances showing different safety advises.

Furthermore the requirements for the information in the supply chain should be limited to the intended uses and it should be clarified how company know-how, such as compositions of special preparations, can be kept confidential.



EUROPEAN COMMISSION

ENTERPRISE DIRECTORATE-GENERAL
ENVIRONMENT DIRECTORATE-GENERAL

The SDS - created as the information tool in the chemical regime - took about 15 years to be established and accepted and has started to improve its quality over the last few years continuously. The effort which was put into this by all stakeholders - in Austria a lot of initiative were set up since 1996 to create and develop SDS as well as to train the downstream users in transforming the SDS into necessary workplace and safety information - will be worthless if it appears that there will be a new system created to provide information. From the experience with the SDS we learn that the CSR system will take at least more than just 15 years or even more to make it run.

It is therefore not reasonable to invent "the wheel" again instead we should **improve the Safety Data Sheet for communication and information as intended** (and also implemented now by the future new member states) and make it a high quality tool.

So the requirements in the safety data sheet should be adapted to cover information needs for registration of specific uses of substances – as such or in preparations - under REACH. The safety data sheet for substances and preparations – maybe in an advanced format, inter alia adequately reflecting risks management considerations and recommendations- could cover the planned chemical safety report. Therefore it should be investigated further, if the introduction of the chemical safety report as a separate format is necessary at all.

4. Registration:

It is regretted that the question whether a certain substance has to be registered **is regulated differently** in several Articles (Pt. 7 scope, Pt. 9 exemptions, Pt. 10 biocides and plant protection products, Pt. 15 polymers, Pt. 18 intermediates, Pt. 22 phase-in substances, Pt. 25 notified substances). The scope and the exemptions should therefore be regulated in a clear understandable manner without being scattered all over the regulation.

There are no exposure-related testing requirements for registration. No consideration of risk management measures taken in advance by industry to guarantee the safe use of substances with unknown properties. Data requirements are only related to production quantities. (Pt. 13). There should be exposure-categories to reduce animal testing, to simplify exposure assessment and for deduction of risk management measures.

There should be **cut-off-criteria** for substances in preparations or in articles so that small concentrations of substances, such as additives < 0,1 %, need not be considered in the registration procedure.

There should be a provision to enable a non EU-producer to register a substance instead of an importer in order to protect his **confidential business information** (CBI), e. g. composition of a preparation. Importers will usually not know all components of a preparation and its composition.

Registration requirements should be limited to intended uses only.

Assessments made previously, such as the OECD SIDS programme should be recognised. There is no provision, that information, already available to authorities, shall not to be registered again, unless the information is in possession of a company.



EUROPEAN COMMISSION

ENTERPRISE DIRECTORATE-GENERAL
ENVIRONMENT DIRECTORATE-GENERAL

The obligation to register all the information on data of the annexes IV – VIII in addition to the safety report, which contains and assess all relevant information in regard to the safe use of a substance, is an **unnecessary duplication** (Pt. 11). The requirement to inform the agency about any research and development programme including a list of customers to get the R + D- exemption will impede the innovation (Pt. 9).

For the registration-procedure foreseen in the REACH System the existing procedures especially the safety data sheet should be used for registration purposes. Therefore the requirements in the safety data sheet could be adapted to cover information needs for registration of specific uses of substances – as such or in preparations - under REACH.

The **registration procedure shall be streamlined and only be performed by the central agency**, thus, avoiding unnecessary time losses by the involvement of member state authorities and providing efficient and harmonised management.

For the purpose of facilitating further R&D efforts the **phase-in-substances should cover all EINECS substances**, and not only those which were placed on the market > 1t (see definition in Point 2.20). This is important to have the pool of all the EINECS substances available for new substance development and applied R&D over the full transitional period. (The provision in Point 29.2 seems to have the same goal, however, it fails to have a sufficient effect, if the definition of a phase-in-substance remains unchanged.)

Besides, down stream users must have the possibility to be involved in the pre-registration period for phase-in-substances on a voluntary basis. This is relevant for them to make sure that all the substances, they need, will be registered for their (intended) use.

5. Polymers:

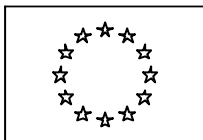
The provision in the draft text, will have the effect, that a large number of polymers (possibly exceeding the number of substances) will fall under the scope of the registration. This is mainly due to the following reasons: Almost all of the common polymers exhibit the dangerous property R10 – flammable (like their starting material), and the introduction of the average molecular weight < 10.000 Dalton is rather arbitrary. (To our knowledge most registration duties in other international legislation are connected to an average molecular weight of < 1.000 Dalton).

In addition the analytical effort to determine whether or not a polymer fall under the registration procedure will be extra-ordinary high.

Therefore we propose, to **exempt those polymers from the registration procedure, for which the starting materials** (present in quantities higher than 2 %) are already registered.

6. Intermediates:

Although the fact, that non-isolated intermediates are completely exempted, is highly welcomed, we fear that the exemption of the other intermediates does not go far enough.



EUROPEAN COMMISSION

ENTERPRISE DIRECTORATE-GENERAL
ENVIRONMENT DIRECTORATE-GENERAL

Especially, the provision for “isolated intermediates transported”, which allows a simplified registration procedure only if two sites are supplied with this intermediate can lead to a major market distortion. Especially, innovative SMEs, which require those intermediates for the production of organic and inorganic specialities, fear that the suppliers of these intermediates will stop deliver this raw material to them, and concentrate on the supply of the two main sites (these might be sites of the same company). Besides, the number two is just arbitrary anyway, and the provision “between or supplied to up to two sites” be deleted completely in the definition (see Point 2.14.(iii)).

Additionally, the classification of these polymers according to the DPD is contradictory to the current and future (GHS) classification scheme.

7. Data requirements:

Since the different data requirements are set on the basis of quantity only, the waiving on the delivery of data (performing of tests) on the basis of risk (impossible exposure for certain intended uses) must be facilitated markedly, especially for low volume substances (< 100 t/a).

Especially for low volume substances (< 100 t/a) the use of a base data set as laid down in the voluntary commitment of VCI, which was taken over by the Austrian chemical industry, must be sufficient, if these substances do not exhibit a high risk. It will also be essential, also as a reward to those companies, which participated at this voluntary agreement, that these data gained by the VCI initiative or ICCA initiative, will be accepted in accordance with Annex IX, without further justification.

The application of Annex IX in the use of existing data will also be crucial for the avoidance of unnecessary animal testing. The same counts for acceptance of the results of the structure-activity relationship (SAR, QSAR). In terms of minimising animal test it is not understandable, why for those substances, where these models predict negative dangerous properties (on a substantiated basis along with the practical experience), “the relevant tests shall nevertheless be performed.”

8. Data Sharing/Consortia formation:

Forced data sharing is against intellectual property and questionable under competition rules (if it would extend to sensible data). It raises a serious issue of confidentiality, competitiveness, and finally industrial policy. In contrary consortia organize agreed data sharing that remain the property of the members and should be kept confidential.

Therefore efforts in research should be recognised in terms of **property** of results and protection of competitiveness of European industry in terms of **confidentiality of data**. The proposed system dismantles intellectual property and confidentiality of data protected by other legislation. Animal protection, presented as a superior interest, should be the only case allowing an exception to these rules.

Concerning the duty to pre-register to get the status of phase-in-substances (transitional period), Pt. 29, the **white book doesn't provide any pre-registration** process and recognises a transitional period for phase-in substances. The regulation should not fall behind the white book. As every company in the EU has to **pre-register** all its phase-in substances **prior to the**



EUROPEAN COMMISSION

ENTERPRISE DIRECTORATE-GENERAL
ENVIRONMENT DIRECTORATE-GENERAL

full registration (Pt. 29) this requirement puts additional, extremely bureaucratic requirements on authorities and industry.

With regard to existing regulation e.g. for **protection periods for data** (unlimited protection for costly tests in annex VIII, 67/548/EC the REACH proposal should not fall behind this level as this would be in contradiction to the White Book.

Data protection is expressly provided only for non phase-in substances (Pt. 26 a). But **data protection has to be regulated under Chapter 1** (Objectives and general rules) that applies also to phase-in substances. An exemption from data protection may be the sharing of vertebrate animal related data.

Consortia (Pt. 11, 12, 17 and 18 b) are now an option apparently limited to producers and importers (Downstream users are treated separately, see points 32 to 34) and parts (each participant must apply individually) of registration (what about authorisation).

Consortia could therefore limit themselves to conducting common tests, and assemble their dossiers individually. This could be a way to protect dossiers, knowing the difficulty to protect confidentiality.

9. Downstream Users

There is **no clear indication**, that a downstream user can rely on the information of the data base or to the information he gets from his supplier. (Pt. 32)

The reduced level **of 250 kg/a** for the reporting requirements puts **downstream users** is disadvantages to manufactures and importers (Pt. 33.6). They might **be forced for testing at a lower level**.

Regarding the provisions concerning the general duty of care, it should be investigated further, how the general duty of care could be allocated in the suitable intensity to the different actors in relation to their possibilities to influence the risk assessment and the risk management procedures.

Although we welcome the stronger involvement of down stream users, especially professional end users, in chemicals management, the necessary involvement of down stream users in the various steps needs to take into account the resources and expertise, since they are predominately SMEs.

In this respect, we want to highlight the necessary changes, for the duty of care, chemical safety assessment and information flow, once again.

- A tiered approach for the duty of care, depending of the involvement of the downstream users in chemicals management (formulator, end user), needs to be incorporated.
- The content of the information up and down the supply chain must be limited to the minimum necessary to obtain the maximum information, in order to get the acceptance of SMEs. **The tool of this information chain shall be the safety data sheet with some additional information concerning risk assessment and risk management, if necessary.**
- The information for preparations shall not give a detail analysis for all the substances in this preparation, since this will overload the information system. Apart from the overwhelming administrative burden the inherent properties of all substances in a preparation will in most of the cases not adequately reflect



EUROPEAN COMMISSION

ENTERPRISE DIRECTORATE-GENERAL
ENVIRONMENT DIRECTORATE-GENERAL

the risk connected with the preparation. Therefore, the information flow shall rely on the SDS as a basis, as mentioned before.

- **The confidentiality of information passed along the supply chain must be secured properly.**
- On the basis of a simple risk assessment based on exposure categories in coherence with the current requirements for OHS, DUs will be able to manage the risks properly. Different risk management measures shall be communicated to the supplier. However, an information to the agency is not necessary from our point of view (see Point 33.1.(b)).

So to aim at a new dimension in data exchange between all involved actors, especially up and down the supply chain, including also smaller enterprises and (professional) end users, as the Consultation Document does, is very ambitious and desirable. The concept of the information flow chain –and the amount of information that should be transmitted seems over-boarding and the process burdensome, and, thus, should be refined thoroughly.

10. Evaluation:

There is **no centralised European evaluation by the EU Agency but evaluations by the authorities of the Member States** (Pt. 35). The duplication and discrepancies likely to occur are to be made up for in a work-intensive bureaucratic co-ordination procedure (Pt. 42). Such a de-centralised process will not lead to harmonisation. We have these experiences already with the new and existing substances regulations. The interpretation and demands of MS are differing quite widely, although quite comprehensive TGD's exist.

Arbitrary inclusion of substances in volumes < 100 tonnes per year in the evaluation leads to no reliability/planning security for companies as such be refined thoroughly as well .

Manufacturers and importers can be requested to perform additional tests to cover uses which were **not registered by them** (Pt. 38) which should not be the case and therefore should be clarified.

Pt. 41 introduces mandatory consortia building. According to the principles in Title IV (Registration Pt. 12, 17, 18 b)) and Title V (Data sharing Pt. 26 a), 27, 28) of the draft regulation mandatory consortia building or data sharing is only acceptable and compatible with fundamental EC-law when and insofar vertebrate animal studies are involved.

There should be provisions for participation of the industry in the decision making process of the member states during the evaluation (Pt. 42) and **possibilities to object** to decisions made.

11. Authorisation:

In the White Paper the authorisation procedure was restricted to CMRs Cat. 1 and 2 and to POPs. The extension to PBTs and vPvBs and even more to “substances giving rise to similar concern” will contribute to a high level of uncertainty, since there is no clear definition for these criteria.

In addition, **the authorisation procedure shall only focus on an EU authorisation by the central agency.** The member state authorisation, which exists in Austria according to different legislative acts than the chemicals legislation anyway, needs to be reconsidered.



EUROPEAN COMMISSION

ENTERPRISE DIRECTORATE-GENERAL
ENVIRONMENT DIRECTORATE-GENERAL

It is not clear whether one can apply for an authorisation for substances or uses for substances after the “sunset date”, for which no authorisation have been requested before this date.

The obligation for downstream users to notify the use of an authorised substance is not necessary and – taking into account that they are predominantly SMEs, who use substances in preparation – can hardly be fulfilled.

The authorisation should be an uncomplicated workable system based on the registration and evaluation taking into account the principle of proportionality.

General authorisation decisions on safe uses (positive/negative lists) should be the preferred option in order to minimise bureaucratic burdens. Only for specific uses there should be company/consortia related authorisations upon request.

A notification procedure is set up for downstream users that utilise authorised substances (Pt. 55). Together with the extensive information and reporting requirements regarding the registration procedure (Pt. 32- 34), this will put additional unaccomplishable burden to SME.

There are both **national authorisation decisions and EU authorisations** that will significantly perturb the harmonisation of the internal market. There should be no national authorisation procedures and decisions. Only EU centralised decisions are coherent with an EU harmonised system (Pt. 48; Para 1).

There should be no extension of the authorisation procedure to other groups of substances, such as endocrine disrupters, without clear definitions of substance properties (Pt. 44). Only cmr-substances (Cat.1+2), which are officially classified should be subject to authorisation. Arbitrary criteria for inclusion of additional substances or groups of substances are not acceptable given that this will probably lead to an unworkable system and legal uncertainty for companies. Other substances which may raise concern can be regulated by restrictions sufficiently.

There should be a general exemption for polymers and substances or uses below 1 t/a.

A significant quantity of information will be published on the internet, such as uses and socio-economic factors (Pt. 52). There are **no clear rules on what has to be kept confidential** in order **to protect company know-how**.

Decisions already taken by the Council of Ministers/EU Parliament should not be re-discussed again. **Uses of substances already regulated should be maintained.**

A chapter on industry’s legal rights and remedies (right to a hearing, right to a second opinion, right to judicial remedy) should be added unless there will be a general chapter on those rights covering the whole REACH Processes.

There are no clear arrangements for certain articles which may lead to a possible disadvantaging with respect to third country competitors.

12. Restrictions:



EUROPEAN COMMISSION

ENTERPRISE DIRECTORATE-GENERAL
ENVIRONMENT DIRECTORATE-GENERAL

It is questionable whether the system of an authorisation and a restriction procedure will work in parallel without a clear linkage. We see no need for a chapter dealing with restrictions if there is a chapter dealing with authorisation. There is no provision to restrict or ban preparations or articles as such, if their use lead to unacceptable risks. The existing legislation applies also to preparations and articles.

Bans of substances, possibly with economic implications are exclusively introduced via a Commission procedure. Therefore, there is hardly any possibility to appeal the decisions.

The participation of industry in the decision making process is not sufficient. To prevent arbitrary measures, there must be systematic rights of a hearing, right of a second opinion and right for a judicial remedy at each step of REACH.

13. Agency

The **involvement of industry in the decision making process is not sufficient**. Stakeholder groups will be involved in the Management Board and possibly in the working groups, but not in the Committees: Therefore there should be a mechanism to ensure the right to have its voice heard.

There are no clear rules for responsibility. The Agency should be the driving force and **responsible for the implementation and working** of the REACH system in the 15 existing and the 10 new member states. Otherwise harmonisation is not achievable.

As the new European Chemicals Agency shall be the responsible body for the implementation, the management and the operation of the new general Chemicals Regulation it is clear that the Agency should operate as independently and efficiently as possible and that the Agency should have the necessary responsibilities and duties to administrate the whole REACH system.

Therefore the legal status of the Agency should be similar to the European Air Traffic Control Institutions.

By reducing any double work and by creating synergies to the highest extent possible, all relevant decisions making processes should be concentrated at the Agency, including the responsibility of the Agency for the Evaluation process of the REACH system. There should be no double structures within the European Commission and the Agency.

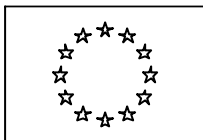
14. Other

a. General Issues/Definition/General Scope

The draft regulation doesn't grant effective remedies which still have to be installed for the whole procedure of REACH. Under remedies we understand a trifold system including in each case, successively, a right to a hearing, a right to a second opinion or appeal and a right to a judicial remedy.

For phase-in substances any remedy must guarantee suspensive effect.

Where reference to comitology-procedures is made participation rights as the right to be heard and the rights of defence of the affected manufacturers have to be granted in accordance with fundamental principles of Community law and the ECJ-jurisprudence.



EUROPEAN COMMISSION

ENTERPRISE DIRECTORATE-GENERAL
ENVIRONMENT DIRECTORATE-GENERAL

The definition of phase-in-substances and the reduction of existing chemicals in the EINECS-register to substances, which had been manufactured/imported over a ten years period, preceding the entry of force of the regulation is not inline with the White Book. Innovation and flexibility of companies, especially SMEs, will be impeded at an early stage, resulting in severe economic consequences.

To keep the regulation as simple as possible and to avoid duplication with existing community legislation, the scope of the draft text shall take care of those substances, which already are regulated under current EC law in a similar manner (e.g. pharmaceuticals, plant protection products, biocides, cosmetics, food ingredients, waste) and exempt them properly.

b. Substances in Articles

The **criteria of releases of substances** exceeding 1 t p. a. out of articles for its registration is **not practicable and not to control**. There should be cut-off-limits for emissions/releases. (Pt. 64)

c. Classification and Labelling

The obligation, to notify the agency each dangerous substance with the classification is a duplication to the registration due to Pt. 11. In the registration the classification had to be submitted. (Pt. 96)

d. Information

The request for confidentiality should not depend on a fully justification by documentary evidence (Pt. 102, 1 and 2), but the competent authority should justify the denial of a confidentiality request.

The competent authority should not be free to deny confidentiality (Pt. 102, 2).

The Information not considered as confidential comprises too many elements and impedes CBI, (Pt. 102, 3).

The obligation of the agency to publish all non confidential information will give away commercial sensitive data and give advantage to competitors outside EU which we can not accept.

f. Enforcement

It is not reasonable to leave enforcement of the REACH system only to Member States (Pt. 107) . This should be a main task for the agency being responsible for the implementing and managing the REACH System.

There should be a stronger co-ordination in the development/harmonisation of national penalty systems (Pt.108)

There is no clear (too general) description of situations in which fines will be needed (Pt. 108)and there is no clear system on how to object.

The approach that fines are based on the world wide turnover of the offender is inappropriate and not acceptable.

g. Transitional and Final Provisions

If it is really a matter of establishing an overall new and efficient system of chemical management there is no need for a safeguard clause which will turn down all efforts towards a EU wide harmonisation. If a central agency is fully responsible for the new REACH system there is definitely no need for such a clause.

h. Annexes

The provisions for the assessing substances and preparing chemical safety reports are very bureaucratic, cumbersome and need specialised experts. **SME**



EUROPEAN COMMISSION

ENTERPRISE DIRECTORATE-GENERAL
ENVIRONMENT DIRECTORATE-GENERAL

are not able to fulfil those requirements. (Annex I and Annex XI). Exposure categories should be the basis for the assessment in order to simplify the procedure.

In **Annex III** Pt. 9 "coke" should be added to the exemptions

The information for substances 1 – 10 t/a is excessive. It should be reduced to a minimum data set, which SME can afford. (**Annex V**)

The waving of tests in **Annex IX** is not practicable for SME. They have no experts to justify waving. In addition there is no provision to wave on exposure for the required information for substances > 10 t/a.