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EEC / US meeting of 29 - 30 June 1978

Item 2 of the Agenda

The European Community's approach to the control of new chemical substances

I believe that most people here will be aware that the European Community, that is to say the EEC or - as it is often referred to in the United States - the Common Market, has an environmental action programme.

This programme was adopted by the EEC Council in November 1973. It is a wide-ranging affair, covering water pollution, air pollution, noise, waste, as well as general measures in the field of planning and conservation. Amongst the priorities laid down in this EEC programme for the environment is action in the field of chemicals.

I don't want to deal today with this topic in general. As you may know, some directives have already been adopted by the EEC Council regulating the composition and use of certain products, such as synthetic detergents, sulphur in heating-oil, lead in petrol, PCB's and so on. Other directives are in the course of preparation. What I want to do today is to concentrate on EEC legislation, or more accurately, draft legislation as far as the problem of new chemical substances is concerned.

In the light of the presentation we have just heard from the US premanufacturing/notification group, I am convinced that a detailed discussion at this stage of the EEC's approach to this question may in fact serve a very

.../... useful purpose.

useful purpose. Comparison of the US and EEC approaches is in itself a valid exercize. At a purely technical level we may be able to learn a great deal from each other. What is more, if we are looking further down the line (as you know we are) towards an eventual agreement with the United States on certain aspects of the implementation of toxic substances legislation, one of the key building blocks of such an agreement is going to have to be found in this field of premanufacture or premarketing notification.

I am not saying that there will be a need for an absolute identity between our two approaches. That may be difficult to achieve, given the different political and social climates in which we operate and differences in the patterns of trade, particularly trade in chemicals, as between the Community and the United States. But what we will need to develop is a mutual understanding of each other's approach and a mutual confidence in each other's systems for the control of new chemical substances. I hope this meeting will help towards achieving that goal.

When the EEC Council adopted the Environment Action Programme in November 1973, it specifically charged the Commission - and I quote - "to investigate the measures still required to harmonize and strengthen control by public authorities over chemicals before they are marketed". While we were still conducting our preparatory examinations, the French Government - in June 1975 - notified the Commission - in accordance with the information agreement which operates between the Member States and the

.../... Community - of a draft

Community - of a draft law on the control of chemical products dispersed in the environment. The Commission invited the French authorities to postpone the application of the measures envisaged in order that it could prepare proposals for Community measures to be presented to the Council.

Between June 1975, when the French Government notified us of its intentions, and September 1976 the Commission sat down with a group of experts who came from all the nine Community countries to try to work out the details of the approach which might be followed at Community level. From the start we had a double objective : that of protecting the health and safety of workers who might handle, or be exposed to the effects of, toxic substances in the work place, and also that of protecting the environment as a whole. We defined "environment" in the sense in which, I believe, it is already defined in the United States namely : 'water, air and land and the interrelationship which persists among and between water, air and land and all living things'. We are therefore concerned with man as a direct or indirect target of toxic substances. We are also concerned with the integrity of the ecosystem as a whole.

I should mention at this point that there already existed within the Community a Council Directive known as 67/548. This Directive, adopted originally in 1967 and amended several times since, dealt with the classification, packing and labelling of dangerous substances. The Directive established various categories of dangerous substances, such as explosive, flammable, corrosive, irritant and so on, and imposed an obligation on the Member States of the Community to classify dangerous substances according

.../... to the nature of the hazard

to the nature of the hazard and to ensure that they would not be put on the market unless they are packaged and labelled according to the provisions of the Directive. Specifically, the Directive required that every package must show clearly and indelibly :

- the name of the substance
- the origin of the substance
- the danger symbol, where this had been laid down, and an indication of the danger involved in the use of the substance
- a reference to special risks.

The Directive provided a list of standard phrases for indicating special risks and also some standard wording for safety precautions. The Directive also provided for a mechanism, which we call the Technical Adaptation Committee, for a Community list to be established of substances which have been classified under the Directive. At the present time the list of dangerous substances which have been classified under the Directive runs to over 800 substances.

In a sense then this 1967 Directive relating to the classification, packaging and labelling of dangerous substances was already a pre-marketing notification. After much consideration and many meetings with the experts of the Member States, the Commission decided that the 1967 Directive was an appropriate vehicle to handle the question of the notification of new chemical substances which could, in the sense I have already described, be considered 'dangerous' for the environment. In September 1976 the Commission sent a

.../... proposal to the Council

proposal to the Council for a sixth modification of the 1967 Directive. This proposal, which we sometimes refer to as the sixth amendment, is in essence the Community equivalent to the US pre-manufacturing requirements which we have just heard described.

For almost two years now the EEC Council, in the form of its specialist working groups, has been discussing this Commission proposal. What I want to do now is to describe the essential features of the proposal as it has evolved during the discussions so that later on this afternoon we can focus on any important differences which there may be between our approach and yours. I should make it clear at the outset that what I am going to say does not necessarily represent the final agreed position of the Community. Discussions are still continuing on various important points between the Member States and the Commission and no doubt they will go on right up till the moment the Council finally adopts the 6th amendment. In fact, it would be fair to say that, within the Community itself, a major exercize of international harmonization is at present being carried out. If we can resolve our differences within the EEC on some of the key questions relating to the control of new chemicals, we may be setting a hopeful precedent for wider international agreements.

Let me turn now to the main points of our proposal.

First of all let me repeat that our conccern, in the sixth amendment, is with <u>new</u> chemical substances. We are well aware that TSCA deals also with the control of existing chemicals, but that is a different question and a

.../... different point on +

different point on the overall agenda of these discussions. The 6th amendment is more limited in scope than TSCA. It is aimed at substances which have not previously been placed on the Community market either as a substance or as a mixture before a certain date. In our original proposal we suggested that that date should be 1 January 1979. But there has been "slippage" on our side just as there has been slippage on your side and realistically that date may have to be postponed.

In principle our proposed Directive is concerned with all new chemical substances when these are placed on the market. However we recognize that it may be necessary to envisage certain exceptions or exemptions. We are currently considering exemptions for new substances which are placed on the market so that their physical, chemical, toxicological or ecotoxicological properties may be investigated for the purpose of the application of the Directive, or for other purposes of research or analysis in quantities of less then one tonne per annnum per manufacturer or importer. In this latter case, the moment the quantity per manufacturer or importer exceeds one tonne per annum, all the obligations of the 6th amendment would apply.

I might add at this point that in our discussions a very important question has been raised and that is the question of chemicals which are already on the market in very small quantities, say less than one tonne per annum per manufacturer. There may be many hundreds of such chemicals. In our definition of new chemicals as chemicals which have been put on the market after 1 January 1979 or whatever date it turns out to be, these

.../... compounds would slip

compounds would slip through the net of the Directive. Even though they only come into full-scale commercial use after the entry into force of the Community law, the obligations of that law would not apply. One way of resolving the problem on our side - and this is something we are now considering - is to extend the definition of new substances to cover also substances which have been placed on the Community market for research purposes in amounts smaller than one tonne per annum and which, after the operative date of the Directive, will be placed on the market in quantities greater than one tonne per annum.

As we understand it, this problem may not arise in quite the same way in the United States. Under TSCA, a "new" chemical substance is anything which doesn't appear on the inventory when this is published. On our side we have recognized the usefulness of an inventory and, when the Sixth amendment is adopted, the Commission will be called upon the the Council to take the necessary steps to draw up such an inventory on the basis of information supplied by the Member States. (The relationship between the US inventory and the EEC inventory is another item on our overall agenda). At the present moment, however, the operation of the EEC law on new chemicals will not depend on the prior production of an inventory.

Having defined a "new substance", our Directive imposes an obligation on the manufacturer or importer who places such a new substance on the market to 'notify' the competent authority of a Member State. In other words, we have expanded the central principle of the 67 Directive so that it will now provide that substances not only be labelled and packaged in the

.../... appropriate way, but also

appropriate way, but also that they be properly notified.

The question immediately arises : when does the notifier notify and what does he notify?

Let me deal with the 'when' first.

In our original proposal we specified that anyone manufacturing or importing into the Community a new chemical substance would have to notify the competent authority at the latest on the date of marketing. We did not wish - and do not wish - to give the impression that the competent authorities of the Member States are in the business of licensing, as it were, the marketing of chemical substances. The central philosophy is that it is the primary duty of the notifier, that is to say of the manufacturer or importer, to satisfy himself as to the characteristics of the substance which he is putting on the market. There can be no transfer of responsibility or liability. The role of the competent authority, in our view, is not to license a substance but, in a general sense, to supervise its introduction and continued use. I shall say more about this in a moment.

In order to allow the authority a greater chance of performing this role in a satisfactory manner, we are now discussing whether notification might be made, say, 30 days prior to marketing. There is a tendency to favour this provision. But even if the 30-day period is introduced, this should still not be seen as a step towards a licensing system. Provided that he has notified the competent authority in accordance with the

.../... requirements of the

requirements of the Directive, the manufacturer will be entitled - solely by virtue of that notification - to put this substance on the market.

In fact we go further than this. The sixth amendment establishes the principle that notification should take place in the country of manufacture or, if the substance is imported from outside the Community, in the country into which it is first imported. But there is a general agreement that a notification which has been properly made in one Member State of the Community should automatically be valid in other Member States. In other words, if a manufacturer or importer can show that a substance has been properly notified in the country of origin or of first importation he is free to put it on the market in other countries of the Community. Which is another way of saying that unless the authorities in the other countries invoke the safeguard clause which enables them to restrict temporarily the entry of a substance which they consider to be a hazard to health and safety, they are bound to accept the free circulation of that substance.

I hope it will be clear from what I have just said therefore that in our view the 6th amendment is not only designed to protect health and the environment. It is also designed to remove important barriers to trade within the Community, i.e. intra-Community trade. A manufacturer may safely project sales on a Community-wide basis without the fear that in one or more countries of the Community, his product will be blocked by capricious regulations concerning marketing. It goes without saying that

.../... by substituting one single

by substituting one single notification procedure for nine possibly very different notification procedures, the manufacturer may save much time and expense. The possible analogies as far as international trade in chemicals is concerned will, I am sure, not escape the notice of anyone in this room.

What is this notification procedure? To put it briefly, the essential element to be provided by the notifier is a technical dossier which, in our view, should "supply the information necessary to evaluate the foreseeable immediate or deferred risks which the new substance may entail for man and for the environment". In particular the draft Directive prescribes that the technical dossier should contain at least the information and the results of a series of studies which are laid down in Annex VII of the Directive.

When I speak of Annex VII I am in fact referring to our 'base set'. The base set is a bundle of information which we have arranged under six broad headings. The first three headings relate to :

(1) the identity of the substance, e.g. its chemical name, empirical and structural formula and composition, including impurities

(2) information relating to proposed uses and estimated production and/or imports for each of the anticipated uses or fields of application

.../... (3) physico-chemical properties

(3) <u>physico-chemical properties of the substance</u>, e.g. melting point, relative density etc.

The fourth heading deals with the results of toxicological studies. Here we are talking about a series of tests which include assessment of acute effects, and of irritant or corrosive effects on the skin and eyes, a sensitization test and a mutagenicity test. There is not yet a final agreement among the Community countries to include a sub-acute toxicity test in the base set but I think it is fair to say that there is a strong tendency in that direction.

The fifth heading deals with the results of ecotoxicological studies. Here we are talking about acute effects on fish and acute effects on daphnia, as well as certain tests of degradation.

As far as these environmental tests are concerned I should once again point out that there is not yet total agreement within the Community that these should be included but again I think it is fair to say that this is the direction in which we are headed.

The last heading in the 'base set' or Annex VII deals with the possibilities of rendering a substance harmless.

In addition to the actual tests themselves, a certain level of agreement has been reached as far as methodology is concerned. For example, for the acute toxicity test we have specified that a minimum of

.../... two routes of administration

two routes of administration are required on both male and female rats, one of which should be the oral route.

We have brought with us copies of our 'base set' as it stands at present, so that you can see how far we have got. Where we have not specified a test method in the text of the annex itself, we are in agreement that tests must be conducted according to methods recognized by existing good laboratory practice and recommended by the competent international bodies where such recommendations exist.

So much for the base set. I am sure we will want to come back to it in the discussion. For the moment I would like to continue with the analysis of the notification procedure as it is presented in the 6th amendment.

In addition to presenting the technical dossier, with the elements that I have described, the notifier must present to the competent authority :

- a declaration concerning the unfavourable effects of the substance in terms of the various uses envisaged and,

- a proposal for the classification and labelling of the new substance in accordance with the Directive. In addition to the categories which I cited earlier -

.../... toxic, inflammable and

toxic, inflammable and so forth - the sixth amendment invents a new category 'dangerous for the environment'. In our original proposal we had a symbol as well - a bird on its back - but this has been dropped during the Council discussions,

- the notifier also has to make proposals to the competent authority for any measures relating to the conditions of use which are recommended to limit unfavourable effects.

As the 6th amendment is presently drafted, the obligation to notify will apply to a manufacturer or importer who puts a chemical substance on the market for the first time, i.e. one which he has not previously put on the market. In the case of a new substance which has already been notified, the competent authority may agree that the second or subsequent notifier of that substance may refer, as regards the technical dossier, to the results of studies carried out by previous notifiers, with the agreement of the latter. One of the obvious questions here is to what extent toxicological and ecotoxicological information will be published. If it is published, then second and subsequent notifiers may in some sense get a free ride.

Under the 6th amendment any notifier of a substance already notified would be required to inform the competent authority of changes in the annual or total quantities place on the market; new knowledge of the effects of the substance on man and/or the environment; new uses for which the substance is placed on the market, as well as changes in the composition of the substance which may result from a modification of the

.../... manufacturing process.

manufacturing process.

As you know, one of the things which we have been discussing very intensively within the Community is the possibility of extending the notification requirement beyond the base set. In other words we are looking at a step-wise or hierarchical system of testing. Sometimes we refer to this as the Stufenplan which is what this approach is called in Germany.

The broad lines of the approach which we are currently considering are these :

At a certain level of commercialization, say ten tonnes per year for the individual notifier or an accumulated total of, say, fifty tonnes per notifier, the competent authority - taking into account present knowledge of the substance, known and planned uses as well as the results of the tests which have been carried out as part of the basic dossier - might ask for some additional tests. We have not yet decided what those additional tests ought to be and obviously the presentation which we have heard from the American side this morning has given us much food for thought. Obviously, some of the additional tests will be triggered - at these levels of commercialization - by the results of the base set. Community experts are looking at sub-chronic toxicity tests, carcinogenicity, mutagenicity, bioaccumulation tests and further degradation studies as possible candidates for this Stage 1 additional testing. (I am counting

.../... the base set as Stage 0

the base set as Stage 0).

I said that at the 10 tonne level the competent authority might ask for additional tests to be carried out. But we envisage that a notifier would have an absolute obligation to inform the competent authority when the quantity of a substance he puts on the market reaches 100 tonnes per year or 500 tonnes accumulated. At that moment the authority would have to ensure that the additional tests were indeed carried out within a time-frame which the authority would itself establish.

We are also discussing the possibility of a Stage 2 test programme. Here we envisage that when the notifier has put on the market 1000 tonnes of the substance a year or 5000 tonnes accumulated, he would again have to inform the competent authority. The competent authority would in turn establish an extended test programme, to be carried out by the notifier, so as to make it possible for the risks of the substance to man and to the environment to be evaluated. Here again Community experts are trying to decide which tests should form part of the Stage 2 package. Possible candidates include chronic toxicity tests (including carcinogenicity), mutagenicity, teratogenicity, fertility and behaviour tests and further environmental studies. Once the package has been agreed, there would be a strong presumption in favour of carrying out the tests envisaged. An authority which decided not to ask for a certain test to be carried out would need to give its reasons. We obviously want to avoid a situation within the Community where the authorities in one country take a different

.../... view of the tests to be

view of the tests to be undertaken than do the authorities in another country.

The Stufenplan concept as I have presented it here has, or will have, a certain degree of automaticity. Certain tests would be performed at certain levels of commercialization. But under the sixth amendment the authority would at all times be able to conduct a dialogue with the notifier and to ask for further information and/or tests. It will be the duty of the authority in the light of all the evidence it receives to take appropriate measures relating to the use of any new chemical substance.

Now obviously we are within the EEC operating within the framework of a common market. I have explained that a substance properly notified in one country of the EEC will by that fact alone have been notified in all other countries of the EEC. But barriers to trade will clearly be created if widely different conditions of use relating to new substances are imposed in different Community countries. We envisage therefore that any measures taken by one country will be of a temporary nature pending the introduction of Community provisions.

There are of course several ways for such Community provisions to be introduced. The 6th amendment provides that a Member State which has received the notification dossier or any additional information shall immediately send a copy of it to the Commission with any relevant comments. The State should explain any programme of additional tests which it may

.../... have required and the

have required and the evaluation which it has made. The Commission is charged with sending all this on to the other Member States. The competent authority of any Member State will be able to consult directly the competent authority which received the original notification or the Commission on specific details of the data contained in the dossier.

If the competent authority in one Member State proposes that a particular substance be classified 'dangerous for the environment' or recommends certain precautions as far as regards, for example, storage and handling, the other Member States will be aware of this through the exchange of information procedure which I have just described. The 1967 Directive provides for the Technical Adaptation Committee (TAC) to ensure that proposals for classification etc. which may be made in one Member State are examined at Community level and adopted, if this is appropriate, on a Community basis. Where major restrictions on the use of a chemical, restrictions having an important economic or social impact, have been introduced in one Member State, the attempt to "harmonize" approaches throughout the Nine may be undertaken not through the accelerated procedure of the TAC but through the more formal channel of a Commission proposal to the Council. The Commission might, for example, propose an amendment to the 1976 Directive of the Council on the approximation of the laws of the Member States restricitng the marketing and use of certain dangerous substances and preparations. This Directive at the moment applies only to PCB's and MVC's but there is no reason why it should not

.../... be added to in the future.

be added to in the future. (The 1976 Directive may of course equally serve to regulate existing chemical substances on a Community level, once the priorities for selecting such substances for screening and/or control have been established.)

In addition to substances which are inscribed in Annex I of the 1967 Directive through the TAC procedure, or covered by other specific Directives, all other substances which have been notified under the Directive will be catalogued by the Commission. Member States may be called upon to give the Commission any information which will facilitate the updating of this catalogue, notably as regards quantities placed on the market.

It can be seen therefore that, in our concept, a "new" substance does not become an "old" substance once it has been notified. Once new, always new. The 6th amendment, with its provisions for dialogue, information, notification and renotification provides in our view a flexible mechanism for the continuous surveillance and review of chemicals in the environment. Eventually, more and more of the new chemicals notified under the Directive will become important "existing" chemicals from the point of view of the chemical industry. Even though the 6th amendment does not have the same scope as TSCA in so far as chemicals which are already on the market in commercial quantities will escape from its provisions, we can expect it with the passage of time to take an increasingly important place as far as chemical regulation in the EEC is concerned.

.../... And since substances

And since substances imported into the EEC will, under the present proposal, be treated identically with those that are manufactured within the EEC, it must be apparent that the 6th amendment will have important international as well as important Community implications.