



Afton Chemical Corporation
500 Spring Street
Richmond, VA 23219

December 16, 2004

Office of the U.S. Trade Representative
600 17th Street,
N. W. Washington, DC 20508

Re: Public Dialogue on Enhancing the Transatlantic Economic Partnership

Dear Sir or Madam,

I am writing on behalf of Afton Chemical Corporation ("Afton"), and pursuant to the request (Federal Register Vol. 69, No. 158 and updated in Federal Register Vol. 69, No. 216) by the United States Trade Representative for written public input on ideas for deepening transatlantic economic ties, to submit comments concerning what should be done to better mesh US and EU regulatory approaches.

Afton, headquartered in Richmond, Virginia, manufactures and markets globally fuel and lubricant additives. For over 20 years Afton (previously Ethyl Corporation) has sold MMT®, a fuel additive that is used to enhance octane and the performance of automotive fuels. For many refiners, MMT® is the lowest cost and safest option for producing clean burning unleaded petrol. In addition, MMT® does not require significant additional expenditures for plant and equipment. MMT® is currently used in the United States, Europe, Asia, and Central and South America.

Yours faithfully,

Richard M. Mendel
Vice President – Fuel Additives





What should be done to better mesh US and EU regulatory approaches?

Companies of American parentage operating in the European Union (EU) often find that products they are marketing in both the EU and US are subject to separate – and sometimes very different – risk assessment and regulatory review procedures. Such differences can have adverse consequences, both in terms of the costs imposed on the companies involved and the time and resource burdens imposed on the respective regulators. These differences can also accentuate the risk that EU and US regulators, when reviewing the same product, may come to divergent conclusions that then give rise to frictions in the EU/US trade relationship.

Afton Chemical accepts and agrees that every regulatory authority has not only the right, but also the responsibility, to ensure that specific products are suitable for use in the territory for which that regulator is responsible. Afton believes, however, that promoting greater consistency between EU and US risk assessment and regulatory review procedures can benefit affected companies, the broader public and responsible regulators.

There are a number of ways to promote such improvements. These can range from full-blown mutual recognition agreements to sector-by-sector initiatives aimed at promoting conformity in product approval applications (e.g. such as are now being discussed in the pharmaceutical sector).

Importantly, however, they can also include a commitment by EU and US regulators that they will apply – across all sectors – an agreed set of fundamental principles designed to put into practice the general commitments that each side has undertaken with respect to regulatory transparency, stakeholder involvement and reliance upon sound science.

Adherence to such principles can promote much needed efficiencies in the conduct of risk assessments and regulatory reviews. In some instances, for example, it can prevent time-consuming and expensive duplications of effort by alleviating the need for one reviewing authority to commission, oversee and interpret certain kinds of elaborate test work (e.g., in cases where directly analogous work has already been undertaken or completed by another competent regulatory authority). And, by ensuring less divergence in the review processes applied by EU and US regulators, adherence to such principles should, over time, help to ensure fewer instances in which EU and US regulators reach divergent judgments about the same product or potential risk.

We outline below a set of principles encompassing specific procedural rights and responsibilities on which we believe the EU and US can find common ground (where appropriate, we also point out the many ways in which application of these principles is grounded in, or would be consistent with, more general policy commitments that the EU and/or US has undertaken already).

If adhered to by both EU and US regulators, Afton believes these principles, taken together, can contribute to the convergence of regulatory practices on both sides of the Atlantic, and to a lessening of the burdens imposed both on companies and regulators in their conduct of risk assessment and regulatory review procedures.

1. Transparency/access and disclosure of data

Fair risk assessment and review processes will reflect the highest degree of transparency at every stage.¹ This transparency principle translates into several specific rules. First, the structure, timing, means of participation, and modes of decision-making should be made clear to all potential stakeholders. Second, the participation and viewpoint of stakeholders, in and of itself, should be clear to all concerned parties. Therefore, any submissions by parties should be made fully and immediately accessible to other stakeholders.²

2. Right to comment and rebut

Disclosure of stakeholder submissions is necessary, but not sufficient. To ensure that deficiencies and weaknesses in submissions are identified, it is essential that other stakeholders have an opportunity to comment upon those submissions. Moreover, for such comments to be meaningful, all raw data, source documents, and other pertinent information (such as information on test methodologies and experimental methodology, and all test results) relating to the submission and accompanying studies must be made available.³ Only this level of disclosure will ensure adequate scrutiny of stakeholder assertions and the scientific evidence that underpins such assertions.

Stakeholders should be given a reasonable period of time to review and comment on submissions by third parties and on other evidence gathered by the authority undertaking the risk assessment or review. Any such comments should be made part of the record. This is particularly crucial, of course, where information and submissions may form the basis for any official decision-making; any such information must be subject to assessment, review and rebuttal.⁴

¹ This is a principle that the EU has endorsed on numerous occasions. For example, the EU's commitment to transparency and access to government procedures and process is reflected in the Aarhus Convention of June 1998 on public participation in government decision-making.

² This principle is reflected, for example, in the EU Document Access Regulation, which grants any natural or legal person a right of access to documents held by EU institutions, including the European Parliament, Council, and Commission.

³ This is reflected in the EU-US Guidelines on Regulatory Co-operation and Transparency, which are aimed at "promoting public participation through disclosure of and access to supporting documents, particularly the timely release of the supporting rationales, analyses and data for regulatory proposals."

⁴ Broad disclosure and opportunities for comment are consistent with the Community's approach on public access to documents as set forth in Council Regulation No. 1049/2001 of 30 May 2001, which entered into force on 3 December 2001. They are also consistent with the EC-US Guidelines on Regulatory Co-operation and Transparency.

3. Right to challenge other stakeholders' scientific approach & methodology

In some cases, the opportunity for stakeholders to review all relevant submissions, as well as the data and methodology that underpin them, may still not yield an entirely clear scientific picture, potentially leaving regulators in the uncomfortable situation of having to try to resolve a "he said, she said" debate. In such cases, the only means of resolving such a debate may well lie in determining why a stakeholder chose a specific test methodology, or chose to interpret a specific test result in a particular way.

For this reason, it is also essential that the regulator go beyond merely inviting and disclosing stakeholder submissions, or even requiring that those submissions have been independently peer reviewed. Interested parties, who possess specific relevant technical expertise, should have the right not only to rebut other stakeholders' assertions, as well as the data, test methodology, and test results that underpin those assertions, but to directly question other stakeholders on their selection of test methodologies and interpretation of results.

4. Peer review of stakeholder submissions

Scientific data that the regulator intends to invoke in support of a risk assessment conclusion or regulatory decision should be subject to independent and unbiased peer review. Peer review is an important complement to stakeholder review, and should extend to the complete submissions, the comments received on them, and the regulator's position.⁵

In appropriate cases, peer review should also extend to the test methodology, test procedures employed and the resulting data. This is essential to determine objectively what conclusions, if any, can be fairly drawn from the tests and data submitted.

5. Stakeholder involvement in the development of new evidence

Interested parties must have the right to participate fully and effectively in every phase of risk assessments and review processes. Moreover, to the extent that the process itself points up the usefulness of additional testing or scientific examination of products, stakeholders should have the right to input on the design of any test programs, how they will be conducted, and how their results will be reported and evaluated.⁶

⁵ This is not only standard scientific practice, but peer review is, in fact, required by the EU in such areas as chemical risk assessment. See article 10 of Regulation 793/93 which requires that draft risk assessment reports on priority substances are peer-reviewed by the SCTEE (Scientific Committee on Toxicity, Ecotoxicity and the Environment).

⁶ This approach is reflected in the Communication on the Precautionary Principle, where the Commission itself confirmed "its wish to rely on procedures as transparent as possible" and "to involve all stakeholders at the earliest possible stage." In addition, the Communication provides that "all interested parties should be involved to the fullest extent possible in the study of various risk management options." Similarly, as the EU-US Guidelines for Regulatory Co-operation and Transparency state, regulators should "consult with the public, including interested stakeholders, domestic and foreign, in an early and broad manner" and "invite the public to submit comments on the regulation, accompanying explanations, and supporting documents".

6. Full consideration of evidence developed in other markets

As noted above, companies marketing a particular product in the EU or US often develop extensive bodies of scientific data regarding that product and any potential environmental, health or other impacts. To the extent that such evidence was developed under conditions similar to those existing in other markets, it may be helpful in assessing the impact of the use of that product in such markets. It is essential that regulators take full account of all such evidence developed in other markets that also satisfies the other principles set forth in this paper.⁷

7. Role of external consultants & experts in risk assessment & review processes

It is recognised that regulatory authorities, in carrying out risk assessments and review processes, may decide to involve external consultants or experts in different phases of the assessment and review. Afton believes that any such consultants or experts as are brought in to assist, or whose advice the regulator may rely upon in its examination and decision-making, must be made explicitly subject to the same principles that are outlined above. A failure to do so would risk creating a double standard within the review process itself, and would risk consigning those aspects of the risk assessment or review delegated to external consultants or experts to a process that is potentially less transparent, fair and science-based than other aspects.

⁷ This is entirely consistent with the EU's approach in the forthcoming chemicals review process, which requires that evidence developed in non-EU countries should be taken into account. See European Commission White Paper on the *Strategy for a Future Chemicals Policy. COM (2001) 88 final*. It is also consistent with the approach adopted by the EU in the area of environmental liability where the Commission has considered cost data from the United States to evaluate the impacts of the proposed Directive in Europe. Similarly, the EU-US Guidelines on Regulatory Co-operation and Transparency require that regulators should "examine the appropriateness and possibility of collecting the same or similar data about the nature, extent and frequency of problems potentially warranting regulatory action as those collected by their counterparts" and "examine the possibility and appropriateness of using the same data and determining the magnitude and causes of specific problems potentially warranting regulatory action."