EUROPEAN COMMISSION

ENTERPRISE DIRECTORATE-GENERAL
ENVIRONMENT DIRECTORATE-GENERAL

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**
☐ **Other**

NGO

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

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

Introduction

The ATC supports the overarching aims and principles of the White Paper. However, we have a number of significant and continuing concerns about the details as the discussion draws down to draft EU regulation(s). Most petroleum additive companies are either small or medium sized enterprises (SMEs) or reflect the operational dynamics of SMEs on a slightly larger scale. These companies typically deliver the petroleum based specialty chemicals and preparations absolutely essential to the

region's interests in enhanced fuel economy, reduced emissions, extended lubricant drain intervals (waste oil minimization), and significantly improved end of vehicle life durability cycles overall. REACh will have its greatest impact on SMEs whose livelihoods depend upon the financial health of the speciality chemicals industry sector at large. Therefore, petroleum additive producers, formulators, and distributors will be amongst those most significantly and disproportionately affected by the proposed legislation.

The ATC wishes to fully acknowledge that many of the requirements now brought to light in the Consultation Document have instant theoretical appeal. At the same time, several of these regulatory applications reflect an underlying failure to comprehend the practical details inherent in such approaches. The elements we draw your attention to below are indicative, but not restrictive, for the purposes of this brief opportunity to tender feedback and hopefully contribute to the legislative debate which shall follow.

Those aspects of potential REACh legislation of greatest concern to petroleum additive manufacturers are fundamentally rooted in the principals of Intellectual Property Rights (in other words, the sustained to declare and protect legitimate confidential business information from unnecessary public disclosure). This overarching theme impinges upon on several primary Topics of the REACh Consultation Document, including: "***Duty of Care, Chemical Safety Assessments, Information Flow, Registration, Polymers, Intermediates, Data Requirements, Data Sharing/Consortia Formation, and Authorization***". We summarize the following general concerns below, which shall be amplified further by individual topic.

- Loss of competitiveness resulting from current and future unnecessary disclosures of highly valued Intellectual Property (IP) as per Point 102, and the anticipated further erosion of Intellectual Property Rights (IPR) associated with the downstream transmission of Chemical Safety Reports (CSRs) as directed per Point 6 (Annex I.7.B.1).

- Increasing and significantly disproportionate cost burdens on the SME-like petroleum additive companies marketing formulations who will be required to reveal the identity of all substances, including those which are not classified as dangerous.

- The potential loss of ability to formulate using many currently available, highly specialised and functionally diverse essential additives because they are no longer cost effective in Europe. The resulting potential negative impact on existing downstream efforts to ensure a cleaner and healthier environment, which improved additives help to ensure, is in serious jeopardy.

- The predicted loss of additive industry skill sets, jobs and future investment opportunities as companies are forced to either move outside the EU or transfer leading formulation technologies to more favourable market place environments.

ATC believes that the legislation(s) must be carefully tuned to reduce its potentially disproportionate impact on SME-like additive suppliers. We hold that the principal adverse consequences of REACh anticipated by the petroleum additives industry can be legitimately minimised by taking full account of the following specific industry considerations.

1. Duty of Care

The duty of care, as currently drafted, requires manufacturers, importers and downstream users to be directly responsible for the safe handling of the substances they manipulate. In general, a large amount of data about these substances will need to be developed, organized and codified under the process of "chemical safety assessment". Every substance shall be examined in this way whether or not the substance comes under the scope of REACh. This will impose enormous burdens upon the industry, especially in view of the time available for compliance while competing for necessary resource to achieve said compliance in the process.

Assuming that such an information management process is achievable, we are very concerned that the procedures proposed do not provide sufficient safeguards respecting the legitimate business need to keep certain of the data confidential. The tenants of "Transparency" herein must be restricted to fundamentals essential for the complete communication of hazards and risks to Man and the Environment. The indiscriminate release of confidential business information is not essential to this task.

2. Chemical Safety Assessments

The petroleum industry does not shirk its duty to reasonably explore the hazards and risks anticipated by the intended use of our chemicals and preparations. However, specific substance information about supply, structure, market application, downstream customers, etc. is generally irrelevant to the task of protecting Man and the Environment. While we agree that rigorous Chemical Safety Assessments can provide the cornerstone for any robust Risk Management Plan, the consolidation and transmission of this data via Chemical Safety Reports (CSR) for each substance (as currently defined and configured) is largely a redundant and potentially damaging exercise with respect to the longer term success of the business involved. We strongly urge that the content and distribution CSRs be reconsidered taking into account the need to protect the value of Intellectual Property they represent, in part, while also avoiding truly needless redundancies vis á vis Safety Data Sheet publication and distribution.

3. Information Flow

Further to the discussion regarding the preparation of Chemical Safety Assessments, and the legitimate need to communicate the salient learnings of such and exercise, the ATC would like to amplify the need for careful management of sensitive business information within the scope of REACh by pointing out that:

- Commercially sensitive capital intensive Intellectual Property should not directly or inadvertently be forfeit by means of SDSs, labelling requirements, or CSR disclosures. This can be assured by restricting information demands to only those which are truly essential for a proper hazard and risk assessment, and subsequent development of meaningful risk managements practices;

- Ensuring the proper and continuing use of SDSs as the primary hazard communications tool, up and down the supply chain is absolutely essential. ATC believes that the Chemical Safety Report, as currently configured, is superfluous. CSRs will layer a significant and unnecessary burden upon formulators who must seek to maintain and preserve the value of the Intellectual Property associated with their formulating technologies. The proposed requirement to disclose substance identities to immediate downstream customers virtually nullifies all prior existing grants and future opportunities to seek confidentiality protection as provided for by Article 15 of the amended Dangerous Preparations Directive (1999/45/EEC). In essence, Article 15 can not coexist with the REACh specification for CSRs;

- Under Confidentiality (Point 102), a registrant is allowed to 'indicate the information which he considers to be commercially sensitive and disclosure of which might harm him commercially, and which he therefore wishes to be kept confidential'. However, there is no indication of the criteria that the Member State Authority(s) or the Agency will consider appropriate grounds for granting confidentiality. What is clear is that a supplier will be forced to reveal the identity of a chemical substance, its trade name, and other revealing details about the downstream user (Point 102, 3.b & c.). There is little else a competitor needs to know before penetrating a new market without significant additional effort to gain entry. Such enabling detail should not be part of a public document under any circumstances, without the supplier's prior agreed consent.

4. Registration Procedure

The Registration process is fraught with difficulties having to do with resource, timing, and the unbalanced focus upon volumes/hazards as opposed to risks. The views of the ATC have been largely captured by other chemical industry associates, trade associations and NGOs. We do not therefore wish to repeat views already expressed on these points. However, we have very specific concerns about the "Pre-Registration" process which focus upon both workability and confidentiality as well.

Under the duty to Pre-Register (Point 29) for phase-in substances, one can not otherwise make use of the transitional regime (Point 22), thus rendering Pre-Registration *de facto* compulsory, thus supporting the goal to minimise the number of tests involving vertebrate animals. In the 18 months between the pre-registration and registration deadlines, a SIEF must form, share data, agree further data required, and provide all results for registration. Thus, relatively small companies could be involved in dozens of SIEFs having common interests, who in turn must compete with hundreds, perhaps thousands of other SIEFs, all trying to initiate test programmes at

the same time. The lengthy U.S. HPV programme is indicative of the problem, clearly suggesting that 18 months is patently unworkable, in our view. The ATC supports making the SIEFs essentially "consolidators" who review and evaluate test plans with the discretionary remit to extend the window between pre-registration and registration in proportion to the needs identified therein.

5. Polymers

The management of polymers under REACh touches on the more general theme of "exemptions" and/or "derogations". The management of polymers is complex by virtue of nomenclature, inventory listings, and, of course, one's understanding of their intrinsic properties and associated risks. None the less, we take the view that most polymers should be regarded as substances of intrinsically low concern whose Registrations, as an absolute minimum, should be delayed, and their testing derogated through negotiation.

Specifically, polymers made from EINECS listed monomers should be phased-in. The REACh criteria for polymers do not reflect internationally recognised criteria for their notification, nor are they notified based on CAS No. In fact, according to the criteria outlined in the draft regulation, polymers with the same CAS No. can either be exempt or require registration causing confusion and unnecessary expenditures of resource to track in this manner. ATC supports exempting all phase-in polymers from registration.

6. Intermediates

The proposed management of intermediate substance is highly contentious and very controversial. ATC does not wish to unduly exacerbate the debate; however, some essential points must be re-emphasised. The number of chemical intermediates necessary to support the petroleum additives industry vastly exceed the number of actual product substances derived from them. In general we strongly support the granting of qualified exemptions for all site limited intermediates. By definition, the production and storage of these "substances" are already highly controlled on site, and are withheld from the market place by design and intent.

On occasion, intermediates require controlled transport between processing facilities to further their chemical transformation into products for market. ATC takes the view that the current scope for control of so called "isolated intermediates transported" is unnecessarily narrow and should be redefined. The current definition should apply to all substances which are transported either within or between companies for further processing so long as the amount of said substance remaining as an impurity in the final product is sufficiently low as to have no impact on the classification of the final substance or preparation marketed. Failure to do this will remove many substances from the market and unnecessarily diminish the diversity of potential chemicals that formulators would otherwise have available to meet the new technological challenges that they face.

7. Data Requirements

The ATC view with respect to data requirements is straight forward – the value of all existing should be maximized to the greatest possible extent under REACh emphasising the following points.

- The ATC advocates that all tests, irrespective of substance and/or volumes, must be based upon relevant risk(s). Box-ticking and overwhelmingly hazard based approaches should be avoided, since they do not contribute meaningfully to the safe handling of chemicals. The principle of exposure-based testing has only been partially considered in the draft legislation, mainly at the stage of 100 t/y and above, and it applies only to the more complex tests required. In contrast with the White paper's proposal and the current regulatory framework new substance notifications in Europe, the proposed test programs in the Annexes are "over-asking" and much more demanding. QSAR, read-across and data waiving need to be considered more extensively than the Consultation Document suggests or supports at this time.

- It is essential to maximise use of all existing data and other available information on individual chemicals and chemical groups applying globally accepted principals of "read-across" in the process will help guarantee the minimal use of vertebrate animals in future.

- It is also especially important to ensure the maximum use of data already developed on preparations, where minimal data exists for the substances involved will also support the goal; to minimize unnecessary use of vertebrates in this scheme. In many cases, there is no relevant need to generate data for existing substances when they are only marketed in preparations. In such cases, derogations in data generation for those substances should be a negotiable option.

8. Data Sharing/Consortia Formation

The ATC generally supports the formation of voluntary consortia to further maximize the value of existing data while minimizing testing costs. We also support the development of a related voluntary pre-registration scheme as per the CEFIC "Thought Starter". However, the mechanics for establishing consortia, as defined by the Consultation Document text, fail to take into account the underpinning issues of the disclosure of sensitive business data in the process. Forced data sharing, even with cost sharing considerations, runs counter to the unilaterally accepted principals of Intellectual Property Rights. It raises serious issues regarding confidentiality and competitive business practices within the European Chemical Industry. Chemical safety tests reports should remain proprietary to the contracting company (if they so chose) even after 10 years of first registration in order to avoid free-riding and any unwanted disclosures of existing proprietary commercial activities in the region.

We wish to further highlight certain other aspects of the "Data Sharing" philosophy which are inherently problematic on the face of it especially when viewed in the

context of Intellectual Property Rights, and not exclusively within the context of consortia building for any purpose.

- Pre-registration. Knowing which other companies are also registering a substance may represent Confidential Business Information in itself. This knowledge will inevitably become available through Agency actions for sharing information on all potential registrants of a substance during the formation of a SIEF. Any useful pre-registration scheme for chemical groups will include specific provisions for masking supplier/chemical linkages in the process, and any scheme to address a single chemical should be approached on a voluntary basis.

- Sharing of existing data between registrants (Point 28). A new registrant of a substance will be put into contact with previous registrants. Knowing a competitor has previously registered a substance is itself valuable business information. We maintain the all existing and potentially new registrants should only be made aware that other suppliers have interest in the substance(s) without revealing the suppliers involved. The decision to expose (or not) their market positions should then be left up to the individual suppliers;

- "The Agency shall make its opinion and any attachments thereto publicly available on its website" (Point 52.7). This means that substances requiring authorisation and the authorised uses will be publicly available. ATC feels that this information must be restricted to the identity of the chemical involved without connection to use. It should be the duty of the supplier only to reveal the use of an authorized chemical to his immediate downstream customer. Likewise, "details of all substances evaluated will be publicly available on the Agency website (Point 38)". The level of detail available will determine whether the disclosure of CBI is involved. ATC believes that any information not relevant to the assessment of hazards or risks for a substance should remain confidential unless an individually supplier deliberately indicates otherwise.

11. Authorization Procedure

Simply put, the ATC view maintains that the authorisation process should be confined to CMRs, POPs and PBTs (whose harmful properties have been demonstrated, not alleged). Endocrine modulators and sensitisers should be excluded from the current debate and process, but as a bare minimum, it should be confirmed that any mandated additive substitution of a substance be based upon risk, as opposed to hazard, taking full measure of the socio-economic impact of such an action over the entire additive supply chain I the decision making process.