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"OVERVIEW OF THE 6th AMENDMENT"

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Ladies and Gentlemen,

My task today is to give you a general overview of the 6th Amendment.

However, since I arrived here in Washington, I learned that we need to be clear which 6th Amendment we mean.

You have a very important 6th Amendment in your Constitution's Bill of Rights. Our 6th Amendment is less ambitious, and much, much newer.

It is the 1979 amendment to the 1967 Directive on the classification, packaging and labelling of dangerous substances; it simply lays down preconditions for trade in chemicals in the European Community.

But, like your Bill of Rights, I can say that our 6th Amendment also secures due process and equal protection under the law.

It is the foundation for the free movement of chemical across the borders of the 10 Member States of the European Community.

It protects all our citizens against potential, unknown hazards from new, commercial substances.

It gives producers and importers common rules, ~~these~~ prevent the imposition of unilateral conditions by individual governments, ~~and a single court of justice to enforce its laws.~~

Before I go on, let me ~~briefly describe a few~~ underline the basic aspects of the structure of the European Community that you must remain aware of.

The European Community comprises 10 Member States. Despite its colloquial name of "Common Market" in the press, it is far more than a free trade zone or customs union. It is an association of States with a popularly elected Parliament, the power to make laws, ~~to administ~~ ~~to~~ to enforce them and to administer them.

The "6th Amendment" we are discussing here is a Directive. This means that it states precise objectives but must be implemented in each Member State by national laws or regulations.

Outsiders may be led to believe that this gives the Member States great flexibility in implementing the directive. But in fact, uniformity of goals and programs is the heart of the matter. So, uniform implementation is guaranteed by the Member States, watched over by the European Commission, and secured by the European Court of Justice.

The 6th Amendment now is being implemented by the 10 Member States with the strong support of the European chemical industries. It has essentially the same purpose as the pre-manufacturing notification under Sec. 5 of TSCA, but with several differences.

That is, its overriding purpose is to provide a framework for the testing and management of new chemicals, from the time they enter the marketplace.

The 3 main goals are:

- to provide adequate protection for people and the environment from the potentially harmful effects of chemical substances;

- to establish notification procedures that are practical and enforceable;

- and, to protect the viability of the European chemical industries, and even to facilitate trade within the Community by avoiding non-tarif trade barriers.

Many factors needed to be taken into account in preparing a common notification system that would respect the different economies, societies, and political systems of the Community countries.

The European Commission proposed the draft directive in 1976, and we worked together with the industry and national governments for 3 years to ~~prepare~~ establish its final structure.

In the end, some of the most important considerations were:

- the rate of new chemical substances entering the market;

- current experience in testing and evaluating chemical substances;

- the predictive power of individual tests;

- the costs of tests and their duration;

- the capacity of the Member States to perform tests under conditions of good laboratory practice;

- the administrative capacity in the Member States to evaluate the information in the notifications.

Consequently, the system that finally was adopted has two basic elements that must be emphasized:

1. The major innovation in the 6th Amendment is the creation of one single provision for the testing and notification of new commercial chemicals throughout the entire European Community.

   In effect, the competent authority which receives the notification will act as the agent of the other nine Member States in reviewing the notification and admitting the chemical substance to the Community marketplace.

   So that, if a manufacturer or importer has properly notified a substance in the country of origin or first importation, the substance may be marketed in all the other nine countries in the Community.

The directive has created a fundamental interdependency based on mutual trust among the Member States and the Commission. The nine Member States which receive the notification must have confidence in the decisions of their partner State which received the initial notification.

A crucial element of this system, consequently, is the free flow of information among the governments administering the directive.

You might say, in essence, that the free, unhindered flow of new chemical substances in the European markets now is based on the free, unhindered flow of specific information about these chemicals among the Member States.

2. The next original element of the directive is the linkage of the notification requirement to a sequence of mandatory tests based on annual and total production volumes. This ~~"Stufenplan" or~~ "Step-sequence" system of levels of testing seeks to create an equitable balance between economic reality, administrative simplicity, and protection of the environment.

The testing system foresees that the producer or importer submit to the national competent authority an initial file containing a basic technical dossier of information about the chemical's identity, physico-chemical characteristics, potential toxicological and ecotoxicological effects, use, and disposal.

Further information about toxicity and ecotoxicity must be submitted when threhold levels of the new chemical substances are placed on the market, or if the national authorities feel that it is necessary, based on the results of the initial assessment.

Now, I would like to describe the new responsibilities, the new relationships the directive establishes among the three participants in the notification system. I would also like to review the procedures that have been agreed upon for the transfer of information under the directive.

By information, may I remind you preliminarily, I mean the initial notification of a new chemical substance (including the technical dossier required by Annex VII), follow-up notifications, other information relevant to the management of the notified substance, and communications between the Commission and the Member States concerning the file.

I. HOW DOES THE 6TH AMENDMENT ALLOCATE RESPONSIBILITIES?

a) What are the tasks of the chemical industries?

Of course, the 6th Amendment does not modify the ultimate legal responsibility of the chemical industries for the quality and safety of their products. It does introduce the additional, specific task of preparing and submitting to the national government in which the new chemical

substance is first manufactured or imported a proper notification, which includes a technical dossier and information about uses, classification, labelling and safety.

The contents of the notification will be discussed extensively later, so I do not think I need to expand on them now.

Let me now go over the basic structure of notification system under the 6th Amendment, (You will find an outline of this in yours folders.)

1. Who must notify?

The obligation to notify applies to any manufacturer or importer who puts a "new" chemical on the market in the European Community for the first time; that is, one which the notifier has not previously marketed. If the chemical substance has already been notified by another person, the competent authority may agree that the subsequent notifier refer to the results of studies carried out by previous notifiers, with their agreement, to satisfy the requirements of the technical dossier.

2. What must be notified?

Any chemical substance not specifically exempted, which had not been placed on the market between January 1, 1971

and September 18, 1981 must be notified. In other words, any chemical substance that is not on the inventory to be established by the Commission, and is not on the list of exemptions (Art. 8).

This inventory is static. Unlike the TSCA inventory, will not change. All new chemical substances will continue to be subject to notification by each new producer or importer in the future.

3. When to notify?

Anyone manufacturing or importing a new chemical into the European Community must notify it at least 45 days before marketing. The 45-day waiting period permits the competent authority to check the adequancy of the notification. It is not equivalent to a licensing scheme, and the chemical will not be subject to a final hazard ~~or risk~~ assessment during this period.

Keep in mind, however, that this 45-day period will only begin to run after a complete notification is submitted; submission of a file which is lacking elements of the technical dossier, for example, would not be accepted as a proper notification. Consequently, the 45-day period only would begin to run when the file is complete.

4. Exemptions

Certain chemical substances described in Article 8 may be considered as having been notified under the Directive. They include chemicals marketed in quantities less than 1 ton per year, polymers containing less than 2% of a new monomer, and chemicals undergoing research or test marketing under conditions described in the Directive.

A limited Announcement must be made for chemicals placed on the market under 1 ton/year, or for research and development in quantities greater than 1 ton/year. The R & D exemption is limited to 1 year. The announcement must contain the chemical identity, labelling data, and quantity marketed, and the notifier must comply with any special conditions imposed by the competent authority.

5. To whom must the substance be notified?

The chemical substance must be notified to the competent authority in the EC country in which it is first imported or manufactured and placed on the market.

For example, if a chemical is produced in France, the producer must notify in France. If a chemical is produced in the USA and exported to the Federal Republic of Germany, then the resident importer must notify in the Federal Republic of Germany.

6. What is "placing on the market?"

Unlike TSCA, the 6th Amendment links the notification requirement to the marketing of a chemical, not to the manufacture. This is defined as "supplying or making available to third parties". In practice, this definition would cover any transaction involving two different legal entities, such as two different companies in a single country. It would also apply to the same company in two different countries, because each company is a distinct, legal entity.

Colloquially speaking, we could say that just about any transaction that moves a substance from the plant where it was first manufactured to another plant - except possibly through a pipeline - would make the substance subject to notification.

Turning the matter around, we can say that only "site-limited intermediates" would be free from the notification requirement.

7. What information must be in the new chemical notification?

The notifier's obligation includes:

- determining the physico-chemical properties of the substance, toxicity, and ecotoxicity according to Annex V methods

- assessing the real or potential environmental hazard according to annexes VII and VIII;

- classifying and labelling the substance according to annex VI;

- describing the unfavorable effects of the substance related to the foreseen uses; and,

- proposing precautions for safe handling, transport, and disposal of the substance, including emergency measures (Art. 3.6).

So, to put it briefly, the core information to be provided by the notifier is the technical dossier which should "supply the information necessary to evaluate the foreseeable immediate or deferred risks which the new substance may entail" for people and/or the environment.

The information to be submitted in the technical dossier and follow-up notifications must be based on methods recognized and recommended by competent international bodies. This will include test guidelines, good laboratory practices, and eventually hazard assessment. We are striving to secure as high a degree of similarity as possible in the information provided to the authorities, and governmental treatment of that information.

In fact, annex VII sets up a base-set of information designed to be normally sufficient to identify those new chemicals which may warrant immediate further attention, as well as those which do not seem to be potentially significantly hazardous at relatively low levels of marketing. In this way, the base-set operates as a screening device.

This base-set of information also serves as the new chemicals "passport!".

It fulfills the requirements for the initial notification, so that the chemical substance can cross the borders into the other nine states in the European Community. The next testing requirements are linked only to marketing levels of 10 tons/year or 50 tons total.

Now, let us look at what happens to the notification when it has been submitted to the proper national competent authority.

What are the tasks of

b) The national competent authority

The national competent authorities are responsible for receiving the notifications.

First, it must examine the conformity of the notification with the directive. The receipt of the notification will be acknowledged and it will be given a registry number that will be used throughout the Community.

Then, it will review the testing methods and good laboratory practice requirements. Any adaptations or omissions of the information will be examined for adequate justification.

(In your folder, you will find an outline of this testing system, which will be covered by Mr. Smeets this afternoon).

Claims of confidentiality will also be examined for conformity with the directive, but I will discuss this issue in greater detail at a later point in my talk.

The notification will be considered incomplete if it is found to be lacking information in the proper form. This means that the 45-day waiting period before marketing will start to run only when these deficiencies are corrected, that is to say, when a proper notification is submitted to the competent authority. ~~This initial review for completeness is expected to take about 2 weeks.~~

Once the administrative check of the notification is completed, the competent authority must send the dossier or a summary to the Commission, together with any relevant comments (I will discuss the procedures of transferring the notification later on).

The competent authority also may ask for further information or verification tests including accelerated testing under Annex VIII, or carry out sampling necessary for control, or regulate the use of the substance before Community provisions are adopted. Non of these latter measures affect the validity of the notification, so they would not delay the marketing of the new chemical substance. If a competent authority asks for additional information or studies under Annex VIII, it must notify the Commission of the tests chosen, the reasons for their choice, and the assessment of their results.

The Commission will send a copy of the notification dossier or a summary to the other nine competent authorities. They consult the national authority which received the original notification or the Commission about the data; they may also suggest that further testing be required (Art. 10(2)).

The 6th Amendment provides a very general framework for decision making by the competent authorities on the basis of information in the notification (Art. 3(2)). Clearly, this subsequent issue of what regulatory measures may be based on the information contained in the notification is an important area of concern to the Commission, as well as to the chemical industry and the national authorities.

We have begun consultations on harmonizing the interpretation of the data in the notification. We hope that ultimately we will be able to harmonize the assessment of hazard ~~and risks~~ from the chemical substance, as well.

Do not forget that the Member States may not limit the scope of their chemicals policies to the system in the 6th Amendment. Already some States have used the implementation of the directive as a vehicle to regulate chemicals in areas outside the directive, such as in the workplace. Other are creating new possibilities of testing or controlling existing chemicals or exports.

Where are we now in implementing the 6th Amendment? In part thanks to the steady support of the ~~European~~ chemical industries, it has been implemented more rapidly than any other of our some 60 environmental directives.

~~Seven~~ Six of the Member states have the necessary laws or regulations in place for implementation.

Two Member States are still in the midst of their parliamentary procedures for implementing the directive, and one has initiated the implementation process.

However, all 10 Member States have designated contact points to receive the notices of existing chemicals for the EINECS - the European Inventory of Existing Chemical Substances.

And, 9 out of 10 Member States have established competent authorities to receive the new chemical notifications.

Those states which have not yet been able to develop the necessary legal machinery to implement the directive fully will not receive the full summary or dossier. They will only receive a notice from the Commission that a particular chemical has been notified on a certain data in a certain country.

This certification notice from the Commission will enable the chemical to be marketed in countries which have not yet fully implemented the directive (Art. 22).

c) The role of the Commission of the European Communities

The 6th Amendment has assigned several central functions to the Commission which involve the transfer of information, enforcement, and resolution of potential conflicts (Art.s 9, 10).

Broadly speaking, the Commission's overall task is the control of implementation and harmonization of the administration of the directive.

We are already taking all necessary steps to fulfill these several responsibilities which are crucial to the smooth implementation:

- We are drawing up the inventory of existing chemicals, and we will prepare the list of new notified substances (Art. 13).

- we are determining physico-chemical, toxicological, and ecotoxicological test methods, in consultation with the special committee for adaptation to technical progress, which was established under the directive (Art.s 19, 20, 21)

- we are developing guides for the omission, substitution or addition to the tests required by the directive (Annex VII) and,

- we are establishing detailed guidelines for conforming to the classification and labelling requirements of the directive (Annex VI).

Furthermore, during the past two and one-half years, we have met regularly with the responsible officials of the Member States to develop common procedures for implementing the directive.

These meetings will continue.

We in the Commission are also responsible for transferring the notifications among the competent authorities of the Member States. These communications are confidential, and a variety of measures have been taken to ensure that they remain so: we will use double envelopes with special labels. The notifications will be transferred unopened through the Pemanent Representations of the Member States in Brussels, and their respective Foreign Ministries.

The Commission and the Member States have agreed on a summary form containing all the information required in the initial notification. This will provide all the governments with the basic information necessary to carry out an initial hazard assessment on the chemical substance, without overwhelming them with details.

We feel that this summary form will be particularly useful if it is prepared in 2 languages - of course in the language of the country in which a chemical is notified, but in one other Community language as well.

Both Denmark and the Netherlands have taken steps to introduce this approach. In Denmark, the summary may also be prepared in English; in the Netherlands the annexes to the dossier may be submitted in Dutch, English, French or German.

One of the Commission's most important responsibilities will be to promote communication and consultation among the Member States so that we can avoid unilateral actions regarding specific chemicals.

Thus, Article 10(2) of the directive provides that any competent authority may consult with other national authorities or the Commission on specific details of the data in the dossier, their interpretation, or study programmes under annex VIII.

If no agreement is reached informally, the directive provides a decisionmaking procedure by the Commission to ensure that administrative practices and standards are in close harmony with each other (Art. 21).

Our ongoing, informal consultations should strengthen the system of mutual trust I referred to earlier, so that the conflict resolution procedures of Article 21 will only be necessary in exceptional situations.

II. PROTECTION OF COMMERCIALLY SENSITIVE INFORMATION

Of course, a key issue in the preparation of the 6th Amendment was the concern about protecting the chemical industries' investments in new substances. One way to do this, was by protecting commercially sensitive information from disclosure.

The 6th Amendment clearly is based upon the right of the governmental authorities to the information in the dossiers and summaries.

The next question, then, is how to solve the potential conflict between public access to the information contained in the dossiers (without going into justifications for access at this time) and protection of commercially sensitive information.

The directive resolves this by defining 5 items (Art. 11) that may not be held confidential. Other information which the competent national authority receiving the notification determines worthy of greater protection may be treated confidentially. All claims of confidentiality must be given full justification.

On the one hand, industrial and commercial secrecy shall not apply to:

- the substance's trade name;
- its physico-chemical properties under annex VII (3);
- ways of rendering the substance harmless;
- interpretation of toxicological and ecotoxicological tests and the name of the body responsible for the tests
- recommended methods and precautions, and emergency measures under annex VII.

Furthermore, the protection of confidentiality is lost if the notifier subsequently releases this information, and the notifier must notify the competent authority if it does so.

Finally, the identity of a new chemical may be published in encoded form in the list of notified substances - if it is not classified as dangerous - for up to 3 years.

The Member States may be required to give stricter protection to commercially sensitive information coming from states which have stricter than usual practices of protection (Art. 11 (4)).

In recognition of these responsibilities, the Commission and the competent authorities have exchanged information about the measures taken to ensure the confidentiality of commercially sensitive information in the notification dossiers, both in transmission and storage.

Some of the more technical aspects of this protection I have described to you earlier. At this point it is enough for me to say that the Member States clearly are generally satisfied with the information they have received about protection of confidentiality.

We will, of course, keep a careful watch on this issue so that potential problems can be avoided at the earliest stages.

III. MUTUAL ACCEPTANCE OF DATA

I have touched repeatedly on the issue of mutual acceptance of data within the European Community, perhaps without calling it directly by name. Many of the Commission's short and longterm responsibilities under the directive share the goal of creating a strong basis for a notification system where the decisions of one Member State about a notified chemical substances can be accepted by the other Member States.

Also I must stress to you that the Commission regards this problem in a much broader context than one limited solely to the European Community.

A steadily increasing number of industrialized nations are adopting chemicals control laws, that are similar in design or scope to the 6th Amendment or TSCA.

In the current economic climate, protection the freedom of international trade in chemicals can be considered a vital interest of national industries and governments. International trade, after all, is forming a steadily larger part of national revenues.

It seems auspicious then, that the 10 Member States in the European Community were able to agree on a common notification scheme that will prevent unilateral hindrances to trade in chemicals.

Better yet, that the 24 industrialized countries of the OECD have found a common basis of approach on these issues, as well.

Harmonization of good laboratory practices, test methods, and data interpretation can lead to internationally acceptable decisions to control or <u>not</u> to control a chemical substance.

Hence, the OECD Council decision last May on this subject was a major advance towards securing and reinforcing the free international marketplace for chemicals. At the same time, it will secure a potentially consistent basis for protection of the environment.

Under these circumstances, we feel it is all the more unfortunate that our rapid progress towards the internationally harmonized OECD Council decicision on the pre-marketing set of data (MPD) has been roadblocked since last year. We hope this situation can be rectified.

We strongly supported the past work of the OECD in these areas, and will continue to emphasize the need for international harmonization of the administration of chemical notification system, including the harmonization of hazard assessments.

Our commitment to these goals was reinforced at a workshop in Rome, in December 1981, within the context of the bilateral consultations between the Community and the United States Environmental Protection Agency. The participants at that workshop agreed that both the European Community and the United States should continue to support the OECD's work on harmonization of hazard assessment.

IV. CONCLUSIONS

In conclusions, I would like to return for a minute to a more general consideration of the underlying political philosophy of the 6th Amendment. After having studied the trees for 30 minutes, so to speak, let us step back and consider the shape of the forest over the next few years.

The practical implementation of the directive has just begun. It has, in fact, the firm support of all the participants in the intensive consultations that led to its approval by the Council in 1979.

Last month we reiterated our confidence in the continuing, constructive relationships with the chemical industries and the Member States at a 2-day seminar sponsored by CEFIC.

We expect the bulk of the administrative responsibilities to grow very gradually during the initial few years of implementation.

Hence, we hope that diligent consultation and cooperation will enable us to anticipate and resolve potential problems before they grow to a size that may threaten either trade in chemicals or the environment.

I can describe the 6th Amendment as a finely designed, precision instrument to respect and to promote the concerns of the environment, public health, and the international community of chemical industries.

In light of the widespread consensus on goals and means, reflected in the 6th Amendment, I can only invite you to share in the partnership it has established for the benefit of us all.

Moment of notification	At the latest 45 days before marketing
What chemicals must be notified	Those not included in the inventory of chemicals put on the Community market by 18 Sept. 1981 (notified chemicals will not be added to the inventory)
Who notifies	Any manufacturer or importer (whether first or subsequent) of a notifiable chemical
Where to submit the notification	To the competent authority of the Member State in wich the chemical is produced or into wich it is imported into the Community
Exemptions	- research and analysis in view of compliance with directive - research and analysis in laboratories for quantities below 1 t/year/ manufacturer - polymers containing less than 2% of a new monomer - test-marketing (1 year maximum) : brief notification ; registered customers - chemicals produced in quantities below 1 t/year manufacturer : brief notification
Content of notification	- technical dossier containing informations, result and description of studies referred to in Annex VII - declaration concerning the unfavourable effects in terms of the various uses envisaged - proposed classification and labelling - proposals for any recommended precautions relating to the safe use of the chemical
Further testing and information (Stufenplan)	As provided for in Annex VIII : two additional levels. Triggers : previous results of testing + marketing volume
Follow-up information	- changes in marketing quantities - new knowledge of the effects on man/environment - new uses - changes in properties resulting from the composition of the chemical (impurities, additives, etc.)
Confidentiality	Information to be keept secret from all persons other than the competent authorities and the Commission is decided by the authority owing to proposals by the notifier. Secrecy does not apply to trade name, physico-chemical data, ways of rendering the substance harmless, methods, precautions and emergency measures referred to in Annex VII points 2.3, 2.4., 2.5., interpretation of tox./ecotox. testing.

Information submittal: Step - sequence scheme

(Escape clause)

BASE SET

- Identity of the substance
- Informations on the uses and production
- Physico-chemical properties
- Toxicological studies: acute, subacute toxicity, mutagenicity screening tests
- Ecotoxicological studies: LC 50 for fish and daphnia, degradation
- Possibility of rendering the substance harmless

(Escape clause)

1) Q: 10-100 t/y (per notifier) or 50-500 t cumulated (per notifier)

2) Results of base set tests

LEVEL 1

- Toxicological studies : fertility study, teratology study, subchronic and/or chronic toxicity study including special studies, additional mutagenesis tests (including screening for carcinogenesis)
- Ecotoxicological studies : algal test, prolonged study with daphnia, prolonged toxicity study with fish, test for species accumulation, prolonged biodegradation study

(Escape clause)

1) Q : 1000 t/y (per notifier) or 5000 t cumulated (per notifier)

2) Results of base set and level 1 tests

LEVEL 2

- Toxicological studies : chronic toxicity, carcinogenicity, fertility (3 generations) additional teratology study, acute and subacute toxicity on second species, additional toxico-kinetic studies
- Ecotoxicological studies : additional tests for accumulation, degradation and mobility, prolonged toxicity study with fish, birds and other organisms, absorption-desorption study