

ETAD Comments

REACH REGULATION PUBLIC INTERNET CONSULTATION

A - Contact details

(Please enter your contact details)

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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

#

International association of organic colorants manufacturers

NGO

Environmental group

Animal welfare group

Trade union

Consumer organisation

Other

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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

ETAD, the Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers was formed in 1974 to represent the interests of these industries on matters relating to health and environment. ETAD is an international organisation and its currently 45 member companies are based in 14 countries worldwide.

ETAD seeks to base its positions on sound science and to coordinate the efforts of its members to minimise any possible adverse impact of organic colorants on health and environment. Member companies are obliged to adhere to the ETAD Code of Ethics, which is based on the principles of Responsible Care®

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ETAD Position and Comments on the Draft Consultation Document for the EU's New Chemicals Policy

A. General Assessment

Before going into the details of the questions outlined in the template format ETAD would like to summarise its general assessment of the consultation document and to make some constructive proposals for a practicable system.

In its earlier position paper ETAD expressed support for the goals laid down in the EU White Paper: "Manufacturers of Colourants (Dyes and Pigments) support the aim of ensuring high level protection of human health and environment, while at the same time enabling efficient functioning of the internal market and stimulate competitiveness and innovation of their products on the global marketplace".

The current draft consultation document **does not meet the seven political objectives of the EU White Paper.**

Goals	Assessment
1. Protection of human health and the environment.	No advantage for the EU. The additional costs and administrative efforts are disproportionate to the potential advantages. Overall, the opposite will happen: To the detriment of the EU manufacturing industries chemicals and articles (e.g. textiles, printed magazines, books, toys, etc.) will be manufactured in countries with lower health and environmental standards and increase global pollution. ETAD as an international organisation believes that only a global approach will improve the situation.
2. Enhance innovation and competitiveness of the EU chemical industry	The phasing out of the specialty chemical manufacture in the EU will be accelerated with transfer to areas with less stringent regulations and where the administrative burden imposed on the whole supply chain is lower.
3. Prevent fragmentation of the internal market.	The roles of the new Agency vs. the Member States and the Commission are not clearly assigned.
4. Increased transparency	Increased bureaucracy
5. Integration with international efforts	The new chemicals policy is a EU stand-alone framework not compatible with existing chemicals legislation in other major OECD countries. Manufacture, import and export of chemicals in and out of the EU will be impeded.

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6. Promotion of non-animal testing	In the Annexes some good guidance has been developed to avoid animal testing. Exposure and read across data should also be taken into consideration to reduce animal testing.
7. Conformity with EU international obligations under the WTO	Certain aspects of the proposal to regulate chemicals in articles raises concern on trade restrictions.

B. Specific comments

1. Duty of Care

ETAD advocates the principles of Responsible Care[®] and has established its own Code of Ethics which is applicable worldwide. Specific guidance is given to all member companies and to the colorants user industries. ETAD would be against an administrative rule making with prescribed requirements.

2. Chemical Safety Assessment

ETAD believes that a good quality Safety Data Sheet contains the necessary information. The downstream users of our sector are mainly SMEs which do not have experts to understand toxicological and ecological details of the Chemical Safety Report. In any case, the timeframe for the generation of CSRs is not practicable (see under item 4. below)

3. Information through the supply chain

- Adequate information is already required under the current legislation, i.e.
- Classification and labelling under the DSD and DPD
 - Precautionary measures under the SDS

The problem of lack of information is not solved by additional requirements of paperwork but by enforcing existing legislation.

4. Registration Procedure

The registration procedure suggested is highly complex and bureaucratic involving (too) many parties, including Member States and Agency. Export should be exempted as in other major regions (e.g. USA) to avoid competitive disadvantage outside the EU.

The concept of pre-registration has to be re-evaluated carefully. ETAD does not believe that such a complex process involving numerous different parties registering different quantities under different time frames is practicable.

Furthermore, the registration procedure is scaled depending on volumes which are not compatible with the requirements for Chemical Safety Reports!

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5. Polymers

Polymers should be exempted.

6. Intermediates

Intermediates should be exempt from the REACH Regulation because they are already controlled under other regulatory requirements that cover professional use. The Chemical Agent Directive covers on-site use of intermediates and the transportation of intermediates is covered by the transport regulations. Innovation in R&D and competitiveness will be heavily impeded if isolated intermediates could not be transported without registration.

7. Data Requirements

A GLP requirement for all test data is excessive in terms of costs, time and absorbing capacity for testing. Grouping of chemicals is essential to reduce animal testing. The GLP requirement should be limited to new tox and ecotox studies.

Data generated under other national and international programmes should be accepted (US EPA HPV, ICCA HPV). A lot of data has been generated under the EU's Existing Substances Regulation which has not been assessed. It should be avoided to generate data cemeteries.

ETAD supports the derogations in Annex IX part 2, where testing is waived when it is technically not feasible, and part 3, where testing requirements are exposure-driven.

Annex XII should be deleted until PBT screening criteria and the risk assessments derived have got international agreement. The goal must be to screen out potential POPs for priority risk assessment which are of global concern. This cannot be resolved at EU level.

8. Data Sharing / Consortia Formation

ETAD supports the voluntary formation of consortia provided that the rules are workable and equitable to the parties involved.

The current proposal is confusing as elaborated in the CEFIC comments. It should be noted that members in a consortium are competitors in the market which need to retain certain confidential information. This can only be granted by the instalment of a legal entity acting also as a referee. Costs and benefits have to be gauged carefully.

9. Procedures for downstream users

The downstream users of our sector are thousands of SMEs which have to perform safety assessments for each substance as such or in a preparation for each use. In our specialised sector there are tens of thousands of preparations on the market. It will simply not be practicable. As mentioned above these companies will not have the necessary expertise and resources. They will revert to their supplier.

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The focus should be on specific guidance for a range of products and applications. Specific safety assessments should only be needed for uses that are not covered by the assessment of the supplier.

10. Evaluation

Evaluation of data is assigned to Competent Authorities of Member States. Experience of ETAD companies with notification of new substances under the current legislation has shown a lack of consistency in interpretation and regulatory decision taking, influence of national political agenda on MS CA decision taking, slow process due to resource constraints of MS CA's, lengthy processes because of continuous requirements for additional data have been the main issues with the current legislation and its ineffective and inefficient implementation. The political objective of the new legislation will not be achieved if MS CA's are left in the same role.

The evaluating MS CA's have the option to require additional information (Point. 38 1. (c)), if they have reasons to believe that the substances have properties of concern. This is a hazard-based approach that opens the possibility to require any type of information (at Annex VII or VIII level or beyond) at any substance volume level.

There is no clear process to assign responsibilities for Priority Evaluations to MS CAs, for either new or phase-in substances. Any MS CA may start a Priority Evaluation. This is not acceptable and should not be necessary considering the agreement procedure (Point. 42.).

ETAD believes that the Central Agency should be in charge of the evaluation process and should prepare the draft evaluation dossier. The MS CA's have the role to review and comment the evaluation.

11. Authorisation

It is positive that health and environmental risk assessment will be considered in the authorisation procedure (Point 48). Committees for risk assessment and socio-economic impact analysis will be set up at the Agency (Point 75).

ETAD is of the opinion that the current instrument described in the existing "restriction of marketing and use Directive" (76/769/EC) is sufficient.

Authorisation should be limited to CMR (cat. 1 and 2) substances.

The authorisation process is complicated and not transparent.

Uncertainties in timing and outcome will deter investment in the EU.

12. Restriction

Restriction should be amalgamated together with the authorisation process.

13. The Agency

ETAD supports the formation of a strong Agency which has competency and responsibility in the REACH process beyond administration and control.

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As suggested above it should be complemented by an arbitration board, which can resolve issues of interpretation in a reasonable time frame. The current proposal involves too many levels, which will lead to a slow bureaucratic process

14. Others

- Classification and Labelling Inventory (Points 95-99)
There is need for a single inventory including the existing Annex I, also containing substances assessed to be non-classifiable. It should include indications on the availability of test data for substances not classified as hazardous.
- The downstream user chemical safety report (Annex XI) is duplication of the manufacturer/importer's risk assessment. It is a complex task even for experts and it is not realistic to impose this requirement on the downstream user which has not got the experts and resources. The necessary information to take preventive measures is provided in a good quality Safety Data Sheet (SDS)
- Annex XII (PBT substances)
The screening criteria lack international harmonisation. Especially in the case of substances, which are difficult to test (e.g. insoluble organic pigments), read across for similar substances or the use of validated predictive models must be an alternative to experimental data for predicting bioaccumulation potential.

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C. ETAD's Proposals

ETAD makes the following guiding **proposals to meet the seven political objectives of the EU White Paper**:

Objectives	Proposal
1. Protection of human health and the environment	Use available information to prioritise efforts. Limit testing requirements and apply exemption rules based on exposure. Groupwise evaluation of similar substances. The EU should become active to foster a global approach at WTO level which will result in an overall positive effect for health and environment.
2. Enhance innovation and competitiveness of the EU chemical industry	Facilitate R&D and introduce transparent cost-effective legislation, which is enforceable, avoids discrimination and is better than the existing one, which already has led to a decrease of innovation. ETAD companies submitted 25% of all PMNs in the EU.
3. Prevent fragmentation of the internal market	ETAD wants the management of the REACH system to be as centralized as possible in order to create a true level playing field for the handling of REACH throughout the EU Member States. A strong Agency will facilitate the achievement of this goal.
4. Increased Transparency	Simple processes and clear responsibilities are needed.
5. Integration with international efforts	The new legislation should be developed in consultation with major OECD countries.
6. Promotion of non-animal testing	Alternatives to animal test methods need to be validated and have OECD approval. Read across data and human experience should be taken into account. Exposure tailored testing will also reduce animal testing.
7. Conformity with EU international obligations under the WTO	The inclusion of substances in articles has to be assessed vs. the WTO rules. Chemicals that have been phased out because they pose unacceptable risks in articles should not enter the EU through the backdoor of imported goods. It is not sufficient to enact stringent impurity limits (e.g. PCB content): there must also be rigorous enforcement.