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Internal Legal Instruments for the Regulation and Control of the Production and Use of Chemicals and Pesticides

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International Legal Instruments for the Regulation and Control of the Production and Use of Chemicals and Pesticides

Perspectives for a Convention

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A. Introduction[1]

I. Purpose of the analysis

A wide variety of instruments and mechanisms for the regulation and control of chemicals and pesticides are already available internationally. What is missing is an analysis which attempts to systemize the different approaches, create transparency, define overlappings and discover prospective deficiencies and shortcomings. In order to accomplish this task we have chosen to cover legally binding rules as well as recommendations and codes, the international soft-law. The paper's overall purpose is to outline a frame for the future regulation on chemicals and pesticides at the international level. An international convention might be one solution[2].

II. Points needing clarification

The analysis of the international legal instruments needs some clarification, not only in order to determine the scope of the report, but also

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1 Revised version of the report presented to IRPTC/UNEP Ad Hoc Working Group of Experts on the Implementation of the Amended London Guidelines, First session, Nairobi, 15-19 October 1990, Analysis of International Legal Instruments to the Regulation and Control of the Production and Use of Chemicals, UNEP/PIC.WG.3/Inf.4, 11 October 1990. Footnotes and references are restricted to those which are indispensable for the reading and the understanding of the text. The facts on the existing level of regulation in the nation states are largely based on

(1) Administrative and Legislative Aspects of Chemicals Control, Comparative Analysis of Selected Issues, OECD 1985, cited as OECD Comparative Analysis.

(2) Ad Hoc Working Group of Experts for the Exchange of Information on Potentially Harmful Chemicals (in particular Pesticides in International Trade), Second session, Rome, 28 January - 1 February 1985, Comparative Survey of National Notification Procedures and Legislative Definitions, Report prepared by the secretariat, with consultant assistance (E.Rehbinder as emphasized by H.-W.M.) in cooperation with the United Nations Economic Commission for Europe, UNEP/WG.112/4; cited as UNEP Comparative Survey.

2 Cf. Ph. Alston, International Regulation of Toxic Chemicals, Ecology Law Quarterly 7 (1978), 397-456; M. Kloepfer, Aspekte der internationalen Harmonisierung des Umweltrechts - Zur Rechtsvergleichung und Rechtsvereinheitlichung im Chemikalienrecht, UPR 1984/9, 281 et seq.

to supply a framework which facilitates the orientation and formulation of a policy in the field of chemicals and pesticides.

The London Guidelines[3] like a number of other national initiatives cover chemicals and pesticides. It should be clear that the report deals with both categories. Bringing together chemicals and pesticides in one single report entails a number of difficulties. Chemical regulation and pesticide regulation follow different regulatory schemes, at least in the legislation of industrialized countries. This might be different in developing countries. But the more the legislation is scrutinized, the more differentiated it becomes and each product, whether chemicals, pesticides, food additives, cosmetics or medicines, is dealt with separately. International regulation must consider these differences and respond to regulations, that are specific to the product. The UNEP GC Decision 15/30[4] refers to "other activities related to the production and use of chemicals". Once again, clarification is needed. International regulation might concern the **trade** in chemicals but it might also concern the **production**, as in the case of the ILO Convention "Safety in the use of chemicals at work[5]". A distinction can be made between process and product regulation[6]: process regulation aims at the regulation of the manufacturing process, product regulation at the regulation of trade. The analysis focuses on product regulation, although process regulation is taken into consideration mainly in the context of the feasibility to ban the production and not only the use of certain extremely dangerous chemicals and pesticides.

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3 London Guidelines for the Exchange of Information on Chemicals in International Trade, Amended 1989.

4 Decision 15/30 of the Governing Council of the United Nations Environment Programme (UNEP) at its fifthteenth session of 25 May 1989 on "Environmentally safe management of chemicals, in particular those that are banned or severely restricted in international trade".

5 International Labour Organisation, convention concerning Safety in the use of chemicals at work, 1990.

6 Cf. E.Rehbinder/R.Stewart, Environmental Protection Policy, in: Integration Through Law, Europe and the Federal Experience, A Series under the General Editorship of M.Cappelletti, M.Seccombe, J.H.H. Weiler, 1985.

The last point needing clarification concerns the type of instruments available internationally chemical regulations . One possibility could be to look at the "harmonization" of the different national approaches in order to define a level of protection and control which would be acceptable to countries all over the world. The FAO Code on the Distribution and Use of Pesticides[7] would came under that harmonization category. Another possibility could be to start from the idea that the differences in regulating chemicals should subsist, that mechanisms, however, must be found to bridge the differences between exporting and importing countries. The London Guidelines[8] and all other efforts[9] to regulate the export of banned and severely restricted products would come under this category. The intention of such an approach does not seem to be to abolish the existing differences in the legal status of regulated chemicals and pesticides but to find ways and means which secure their trade although they are banned or severely restricted. The analysis should therefore clearly distinguish between efforts that attempt to harmonize chemical regulation internationally and efforts that aim to balance differences in the regulatory status of chemicals and pesticides.

III. Scope of the analysis

The analysis cannot be restricted to international efforts. It must take into consideration the key role of some industrialized countries in regulating chemicals and pesticides. Specific emphasis is put on the role of the **European Community**. With its policy of completing the internal market by 1992[10], the European Community seems to have become the most important international organization in developing regulatory frameworks for bringing together different national schemes in one supranational concept. European initiatives to harmonize chemical and

7 International Code of Conduct on the Distribution and Use of Pesticides (Amended Version), 1990.

8 Cf. Loc. cit.

9 Cf. For further details, supra B.V.

pesticide regulation gain importance far beyond the borders of the twelve member states. Due to the enormous impact of the internal market on EFTA countries, the Europeanisation of chemical and pesticide regulation based on Community law seems to be close at hand. It is against the background of the European Community regulations on pesticides and chemicals and the numerous regulatory efforts of other industrialized countries, that international efforts on behalf of the FAO, the GATT and ILO might be analyzed.

The different national, regional and international laws and regulations will be analyzed following the development of regulatory instruments and strategies to fight risks to man and the environment. Regulation traditionally starts in industrialized countries, with efforts to define the conditions under which the **trade** with chemicals and pesticides could be managed[11]. The overall perspective here is to protect the user of the product as well as the workers who are coming into contact with it. Regulation has been adopted to **classify** the products according to the risks, to develop **packaging** and **labelling** standards and **advertising** rules. Then the emphasis shifts from trade regulation to **access-to-market** regulation. Nation states take over the responsibility of protecting their citizens and the environment against possible harm resulting from dangerous chemicals and pesticides, before they are brought onto the market.

There are different regulatory models, notification procedures, registration and, or licensing procedures at stake, but they all intend to guarantee preventive protection against potential risks. The shift from trade regulation to access-to-market regulation seems logical in order to increase the degree of protection. But even access to market rules can not guarantee sufficient protection to man and the environment in the long run. It seems a common characteristic of chemicals and pesticides that their dangerous

10 Cf. For an analysis, R.Bieber/R.Dehousse/J.Pinder/J.H.H.Weiler (Eds.) 1992: One European Market? A critical analysis of the Commission's Internal Market Strategy, 1988.

nature is unknown at the moment when they are brought onto the market, but becomes clear after years of use and experience. Then the question arises of how and if these products can be taken away off the market. The terminus technicus for regulatory efforts to get rid of the products which have proven to be dangerous, is "post market control[12]".

The analysis of export regulation focuses on existing mechanisms to regulate the exports of chemicals by international and by regional organisations, UNEP, FAO, UN, OECD, GATT, EEC as well as on the national regulations of these countries. Information exchange procedures, export notifications and the recently introduced Prior Informed Consent (PIC) procedure define the requirements for trade with banned and severely restricted chemicals.

B. National, regional and international regulation of pesticides and chemicals

I. Regulatory concepts, common goals and definitions

The overall trend in chemicals and pesticides regulation is to leave the narrow borders of regulatory concepts aiming at the **protection of man** against the exposure of chemicals and pesticides and to integrate into the regulatory concept the **protection of the environment**. This extension entails a shift from protection against **acute damage** or **imminent danger** to **potential hazards**. Regulatory actions are no longer limited to cases where actual harm has already occurred, the actions rather aim at protecting man and the environment against the risks

11 Cf. With respect to the regulation of pesticides; H.-W.Micklitz, Zur Geschichte des deutschen Pflanzenschutzrechts, in E.Rehbinder (Hrsg.), Bremer Kolloquium über Pflanzenschutz, 1991, 44 et seq.

12 Cf. H.-W.Micklitz (ed.) Post market control of consumer goods, ZERP Schriftenreihe, Band 11, 1990.

associated with chemicals. Therefore, the notions of "risk", "hazard", or "danger" are crucial notions in all laws and regulations[13].

The goal of protecting man and the environment against risks may be incorporated in a particular law in different ways. The OECD Paper on Administrative and Legislative Aspects of Chemical Control[14], as well as the UNEP Comparative Survey of National Notification Procedures and Legislative Definitions[15] distinguish between[16]

(1) the notion of risk forming part of a general statement of purpose (goals provisions) of a particular law;

(2) the notion of risk being incorporated in statutory provisions that describe individual duties of care, especially in countries that vest in the manufacturer or importer the primary responsibility for assessing the risks associated with chemicals;

(3) chemical laws which set forth a number of risk categories which represent defined dangerous properties of chemicals and

(4) risk criteria being spelled out in statutory provisions that authorize agencies to take specific regulatory action.

Further details can be drawn from the OECD and the UNEP papers[17]. The overall trends, reported in these two analyses have been strengthened and specified. No common approach, however, can be found in the question of whether and to what extent occupational health and safety should be integrated into chemicals and pesticides regulation. For some countries like the United Kingdom, occupational health and safety regulation seems crucial for the development of sophisticated chemical regulation; other countries, like the FRG, i.e., are integrating aspects of occupational health

13 Cf. E.Rehbinder/D.Kayser/H.Klein, Chemikaliengesetz - Kommentar und Rechtsvorschriften zum Chemikalienrecht, Einführung 37 et seq.

14 Cf. Loc.cit.

15 Cf. Loc.cit.

16 Cf. OECD Comparative Analysis, Nos. 6, 13.

17 Cf. OECD Comparative Analysis and UNEP Comparative Survey.

and safety into chemicals and pesticides regulation (Gefahrstoffverordnung)[18].

The integration of the protection of the environment into chemical and pesticides regulation constitutes a shift from **product related to media-related regulation**[19]. Product related regulation focuses on the specific risks of the respective products (chemicals, pesticides); media-related regulation aims at the protection of man and environment independent of the nature of the respective product. A media-related approach encompasses all kinds of products, chemicals, pesticides, medicines, food additives, cosmetics and raises the question as to what extent criteria can be found to protect man and environment against potential risks. Even modern chemical laws do not really pursue a media-related approach. There are elements of a media related approach, but exemption clauses make clear that product related regulations overrule media-related chemical regulation. This differentiation which is quite common in most of the industrialized countries leads to the paradoxical consequence that the purpose of use decides on the applicable legislation. To say it the other way round: Pesticides, medicines, food additives, cosmetics are all "chemicals", the purpose they are destined for, however, makes it necessary either to apply specific product-related laws or to refer back to the basic chemical regulation. That is why chemical regulation, in practice, focuses on industrial chemicals as a specific category of products being distinguished from pesticides and other "chemicals" like medicines or food additives.

Product-related regulation requires a definition of the legal scope. There is no common understanding on what is to be understood by a "chemical" or a "pesticide". In the field of chemicals, specific difficulties

18 Cf. E.Rehbinder, Harmonisierung des Chemikalienrechts - Harmonisierungswirkungen der Richtlinie 79/831/EWG in den Mitgliedstaaten der Europäischen Gemeinschaften im Lichte des deutschen Rechts, Schriften der Gesellschaft für Rechtspolitik Band 3 Chemikalienrecht 1986, 79-139 (quoted as Chemikalienrecht). The report is an analysis on the implementation of the so-called sixth amendment of the chemicals directive.

arise from differentiating between "industrially manufactured chemicals" and so-called "preparations". The EEC Directives 67/548[20] on dangerous substances and 89/C 89/02 (draft)[21] on pesticides provide some guidance on what is to be understood by a chemical or a pesticide. Guidance does not mean that all possible problems are already solved. It is still unclear whether "preparations" containing one chemical substance which comes under the 6th Amendment do fall under the scope of the directive or whether "preparations" are excluded from the directive[22]. The OECD has developed a glossary of the definitions used within chemical legislations in industrialized nations, mainly member countries of OECD[23]. The glossary is helpful in understanding regulatory differences, but it shows at the same time that there is not yet a common understanding, not even among the industrialized nations. The same is more or less true for the definition of pesticides. The respective EEC Draft Directive 89/C/89 02[24] provides for a common framework for the 12 member states, but the definition given here is different from the notion in the US FIFRA legislation[25]. Under an international perspective the FAO Code of Conduct on the Distribution and Use supplies a glossary which is instrumental for the international regulation of pesticides[26].

As far as the **selection of control action** is concerned, there are still substantial differences in the language and the structure of the laws[27]. The relationship between different levels of risks, the basis of their

19 Cf. E.Rehbinder/D.Kayser/H.Klein, Kommentar, Einführung 21 et seq.

20 Council Directive of 18 September 1979 amending for the sixth time Directive 67/548 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, OJ L 259, 15.10.1979, 10 et seq.

21 OJ C 89, 10.4.1989, 22 et seq.

22 Cf. E.Rehbinder, Chemikalienrecht, loc.cit.

23 OECD Glossary.

24 OJ C 89, 10.4.1989, 22 et seq.

25 Cf. The Federal Insecticide, Fungicide, and Rodenticide Act as Amended, Sec. 2 Definitions (u).

26 Cf. FAO Code, loc.cit. Art. 2.

determination and the selection of control action is subject to different national regulatory approaches. One might summarize the findings of OECD Analysis and the UNEP Comparative Survey[28]" in the arising concept of a "hierarchical system" that links differing degrees of risks to the selection of control action. Under this system, levels of stringency of controls are triggered by corresponding levels of risk. There is an interdependence between the degree of risk and the intensity of regulation[29].

Modern chemical and pesticide laws do not require a causal link between the potential risk and the substance concerned[30]. Statistical evidence and scientific research indicating that a hazard exists usually suffices to legitimate preventive action. However, if measures are taken into consideration to restrict or ban the use or production of a specific chemical or pesticide, the mere potentiality of a risk does not justify action-taking. More concrete evidence is needed if action could and should be taken. One might even draw the conclusion from the experience with chemical and pesticide legislation in industrialized countries that market restrictions are adopted only in cases where the causal link between the damage and the substance can no longer be denied. Although it is already a long way from the potential risk to the acute risk, there is a third category to be reported which requires an even higher degree of risk than in the case of market restriction. Reference shall be made to so-called emergency situations[31].

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27 Cf. UNEP Comparative Survey, No.69.

28 Cf. Loc.cit.

29 Cf. UNEP Comparative Survey, No.70.

30 Cf. OECD Comparative Report, No.18.

31 Cf. For a more comprehensive analysis in the context of product safety control, H.-W.Micklitz (ed), Wahrung der Produktsicherheit in dringenden Fällen - Aspekte der praktischen Durchführung in den Mitgliedstaaten, Studie im Auftrag der Kommission der Europäischen Gemeinschaften, Consumer Policy Service, Vertrags-Nr. 6674/89/12, Typoscript Bremen November 1990.

Here, it is indeed the existence of an imminent danger which triggers mostly intermediary action to mitigate the risk[32].

Other countries leave their control agencies more discretion in selecting the appropriate means. This is particularly true for the United States where there is a sequence of increasingly stringent prerequisites (in terms of probability of risks and necessary basis for its determination) from imposition of a testing obligation via control action in the absence of sufficient information to final control action[33]. Although the regulatory approach between the European Community and its member states on the one hand and the United States on the other, seems to be different in actual practice, the interdependence between the degree of risk and selection of control action is striking.

There are, however, some inherent limits which are, though varying in their legal grounding, recognized in most legal systems, and at times even backed by constitutional law and/or constitutional jurisdiction. These limiting rules require agencies according to the OECD Report[34]:

> a) not to overstep the limits of discretion set out in a law or inherently contained in a delegation of powers;
>
> b) not to disregard the scope of discretion available under a legal authorization;
>
> c) to make use of the discretionary powers in a fair and reasonable manner, avoiding arbitrariness, clear errors of judgment and other abuses of discretion.

Tables visualize the linkage between control action and the degree of danger. They show a complicated and sophisticated system which leaves some doubt on whether the finely tuned differences in hazards and actions are manageable by the agencies.

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32 Cf. UNEP Comparative Survey, No. 70, this is the system that exists in the European Community and its member states.

33 Cf. UNEP Comparative Survey, No. 71.

34 Cf. OECD Comparative Analysis, No. 59.

In adopting specific legislation on chemicals and pesticides, nation states are taking over the responsibility to protect their citizens and the environment against risks resulting from unsafe chemicals and pesticides. Accepting a statutory responsibility for the safety and the environment entails far-reaching consequences at the constitutional level[35]. It is no longer the liberal state who guarantees at the constitutional level individual rights to liberty and freedom. It is the new welfare state who is accepting the responsibility to guarantee protection, safety and a healthy environment. Such an extension of responsibilities is not limited to industrialized countries. Here, the classical liberal rights might be interpreted in the light of the new statutory functions as it is the case in the Federal Republic of Germany. New democracies like Portugal and Spain or Brazil have laid down in their constitution state objectives making it a constitutional task to engage in the protection of man and the environment. But even where health, safety and environmental protection is not discussed at the constitutional level, the existence of a statutory responsibility seems to be widely accepted. The United States constitution does not recognize social rights[36]. The constitution is limited to classical liberal rights, to protect individual liberty and freedom. But the United States have developed within the last twenty years the farest-reaching statutory laws on chemicals, pesticides and other devices guaranteeing the protection of man and his environment.

At the international level, Art. 12 of the International Covenant on Economic, Social and Cultural rights induces a right to safety[37], the 1972 Stockholm declaration is still the Magna Charta for the emergence of a right to a healthy environment[38]. The legal status of the documents is subject to a controversial debate. But their mere existence makes it clear that even on

35 Cf. H.-W.Micklitz, Consumer Rights, in A.Cassese/A.Clapham/J.H.H. Weiler, Human Rights and the European Community: The Substantive Law, 1991, 53 et seq.

36 Cf E. Grabitz, Grundrechte in Europa und USA, 1986 Band 1, Strukturen nationaler Systeme.

37 Art. 12 recognizes the right to physical and mental health, cf. for futher details, H.-W.Micklitz, Consumer Rights, loc.cit. IV.3.b.

the international floor, the right to safety and the right to a healthy environment is now an important question to be taken in hand. Both could form the background for the legitimate developments of an international order on the regulation of chemicals and pesticides. In the long run, international regulations have to integrate in trade regulations health, safety and environmental aspects[39].

II. Classification, labelling, packaging and advertising

In the history of chemical and pesticide regulation, rules on risk classification, on associating specific risks to labelling requirements and the establishment of packaging rules constituted the very first step in the development of chemicals and pesticides regulation.

1. Classification

The EEC Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions related to the classification, packaging and labelling of dangerous substances (**chemicals**) provides for 14 factors determining the hazardous characteristics within the meaning of the directive: explosive, oxydizing, extremely flammable, highly flammable, flammable, very toxic, toxic, harmful, corrosive, irritant, dangerous for the environment, carcinogenic, teratogenic, mutagenic[40]. The EEC Directive 78/631 on the approximation of laws on the classification, packaging and labelling of dangerous preparations (**pesticides**) provides for a similar classification scheme in the field of pesticides[41]. These rank from very toxic, toxic to harmful. Classification is based primarily on the acute oral and dermal toxicity to the rat since these

38 Cf. Ph.Alston, loc.cit. 410 et seq.

39 F.L. Kirgis, Effective Pollution Control in Industrialized Countries: International Economic Disincentives, Policy Responses and the GATT, 70 Michigan Law Review, 1972, 859 et seq.; cf. also S. Rubin & T. Graham (eds.), Environment and Trade 1982; H. Gröner, Umweltschutzbedingte Produktnormen als nichttarifäres Handelshemmnis, in H. Gutzler (ed.) Umweltpolitik und Wettbewerb, 1981, 143 et seq.

40 Cf. Loc.cit. Art. 2 (2).

determining factors are standard procedures in toxicology. The EEC Directive 88/379[42] on the approximation of the laws, regulations and administrative provisions of the member states relating to the classification, packaging and labelling of **dangerous preparations** extends the very same classification approach to preparations other than pesticides. The classification scheme follows the principles laid down in Directive 67/548 on dangerous chemical substances, supplemented by specific provisions on the explosive, oxydizing, extremely flammable, highly flammable or flammable property. The set of these three directives provides for a common classification scheme of dangerous substances, pesticides and preparations throughout the EEC. They facilitate orientation on the market and enhance the development of regulatory concepts based on classification.

At the international level, numerous international organizations have developed classification schemes; it might suffice to recall the efforts of WHO and IRPTC in the field of chemicals pesticides and medicines. However, most of these classification systems are not linked to labelling and packaging requirements. There are two notable differences. The ILO Convention requires specific criteria and systems appropriate for the classification of all chemicals according to the type and degree of their intrinsic hazards[43]. According to the "Recommendations", classification should be based on characteristics such as: toxic properties including both acute and chronic health effects in all target organs; chemical or physical characteristics, including flammable, explosive, oxidizing and dangerously reactive properties; corrosive and irritant properties; carcinogenic effects; allergenic and sensitizing effects; teratogenic and mutagenic effects and effects on the reproductive system[44]. From a lawyer's point of view the prerequisites seem to be similar to the EEC Directive 67/548.

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41 OJ L 206, 29.7.1978, 13 et seq. Art. 3.

42 Cf. OJ L 187, 16.7.1988, 14 et seq. Art. 3 (1).

43 Cf. Loc.cit. Art. 6.

44 Cf. Loc.cit. under II. 6.

The FAO Code refers to the WHO recommended classification of pesticides by hazards as the starting point for labelling and packaging requirements[45]. Classification in the WHO recommended scheme differs from the EEC Directive 78/631[46] because it distinguishes four categories of hazards: extremely hazardous, highly hazardous, moderately hazardous, slightly hazardous.

2. Labelling and packaging

At the EEC level, marketing of classified chemicals, pesticides and preparations is bound to labelling and packaging requirements. Although the labelling and packaging requirements differ according to the category of products concerned, the basic concept derives from Directive 67/548.

Packaging must satisfy the following requirements[47]:

(a) it shall be so designed and constructed that its content cannot escape; this requirement shall not apply where special safety devices are prescribed;

(b) the materials constituting the packaging and fastening must not be susceptibel to adverse attack by the contents, or liable to form harmful or dangerous compounds with the contents;

(c) packaging and fastening must be strong and solid throughout to ensure that they will not loosen and will safely meet the normal stresses and strains of handling;

(d) containers fitted with replaceable fastening devices shall be so designed that the packaging can be repeatedly refastened without the content escaping.

Member states are allowed to go beyond that mandatory level and to prescribe that packages shall initially be closed with a seal so that when the package is opened for the first time, the seal is irrepairably damaged; that containers with a capacity not exceeding three litres which contain dangerous substances intended for domestic use shall have child resistent fastening; that containers with a capacity not exceeding one litre which

45 Cf. Art. 10.2.3. loc.cit.

46 Cf. Loc.cit.

47 Cf. Loc.cit. Art. 16.

contain very toxic, toxic or corrosive liquids intended for domestic use shall carry a tactile warning of danger. The options for packaging rules on child resistent fastenings and tactile warning of danger have been subject to controversial debate throughout the Community. Here, the member states' packaging rules differ considerably[48].

The packaging rules are supplemented by labelling rules. According to Directive 67/548 member states have to ensure that dangerous substances cannot be placed on the market unless the labelling on their packages satisfies the following requirements[49]:

> Every package shall show clearly the name of the substance, the origin of the substance, the danger symbol, when laid down, an indication of danger involved in the use of the substance, standard phrases indicating the special risks arising from such dangers, standard phrases indicating the safety advice relating to the use of the substance.

These factors are then spelled out in the directive in some detail. Harmonization is total, some derogations are allowed though, but the member states are then obliged to inform the Commission thereof. The two directives on pesticides 78/631[50] and on dangerous preparations 88/379[51] supplement these prerequisites by providing further product-related labelling requirements. It is hard to distinguish the different packaging and labelling rules on dangerous substances, pesticides and preparations. Even the Community seems to be somewhat confused, as it has indicated in its last directive on dangerous preparations 88/379, that a review should be undertaken to find out where the differences between the rules are, and where there are loopholes which must be regulated[52]. For an international perspective, it is important that the labelling and packaging rules in the

48 Cf. E.Rehbinder, Chemikalienrecht, loc.cit.

49 Cf. Loc.cit. Art 17.

50 Cf. Loc.cit.

51 Cf. Loc.cit.

Community have led to a total harmonization. That means, products classified, labelled and packed according to these three directives can be marketed all over the Community. There is, however, one exception: As far as there are products which do not fall within the scope of the three directives, considerable differences between national legislations still subsist.

At the international level, packaging and labelling rules on pesticides and chemicals are mentioned in the GATT Agreement on Technical Barriers to Trade[53]. In its preamble, the agreement urges the parties to ensure that technical regulations and standards, including packaging, marking and labelling requirements, and methods for certifying conformity with technical regulations and standards, do not create unnecessary obstacles to international trade. The agreement, however, does not lay down minimum requirements in any form as to the labelling and packaging of chemicals and pesticides as such. The approach used here is to try to get away with possible technical barriers to trade which result from deviating labelling and packaging standards.

Quite specific rules on the labelling of chemicals and pesticides can be found in the Convention on Safety in the Use of Chemicals at Work. The primary addressee of the "labelling and marking requirements" in the convention, is the employee, although the convention applies to all branches of economic activity in which chemicals are used, including production, handling, storage, transport and disposal in enterprises[54].

Art. 7 of the convention requires signatory states to make sure that hazardous chemicals are labelled so as to provide essential information regarding their identity, their classification, the hazards they present and the safety precautions to be observed. The requirements of what should be

52 Cf. Loc.cit. 15.

53 Cf. Agreement on Technical Barriers to Trade, GATT 1979, now under revision in the Uruguay Round.

54 Cf. Loc.cit. Art. 7, Recommendations under II.8.

understood by labelling are then to be found in the "Recommendations"[55]. Here it is specified that labelling requirements should cover in conformity with existing national or international systems:

> (a) the information to be given on the label such as trade names, identity of the chemical, name, address and telephone number of the supplier, danger symbols, nature of the special risk associated with the use of the chemical, safety advice including first aid, identification of the batch, the statement that the data sheet giving additional information is available from the employer,
>
> (b) the legibility, durability, and size of the label and
>
> (c) the uniformity of labels including colours.

Chemical safety data and information sheets shall be established by the competent authorities and then be provided to the employers. There is no link, however, between the classification and the labelling and packaging with a view to the marketing of chemicals and pesticides. Information on the dangerous aspects of chemicals and pesticides could be improved indirectly here, but the Convention is not aiming to regulate the trade with or production of chemicals and pesticides.

The FAO Code of Conduct[56], institutes responsibilities of industry and governments on labelling and packaging for chemcial safety, here mainly pesticides. Pesticide containers should be clearly labelled in accordance with applicable international guidelines such as the FAO guidelines on good labelling practices[57]. Art. 10 of the FAO Code then requires industry:

> to use labels that include recommendations consistent with those of the recognized research and advisory agencies in the country of sale,
>
> to include appropriate symbols and pictograms whenever possible in addition to written instructions, warnings and precautions,

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55 Cf. Loc.cit. under II.8.

56 Cf. Loc.cit. Art. 10.

57 Guidelines on good labelling practice of pesticides, FAO 1985; Pictograms for pesticide labels, FAO.

to use labels that in international trade clearly show appropriate WHO hazard classification of the contents or, if this is inappropriate or inconsistent with the national regulations, use the relevant classification;

to include in the propriate language or languages, a warning against the reuse of containers and instructions for the safe disposal or decontamination of empty containers;

to identify each lot or batch of product in numbers or letters that can be read, transcribed or communicated by anyone, without the need for codes or other means or deciphering;

to use labels that are marked with the date, month and year of formulation of the lot or batch and with the relevant information on the storage stability of the product.

Art. 10. (3) refers to packaging, storage and disposal of pesticides which should be in conformity with the principles laid down in the FAO Guidelines for the Packaging and Storage of Pesticides[58], the FAO Guidelines on the Disposal and Surplus Pesticides and Pesticides Containers[59], and the WHO Specifications for Pesticides used in Public Health[60]. Last but not least, governments are invited to take the necessary regulatory measures to prohibit the repacking, decanting or dispensing of any pesticide into food or beverage containers in trade channels and rigidly enforce punitive measures that effectively deter such practices.

The FAO labelling and packaging rules, although not mandatory, are coming close to the essence of the national and regional rules. They provide indeed for a minimum standard in labelling and packaging, a minimum standard which has not yet been achieved in the field of chemical substances and preparations.

3. Advertising

Even modern chemical laws do not provide for mandatory rules on advertising. This lack is due to the fact that chemical laws, in principle, are restricted in their scope to industrially manufactured chemicals; they exclude preparations dedicated to end users. That is why advertising rules

58 Adopted in 1985.

59 Adopted in 1985.

are in principle outside the regulatory perspectives of chemicals. This is not the case when chemicals are sold in a manufactured form to end users like preparations or pesticides. Here, advertising rules might be of importance to the user. This is particularly true for pesticides, where unfair practices have been reported mainly from Third World countries[61]. Industrialized countries have not developed specific rules for the advertising of pesticides. The advertising of pesticides is usually subject to rules and regulations concerning unfair marketing practices. The point of reference is not a specific category or product but the market transaction. Equivalent rules do not yet exist on the international level. There are regulatory efforts by the International Chamber of Commerce or the United Nations that attempt to lay down codes on fair practices.

Particular efforts can be seen in the FAO Code of Conduct. Art. 11 provides extensive rules for the regulation of advertising with pesticides. The primary addressee of Art. 11 is industry itself, but international organizations and public sector groups are invited to call intention, to departures from this article[62]. Governments are encouraged under this code, to work with manufacturers to take advantage of their marketing skills and infrastructures in order to provide for public service advertising regarding the safe and effective use of pesticides. Advertising could then focus on such factors as the proper maintenance and use of equipment, special precautions for children and pregnant women, the danger of reusing containers and the importance of following label directions. Although these rules are quite general in nature and in principle apply to all kind of transactions wherever they take place, they are shaped according to the needs of the international trade between the pesticide producing country and the Third World importing country.

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60 World Health Organisation, 1985.

61 Cf. D.Weir/M.Shapiro Circle of Poison, Pesticides and the People in a Hungry World, 1981; D.Bull, A growing problem, pesticides and the Third World Poor, 1982; IOCU, The Pesticide Poising Report, A survey of some Asian countires by Foo Gaik Sim, Penang, 1985.

III. Pre-market control of chemicals and pesticides

The Council Directive amending for the sixth time Directive 67/548[63] on dangerous substances, limits the scope of application explicitly to **newly** marketed products. The US TSCA[64] quite to the contrary, provides explicitly for control of "old chemicals" as well as of "new" chemicals. Pesticide control regulations suffer from the same sort. Any kind of pre-market control presupposes in principle that all those products which shall be marketed are presented to statutory review and not those which are already marketed[65].

1. Spectrum of preventive control measures

Three types of preventive control might be distinguished[66]. Prior approval procedure, notification procedure and regulatory mechanisms where the primary responsibility rests with the manufacturer. The last category presupposes that there is no statutory regulation on chemicals and pesticides and that the manufacturer alone has to decide which kind of product he will manufacture and under what conditions he will offer the product on the market. Most of the industrialized countries have introduced either prior approval procedures or notification procedures, but there is still a considerable number of developing countries where there is no pre-market control of chemicals and pesticides[67]. One could understand notification

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62 Cf. Problem Pesticides, Pesticide Problems, IOCU 1987.

63 Cf. Loc.cit.

64 Toxic Substances Control Act, as Amended.

65 Cf. For a comparative analysis of the EEC sixth amendment and the US TOSCA legislation cf. G.B.Wilkinson, The Sixth Amendment: Toxic Substance Control in the EEC, Law and Policy in International Business 12 (1980), 461-501 and R.A. Wyman, Control of Toxic Substances: The Attempt to Harmonize the Notification Requirements of the U.S. Toxic Substances Control Act and the European Community Sixth Amendment, Virginia Journal of International Law 1980, 417-458. Although somewhat outdated they provide a valuable analysis of both regulatory schemes. Helpful: International Regulations of Toxic Substances, American Society of International Law, Proceedings of the 73rd Annual Meeting, April 26-28, 1979 Washington, 76 et seq. For a more recent perspective, cf. R. Brickmann, Controlling Chemicals: the politics of regulation in Europe and the United States, 1985.

66 Cf. E.Rehbinder/D.Kayser/H.Klein, Kommentar, Einführung 5 et seq.

procedures as a mechanism of shared responsibility, because the manufacturer has to notify his intention to manufacture or market a new chemical to the competent authority which then takes the necessary decision to make sure that the chemicals are adequately tested, classified, labelled and packed. This procedure is different in countries where chemicals and pesticides are subject to a prior approval procedure. The competent authorities have to make a positive decision, an approval, in order to ensure that the chemical or pesticide in question is manufactured and marketed.

2. Chemicals

A substance-related licensing procedure has been used in Japan[68]. The procedure consists of a screening mechanism which is designed to assess the risks associated with a particular substance, and of a subsequent procedure of formal control. It determines whether the substance belongs to the category of "specified chemical substances", i.e., if the substance is persistent, tends to accumulate in living organisms and has toxic properties. The majority of licensing schemes provided in the various chemical laws have a much more limited scope and purpose. In the Federal Republic of Germany, Denmark, Norway, Sweden, New Zealand and Switzerland a licensing procedure has been introduced as a control device for the manufacturer and/or sale and use (in the case of New Zealand only for the sale) of individual, particularly hazardous substances. A general substance-related control of chemicals is not intended in these countries[69].

The purpose of the licensing procedures provided for in the Netherlands and in the United Kingdom seems to be broader and would allow the introduction of a substance-related control. Under the Dutch chemical regulation a competent agency is authorized to deny a permit, where it is considered necessary to protect man and the environment. It has

67 Cf. UNEP, Informal Consultative Meeting on the Implementation of the amended London Guidelines, Geneva, 2-3 April 1990, Review of Environmental Activities related to the production and use of chemicals, UNEP/PIC.CONS.1/4.

68 Cf. OECD Comparative Analysis No.23; UNEP Comparative Survey, No. 50.

69 Cf. UNEP Comparative Survey, No. 48.

been disputed whether the 6th Amendment of the directive on dangerous substances of the European Community provides for the opportunity to introduce such a license scheme. With respect to manufacture and use, the member states are not bound by the directive as long as the procedure is not seen as a disguised attempt to control the placing of substances on the market that have already been notified under the directive and thus can be freely sold in the Community. A licensing procedure that protects against **specific risks of manufacture** seems permissible[70].

But a licensing procedure in the area of chemical regulation is much more the exemption than the rule in the industrialized countries. The widest-spread attempt of introducing pre-market control in the area of chemicals is based on the idea that a notification procedure suffices to guarantee the protection of man and the environment. This is particularly true for the member states of the European Community, but also for the EFTA countries and the United States. When analyzing the implementation of the 6th Amendment in member state legislation, differences have emerged, which might be significant in the context of the European integration process[71]. But in an international perspective it is much more important to stress the relative harmony between most industrialized countries with respect to the necessary limitation of pre-market control notification procedures.

The history of this international process of harmonizing chemical regulation illuminates the incentives for the development of an international model for chemicals control. Since the early '70s, a number of industrialized countries habe been discussing the necessity of adopting chemical regulations. In Europe, France set the European legislative machinery into motion by notifying the Community of its intentions to adopt chemical legislation[72]. On the other side of the ocean, the United States were already in the process of preparing specific chemical-related legislation. Both initiatives were pooled within the OECD. The OECD and the EEC, both

70 Cf. UNEP Comparative Survery, No. 49.

71 Cf. The study of E. Rehbinder, Chemikalienrecht, loc.cit.

international organizations, both grouping highly industrialized countries, initiated an intensive period of cooperation to guarantee that a harmonized approach of regulation within the most industrialized countries would prevent the emergence of new technical barriers to trade. One might even conclude that these intra-supranational initiatives of OECD and EEC were quite successful. At least, there is no evidence that the still-remaining disparities between the EEC and the United States regulation on the control of chemicals have led to problems in international trade.

The similarities between the legislative effort of industrialized countries to control chemicals do not cancel out quite a number of important differences[73]. In the United States, manufacturers have to notify the competent agencies **prior to manufacture** of the new chemical. Under the 6th Amendment, notification is only necessary **prior to the marketing** of the newly manufactured chemical. This difference is not important only for deciding to what extent member states are still allowed to introduce licensing procedures relating to the manufacture and use of specific highly dangerous chemical substances. The difference between premanufacturing and pre-marketing notification is above all important for the conditions under which chemicals which are not notified, might be exported to countries outside the Community or outside the United States. Pre-manufacturing notification excludes such an opportunity in principle. Pre-marketing notification allows manufacturers to produce chemicals without notifying them to the competent authorities if they are able to demonstrate that these chemicals have been produced for export only.

Many more difficulties in the negotiations between OECD and EEC resulted from the notice procedure in the United States and the notification procedure under the 6th Amendment[74]. Section 5 of the TSCA requires premanufacturing notice and testing requirements for new substances and substances which are subject to significant "new uses". The 6th Amendment

72 Cf. G.B. Wilkinson, loc.cit. 471.

73 Cf. G.B. Wilkinson, loc.cit. 495; R.A. Wyman, loc.cit. 442 et seq.

provides for elaborate notification documents including testing results. Unlike TSCA section 5, which confers no competence on the Environmental Protection Agency to compel manufacturers to conduct testing, the 6th Amendment establishes a mandatory testing scheme for all new chemicals. In the European Community the responsibility rests upon the manufacturer to judge the possible risk of the notified chemical, in the United States responsibility lies with the competent Environmental Protection Agency that is in charge of reviewing the notice and requesting additional information if necessary for the risk assessment. The different approaches between mandatory testing combined with the manufacturers' responsibility to assess the testing result versus mere paper notice in conjunction with a statutory risk assessment had led to a situation where the testing disparities have become the crucial areas of concern in the dialogue between the OECD and the EEC.

The EEC 6th Amendment pleaded for a unique mandatory test screening, valid for all types of chemicals, whereas the United States' approach focused on the possible toxicity of the product. The differences in the test philosophy reflect the differences in risk assessment. The EEC has chosen a quantity triggering mechanism, where chemicals are subject to a basic test, supplemented by an additional test if a certain production quantity is superseded. The United States risk assessment procedure is less rigid and less predictable, because it focuses on the toxicity of the chemical substances alone.

Here the OECD stepped in and tried to develop a common frame for the testing procedure[75]. Two recommendations, the Guidelines for Testing of Chemicals, adopted in 1982, and the Good Laboratory Practice in the Testing of Chemicals, 1982 had been of considerable importance in bringing together the different approaches. The Guidelines for Testing of Chemicals formulate a minimum set of testing, which makes the European mandatory testing scheme compatible with the American optional testing in case of

74 Cf. G.B. Wilkinson, loc.cit. 489; R.A. Wyman, loc.cit. 443 et seq.

presumed toxicity. The EPA used the international forum at the OECD level to push the development of minimum testing requirements, although it had no competence under TSCA to adopt such minimum mandatory standards for testing[76]. American manufacturers were supporting EPA in the early '80s in order to be sure of what might be expected by EPA in assessing the information provided together with the notice[77]. They were willing to accept the existence of a basic testing set for the reason of greater "Rechtssicherheit". European manufacturers on the other hand had to swallow common Guidelines on Good Laboratory Practice in the testing of chemicals. Most of the member states of the European Community are making reference in their national legislation to the OECD Guidelines in one form or another[78]. The Guidelines are not directly integrated into the laws and are not mandatory in strictly legal terms, but they seem to play a major role in present practice.

There is no equivalent pre-market control legislation whatsoever on the international floor. The Ad Hoc Meeting of Senior Government Official Experts in Environmental Law, Montevideo 1982, adopted a program for the development and periodic review of environmental law[79]. It concluded that the international trade **in potentially harmful chemicals** calls for action. But this mandate has not yet been realized so far.

3. Pesticides

Most industrialized countries require the registration of a pesticide prior to its circulation on the market either by authority of special pesticide laws or general chemical laws[80]. The registration procedure in substance is

75 Cf. G.B. Wilkinson, loc.cit. 497 et seq.

76 Cf. The very detailed presentation of the OECD policy M.C. Bracken, in International Regulation of Toxic Substances, loc.cit. 88 et seq; cf. mor EPA's role in OECD negotiations, R. Brickmann, loc.cit. 298.

77 Cf. G.B. Wilkinson, loc.cit. 489, 490.

78 Cf. References in E. Rehbinder, Chemikalienrecht, loc.cit.

79 Montevideo Programme for the Development and Periodic Review of Environmental Law, Ad Hoc Meeting of Senior Government Officials Expert in Environmental Law,

a substance-related licensing procedure. Many countries call it "prior approval procedure" thereby underscoring that the pesticides can be marketed only if the competent authority has positively approved the safety of the pesticide (e.g. Denmark, France, Federal Republic of Germany, Switzerland). The same type of prior approval procedure is commonly accepted in the field of medicines[81]. Grosso modo, he who intends to manufacture and market a new pesticide has to undertake a series of tests, the results of which have to be presented to a competent agency who is in charge of assessing the results. He must also initiate, if necessary, additional testing and decide whether, under what conditions, and for what purpose the pesticide might be put on the market[82].

The normal prerequisites for approval are that the pesticide is sufficently effective and suitable and does not present unreasonable risks to man, animals or the environment (Denmark, Federal Republic of Germany, Netherlands, Japan, Sweden, Switzerland, United States)[83]. The integration of environmental protection into the licensing procedure is relatively new. The main objective is still to guarantee the protection of man; environmental protection does not benefit from the same status. Countries tend to make a two-pronged approach, thereby ranking the protection of the environment behind the protection of health and safety (Federal Republic of Germany). Sometimes there are additional prerequisites related to the producer or methods of production. In the United Kingdom, there has been a voluntary certification scheme under a joint industry - government agreement (Pesticide Safety Precaution Scheme) by virtue of which, basically, the same kind of assessment is undertaken. Such a voluntary arrangement has

Montevideo, 6 November 1981; Decision 10/21 of the Governing Council of UNEP, of 31 May 1982.

80 Cf. For a comparative analysis K. Bosselmann, Recht der Gefahrstoffe, Rechtsvergleichender Überblick, 1987; Ch. Uram, International Regulation of the Safe and Use of Pesticides, Northwestern Journal of International Law and Business, 10 (1990), 460 et seq.

81 Cf. For a recent analysis in the European context, D.Hart/N.Reich, Integration und Recht des Arzneimittelmarktes in der EG, ZERP Schriftenreihe, Band 13, 1990.

82 Cf. UNEP Comparative Survey, No. 52.

preceded the 1968 introduction of the prior approval procedure in the Federal Republic of Germany. But in 1986 the UK joined the majority of the industrialised countries and inserted a prior approval procedure in its pesticide legislation.

At the European level, pre-market control of pesticides has never reached the same degree of public and political attention as pre-market control of chemicals. The Commission of the European Community had already presented in 1976 a proposal for the establishment of a European-wide prior approval procedure[84]. The draft was meant to supplement Directive 78/631[85] on the classification, labelling and packaging of pesticides but did not get support from the Council. The White Paper on the Completion of the Internal Market by 1992 gave a new impetus to the harmonization of pre-market control in the European Community[86].

In 1989 the Commission came out with a new completely revised draft[87]. It provides for a two-tier system, distinguishing between the registration of "active substances" and the prior approval of "preparations". Prior approval of preparations (pesticide products) should be left to the member states. The member states, however, could approve only those preparations whose "active substances" appear on a so-called "positive list". Art. 5 states that an active substance shall be included on the list for an initial period not exceeding ten years only if

> (a) its residues in edible plant products, edible livestock products or the environment, consequent to an application consistent with good agricultural practise do not have any harmful effects on human or animal health or any unacceptable effects on the environment, and the said

83 Cf. UNEP Comparative Survey, No. 52.

84 Cf. OJ C 212, 9.9.1976, 3 et seq.

85 Cf. Loc.cit.

86 Cf. COM (85) 310 final, 14.6.1985.

87 Cf. OJ No. C 89, 10.4.1989, 22 et seq.

residues can be measured by appropriate methods. These conditions shall be deemed satisfactory if it is possible to set a daily absorption quantity tolerable by man,

(b) it may be expected, on the basis of scientific and technical data, that use of the active substance by means of pharmaceutical products manufactured from it will meet the requirements of the member states prior approval procedure. Compliance with these conditions may be assessed by setting whenever possible, a maximum tolerance exposure value for users of such plant protection products, and by means of criteria for assessing the effects on the environment, such as the biodegradability, mobility and accumulative capacity of the substance.

The draft does not yet contain a list of active substances. It should be drawn up later by the Commission's Standing Committee on Plant Protection. Prior approval of preparations by the member states require a listing of the active substances at the Community level and if

(b) it is established that, in the light of the current scientific and technical knowledge, when properly applied for the purpose intended, and having regard to all normal conditions under which it may be used:

(i) it is sufficently effective
(ii) it has no unacceptable effect on plants or plant products,
(iii) it has no harmful effect on human or animal health,
(iv) it has no unacceptable influence on the environment.

(c) the nature and quantity of its active substances and, where appropriate, any significant impurities, can be determined by appropriate methods in general use,

(d) its physical and chemical properties have been determined and deemed acceptable for purposes of the appropriate use and storage of the product.

Once a pesticide is registered by one member state, all the other states would have to allow their marketing as well. A harmonized Community

procedure for national registration is still lacking. Again, a future definition of this procedure should be left to the Standing Committee of Plant Protection.

The draft has raised much criticism by member states with a high level of protection, as well as by environmental activists[88]. The draft is said to promote the free flow of pesticides and to set aside the necessity of protecting the environment effectively. The prerequisites for listing active substances require that there are no "unacceptable effects on the environment", the prior registration of the preparations requires that there is no "unacceptable influence on the environment". These standards have been accused of not keeping up with existing standards of industrialized countries where mere **effects** on the environment have to be considered in the risk assessment, and not only "harmful" or "unacceptable" effects[89]. Another point of critique is the lack of clear criteria for the listing of the active substances and the prior approval of preparations. The task would again be left to a Committee without any parliamentary and public control. The lack of common criteria combined with the obligation of mutual recognition (Art. 10) means that pesticides could enter the Internal Market through the country with the lowest registration standards. Therefore, a mechanism exists that would allow pesticides already banned in some member states to return on the market in those states. The extensive involvement of FAO in developing common registration standards might contribute to harmonizing the registration procedure even in the European Community.

The FAO Code of Conduct on the Distribution and Use of Pesticides requires governments in Art. 5 under the heading "Reducing health hazards", which have not yet done so, to "implement a pesticide registration and control scheme". Art. 6 states:

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88 Cf. PAN Europe Newsletter, Volume 4, Nr 15 and 16, December 1989, 21-27.

89 Cf. E. Rehbinder, in E. Rehbinder (Hrsg.) Bremer Kolloquium, loc.cit. 3 et seq.

> Governments should take action to introduce the necessary legislation for the regulation, including registration of pesticides, and make provisions for its effective enforcement, including the establishment of appropriate educational advisory, extension and health-care services. The Guidelines for the registration and control of pesticides should be followed as far as possible, taking full account of local needs, social and economic conditions, levels of literacy, climatic conditions and the availability of pesticide application equipment.

The FAO Code formulates the *surrounding conditions* of pre-market control rather than the procedure itself. The latter is spelt out in the FAO Guidelines on the Registration and Control of Pesticides[90]. The Code itself manifests the autonomy of the nation states to decide on the admissibility criteria for the marketing of a pesticide. Reference is made to the different climate, the different economic resources and implicitly to the different possibilities of securing the safety of those who apply the pesticides[91].

The Guidelines for the Registration and Control is meant to present a model scheme for the registration procedure. As this scheme turned out to be too sophisticated for countries lacking the necessary infrastructure, FAO is preparing Guidelines on the Initial Introduction of a Simple National Pesticide Registration and Control Scheme. Testing requirements are laid down in the Guidelines on Environmental Criteria for the Registration of Pesticides[92], presently under revision. The Guidelines on Good Laboratory Practices define minimum standards for the execution of testing[93]. There are another 10 guidelines already published, under revision or under consideration which may lead to the conclusion that the FAO fulfills the same role in the development of common testing rules on the international

90 Guidelines for the registration and control of pesticides (including a model scheme for the establishment of national organisations), FAO 1985; Addenda to the guidelines for the registration and control of pesticides, FAO 1988.

91 The Code has been blamed for legitimising "double standards"; cf. Problem Pesticides, Pesticide Problems, 1987.

92 FAO 1985.

trade in pesticides as the OECD in the international regulation of chemicals. Industrialized countries have pooled their interest in chemical regulation within OECD, a forum, which Third World countries have no access to. FAO is open to all nation states, developing countries may bring their influence to bear. But it is primarily an organisation dealing with food and agriculture and not with health, safety or environmental protection. It has, however, seriously begun to consider these objectives in the seventies. This might explain, why FAO is seen as the appropriate forum of international coordination and cooperation.

IV. Post market control of "old" substances and "old" pesticides

Post market control mechanisms cover two different areas of concern: First, regulatory mechanisms have to be found for the handling of risks resulting from chemicals and pesticides which were brought into circulation before pre-market control legislation was adopted. Second, measures are now needed to withdraw from the market or even to ban the production of products, which were legally brought into circulation under existing pre-market control mechanisms, but which then turned out to be dangerous. At an injuncture, where there is no common denominator on pre-market control mechanisms of pesticides and chemicals in sight, it might sound strange to put emphasis on post market control mechanisms at the international level. Public attention, however, is increasingly focused on the risk of those chemicals and pesticides which are legally manufactured and legally marketed all over the world, but nevertheless constitute risks. The lesson to be learned is that existing pre-market control mechanisms cannot guarentee that long-term hazards will not emerge.

1. Concept of post market control

Post market control of old chemicals and old pesticides is exercised in a three-step procedure. A competent regulatory authority must first make the concept of safety operable for the performance of post market control

93 The FAO Code of Conduct, loc.cit. explictily refers to the OECD Guidelines which have prepared for the testing of chemicals but expanded then to pesticides, 33 Note 4.

mechanisms. It has then to investigate the arising dangers from chemicals and pesticides, before it enters into the decision-making process. Although regulatory concepts all over the world create more problems than they pretend to solve in distinguishing more and more sophisticated degrees of dangers, there seems to be a commonly accepted difference in chemicals and pesticides legislation in so far as pre-market control relates to the potential hazards of chemicals and pesticides, whereas post market control relates to suspected and known risks[94]. The "definition of risk" is the starting point for the "investigation of the danger". Competent regulatory bodies can only take post market control action if they get the necessary information on risks to man and the environment. Once the information is available, the competent authorities have to enter into the decision-making process. Modern chemical laws and pesticide laws provide for a whole set of regulatory instruments to fight possible dangers[95].

Although post market control in industrialized countries is a relatively new regulatory field, some common trends are already becoming clear. There is an overall tendency on confer the performance of post market control mechanisms on those statutory competent authorities, which are already responsible for pre-market control. These competent authorities have gained substantial power. They benefit from the uncertainties in defining risks, from comprehensive mandates in investigating dangers and from discretion in taking the appropriate measures[96]. This tendency might be somewhat counterbalanced by splitting competences. Industrialized countries tend, indeed, to establish competent authorities for each single category of products, one agency for chemicals, another agency for pesticides. If competence is brought under the very same umbrella organisation, separated divisions on chemicals and pesticides are usually set up, as in the case of the United States Environmental Protection Agency. There is an important difference in the regulatory philosophy between

94 Cf. Terminology in OECD Comparative Report, loc.cit. No. 10 et seq.

95 Cf. OECD Comparative Analysis, Table 4 on page 21.

96 G. Majone, Cross-National Sources of Regulatory Policy-Making in Europe and the United States, to appear in Journal of Public Policy, Spring 1991.

European competent authorities and the United States authorities. Although US and European governments have addressed the problem of chemical and pesticide control at roughly the same times and have assumed similar responsibilities, they have developed markedly different procedures for reaching regulatory decisions[97]. Two distinct patterns emerged[98]: "American regulatory processes stand apart with the complexity of their procedures, the heavy reliance on formal analysis of risks and benefits, the openness of administrative decision-making and the active supervision of executive agencies by Congress and the courts. European processes, despite some notable differences among them, share simpler administrative procedures, greater informality in the analysis of evidence, less complete public access to decision-makers, and relatively little oversight by parliament or the courts. Yet, on the other hand, one of the most striking conclusions seems to be that these contrasting methods of decision-making have led to remarkably similar policy choices, particularly in the selection of specific chemicals as targets of regulation".

Access to information plays a key role in the execution of post market control mechanisms. The '80s have demonstrated the growing power of national and internationally operating non-governmental organizations in bringing risks of chemicals and pesticides to the public's attention and in pushing regulatory agencies into action. Effective post market control requires that information on even potential risks of chemicals and pesticides which are manufactured and marketed world-wide should be made public as early as possible. Access to information, however, has to be weighed against legitimate interests of manufacturers to protect data on chemicals and pesticides for reasons of intellectual property. The industrialized countries have not yet come to a common solution. The United States TSCA obliges manufacturers to make all those data on chemicals publicly available which are related to health, safety and environmental protection[99]. The 6th Amendment has chosen a much more

97 Cf. R.Brickmann, loc.cit. 23.

98 Cf. More or less literally taken from, R.Brickmann, loc.cit. 23 et seq.

restrictive approach. These data are not made available to the public since manufacturers may require their confidentiality. The OECD has tried to harmonize differences between the United States and the European Community. Two guidelines on the confidentiality of data protection have been developed. It has never been investigated to what extent European manufacturers and American manufacturers have come to a solution with regard to harmonizing the differences. But as far as we know, problems have not arisen, although mainly European manufacturers had feared the liberal approach of the United States to data protection. Even within the European Community, the policy seems to have changed as the newly adopted Directive on Freedom to Information indicates[100].

Whatever solutions found among the industrialized countries to balance out conflicting interests of the public at large in having early access to potential hazards of chemicals and pesticides, and of the legitimate interests of manufacturers to, quite on the contrary, protect these data, there is much pressure for international organizations and non-governmental organizations as watch-dogs of the international trade in chemicals and pesticides to establish their own data collection systems[101]. But these data systems can never reach the same level and quality of information systems erected within multinational enterprises or collected in competent authorities in the main chemical and pesticide producing countries. International information systems which do not distinguish between confidential and non-confidential data on potential risks of chemicals and pesticides and which guarantee access to information, run the risk of stocking only the "second best" data.

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99 Cf. G.B. Wilkinson, loc.cit. 483, more comprehensively, R.B. Wyman, loc.cit. 451 et seq.

100 OJ L 158, 23.6.1990, 56 et seq.; cf. G. Winter (Hrsg.) Öffentlichkeit von Umweltinformationen, Europäische und nordamerikanische Rechte und Erfahrungen, Schriftenreihe des Zentrums für Europäische Rechtspolitik Band 12, 1990.

101 Cf. Y.Domzalski, Les Interpols des Associations de Consommateurs, BEUC/113/84, 1984.

2. *Information collection and information exchange*

At the national level, highly sophisticated regulatory systems have been developed in the EEC, the EFTA countries and the United States. Despite considerable differences in detail, there seems to be an interrelationship between the density of pre-market control and the state of post market control. To put it the other way round: in countries where there is a well-developed system on pre-market control of pesticides, as in the Federal Republic of Germany, post market control is developed to a lesser degree. Quite the opposite is true for technical consumer goods. These goods are usually not subject to any kind of statutory pre-market control, but highly sophisticated systems exist to withdraw unsafe technical consumer goods from the market[102]. Well-developed data collection is based on accident surveillance systems, on notification duties of manufacturers, suppliers and importers and of mechanisms to guarantee that informal information coming from individuals or organizations is dealt with in an appropriate way. The overall intention of all these mechanisms is to guarantee that the competent authority is brought into a position where it is posssible to assess the reported risks under the legal requirements.

At the EEC level a sophisticated system of information collection and information exchange is operating only in the area of technical consumer goods. Here, the so-called Rapid Exchange System, Council Regulation 84/133[103], provides for a mechanism under which formal and informal regulatory actions of competent member states' authorities have to be reported to the Commission, which guarantees the exchange of information with all the other member states. The Draft Directive on Product Safety 90/C 156/07[104] even tries to establish a mechanism under which the

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102 Cf. Ch.Joerges/J.Falke/H.-W.Micklitz/G.Brüggemeier, Die Sicherheit von Konsumgütern und die Entwicklung der Europäischen Gemeinschaften, Schriftenreihe des Zentrums für Europäische Rechtspolitik, Band 2 1988; now available also in Englisch EUI Working Papers in Law, No. 91/10 - 91/14 (5 Volumes).

103 OJ L 70, 13.3.1984, 16 et seq.; for a critical review, cf. J.Falke, What should be the Content of an E.E.C. General Directive on the Safety of Technical Consumer Goods, BEUC Legal News No. 16 (Nov./Dec. 1986), 16 et seq.

Commission itself is able to take action at the Community level in emergency situations.

There is no equivalent to be found for controlling chemicals and pesticides at the EEC level. There is no mechanism obliging member states to exchange information with the Commission and the other member states on possible risks resulting from unsafe chemicals or pesticides. At the present time, the consultative committees constituted under the respective directives being composed of representatives of member states and the Commission, guarantee that an informal exchange of information can take place. But these committees are working behind closed doors; neither public interest groups nor manufacturers have been offcially granted access to the committees. And the committees themselves are under no consecutive duty to report on their activities[105].

The situation is different in cases where member states want to take action to prohibit or restrict the marketing of chemicals or pesticides which do comply with already accepted European standards. Here, the directives provide for a so-called safeguard procedure under which member states have to notify their intention to take action to the Commission who, in turn, initiates a procedure where a common position at the European level should be found. But to repeat it bluntly: there is no legal obligation to come to a joint solution. The Community has no power to take action if one member state legitimately prohibits the import of certain unsafe chemicals or pesticides for heath, safety and environmental protection reasons. This mechanism which has been established under the 6th Amendment might be chosen in the Draft Directive 89/C 89/02[106] on pesticides, too.

Information collection and information exchange on **posssible risks** resulting from dangerous pesticides and chemicals and of regulatory

104 OJ C 156, 27.6.1990, 8 et seq.

105 H.Bentlage, An advisory board for consumer product safety: The German experience - European perspectives, Zentrum für Europäische Rechtspolitik, Studie im Auftrag der Europäischen Gemeinschaften, Vertrags-Nummer 6674/89/15, November 1990.

action of nation states taken to mitigate these very risks constitute one of the predominant areas of concern for international organizations[107]. UN organisations concentrate their efforts related to toxic chemicals on the collection, evaluation and dissemination of information on chemical risks. The environmental health criteria program, for example, compiles and analyzes the available information on the health effects of a limited number of selected pollutants. These evaluations are published in a series of reports, some of which conclude even with regulatory recommendations. WHO has established a similar programme on work place hazards[108].

Two UN programmes focus more on dissemination of information than on evaluation. The International Register of Potentially Toxic Chemicals IRPTC is charged with developing an international data bank on toxic chemicals, particularly common agrochemicals. ILO publishes bibliographies and an encyclopedia of occupational health and safety, both of which contain information on chemical hazards. The international programme on chemical safety (IPCS), an effort co-sponsored by WHO, ILO and the United Nations Environmental Programme (UNEP) has been set up to register national institutions and support agencies in a coordinated program of new research on specific hazards[109].

In contrast to the programmes of the European Community or even the OECD, these efforts of the UN organisations in the area of toxic substances control seem rather fragmented and even duplicative. They intend to achieve, however, what is undoubtedly their principal purpose and value: to render service to those countries that lack an indigenous capability and evaluate the world literature on chemical hazards. In fulfilling these functions, the UN agencies help to extend the benefits of scientific

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106 Cf. loc.cit.

107 Cf. R. Brickmann, loc.cit. 291 et seq.

108 Cf. For a comprehensive overview, OECD 1982, Report of the Expert Group on Information Exchange related to Export of Hazardous Chemicals.

109 Cf. Ph. Alston, loc.cit. 410 et seq.

information and increased sophistication in controlling risks to less advantaged regions of the world[110].

From information collection on toxic chemicals risk, mechanisms have to be distinguished aiming at the collection of **regulatory action**. It is right here where the international organizations have demonstrated their willingness and their involvement to play a key role. The emergence of information collection and information exchange in the field of regulatory action restricting or banning chemicals and pesticides is closely related to the discussion on international efforts to regulate the export and import of severely restricted and banned chemicals and pesticides[111].

The OECD is playing a lead role in the management of risks resulting from **old chemicals and old pesticides** being produced and marketed long before the developed mechanisms of pre-market control in the industrialized world took hold to grip. The OECD, supported by the main chemical producing countries all over the world, is trying to develop a program on what to do with these old chemicals and pesticides. As yet, there is no common methodological concept for selecting these old substances. Different criteria are under discussion, resulting from the divergent experience within the key competent authorities. The German Federal Environmental Agency, for instance, composed of representatives of the chemical industry, the competent authorities and science, pleads for a multi-step procedure. From the original list of 4554 substances, only 60 remain to be further examined. The parallel to the late '70s when the introduction of pre-market control mechanisms on chemicals was discussed in Europe and in the United States is striking. Once more, it might be necessary to find a common denominator in order to evaluate the 100.000 chemical substances and to decide which require the highest degree of public attention[112]. A first

110 Cf. R. Brickmann, loc.cit. 291 et seq.

111 Cf. Supra B V.

112 Cf. OECD's Work on Investigation of High Production Volume Chemicals, International Environment Reporter, June 1990, 263 et seq.

step in that direction might follow from a recent EEC initiative which translates the OECD programme into an EEC legislation[113]

3. Rules to ban or restrict the production, marketing and use of unsafe chemicals and pesticides

Decision-making and decision-taking to ban or restrict unsafe chemicals and pesticides entails a complicated procedure of weighing interests. This procedure takes place at the national level. The nation states define the set of instruments and chose the regulatory form under which the action is taken. In the FRG and Japan, partial bans or restrictions of chemicals are taken by way of a regulation. Most of the countries confer the competence to regulate the marketing of chemicals to the authority being in charge of the pre-market control procedure.

There are considerable differences in the set of instruments available to take action. The OECD Report gives an overview in form of a set of tables, linking the trigger mechanism to the selection of control action[114]. It should be noted, however, that most of the industrialized countries provide for the possibility not only to restrict or ban the marketing of unsafe chemicals but also to intervene in the production process itself and to prohibit the manufacture of dangerous chemicals.

Member states of the European Community are still responsible for restricting or banning the manufacture, use and marketing of unsafe chemicals and pesticides. There is not yet an agreement, not even with a view to completing the Internal Market, to manage post market control at the European level. The two directives to ban and restrict unsafe chemicals, Directive 76/769[115] and to regulate unsafe pesticides 79/117[116] provide for a regulatory frame which could be regarded as the entrant to a European

113 Cf. OJ C No 276, 5.11.1990, 1 et seq; thereto H.-W.Micklitz, Organisational Structures, loc.cit.

114 Cf. OECD Comparative Report, Tables 2, 3 and 4.

115 OJ L 262, 27.9.1976, 201 et seq.

post market control management. The adoption of a ban or a restriction, however, entails the setting into motion of the complicated and lengthy agreement procedure within the European Community. It is not the Commission, as the executive organ of the Community, who is taking the decision but it the Council as the "legislative" organ. Agreements are often reached at the lowest common denominator and measures adopted after a considerable delay. It is not surprising that there is little harmony within the Community as regards which particular chemicals and pesticides are to be restricted or banned[117]. The example of pentachlorphenol, where the Federal Republic of Germany decided to adopt a product ban after having informed the Commission and having waited more than one year for a joint approach, might illustrate the difficulties[118].

At the international, level banning or restricting the production, use and marketing of unsafe chemicals and pesticides requires an agreement in the competent international organizations either to issue a recommendation or to develop a binding convention. There are only a few examples so far where a world-wide agreement is being considered to regulate unsafe chemicals and pesticides. Reference can be made to the OECD recommendation to ban PCB[119] and the most recent Montreal protocol to reduce the production of the ozon layer[120].

International organizations had to develop more flexible systems which compensate for their lack of regulatory competence. One very well known but highly controversial mechanism to initiate world-wide banning and restricting of unsafe chemicals and pesticides constitutes the adoption of

116 OJ L 33, 8.2.1979, 36 et seq.

117 Cf. For an overview on the proposals under discussion H.-W.Micklitz, Organisational Structures of Product Safety Regulation in B.Stauder (ed.) La sécurité des biens de consommation, intégration européenne et consommation suisse, forthcoming.

118 BGBL. Teil I, 22.12.1989, 2235 et seq.

119 Cf. OECD Council Decision, Protection of the Environment by Control of Polychlorinated Biphenyls (Feb. 13, 1987), for further details, cf. Ph. Alston, loc.cit. 423. et seq. References in the OECD Chemicals Programme, 1984.

the UN Consolidated List which has most recently appeared in its third edition[121]. This list compiles information of regulatory actions on chemicals and pesticides in order to show, mainly to developing countries, what kind of actions are taken in the industrialized countries to fight against unsafe chemicals and pesticides. The Consolidated List does not produce legally binding effects, but it may unfold a moral effect in so far as the products being on the list are morally blamed and difficult to market worldwide. The list may initiate regulatory action in developing countries and be made instrumental by non-governmental organizations to fight against the trade in pesticides and chemicals where the risk to man and the environment is well known, like for instance the Dirty Dozen Campaign of the Pesticides Action Network (PAN).

V. Regulation on the export and import of banned and severely restricted chemicals and pesticides

There are quite a number of national and international rules on the export and import of banned and severely restricted chemicals and pesticides which have to be taken into consideration. Under a national perspective, once more, efforts from the United States mainly during the late '70s and the early '80s in regulating the export of pesticides and chemicals in the respective legislations have to be mentioned[122]. Under a regional perspective, reference should be made to the Council Regulation No 1734/88[123] concerning the export from and import into the Community of

120 Protocole de Montreal relatif à des substances qui apprauvissent la couche d'ozone, Acte Final 1987.

121 Cf. Analysis in H.-W.Micklitz, Export of dangerous pharmaceuticals to third world countries, ZERP-DP 5/87.

122 Cf. Still the leading article, F.Schulberg, United States Export of Products Banned for Domestic Use", Harvard International Law Journal 20 (1979), 331-383; in an international perspective M.Pallemaerts, Diplomacy and Double Standards, The Regulation of International Trade in Pesticides, Master Thesis Harvard Law School, May 1985 unpublished manuscript; E.Rehbinder, Export von Schädlingsbekämpfungsmaßnahmen: Gemeinsame Verantwortung von Export- und Importstaat? in Jahrbuch des Umwelt und Technikrechts 1988, UTR Band 5 1988, 337 et seq; L.Gündling, Prior notification and consultation, in G.Handl/R.E.Lutz, Transferring Hazardous Technologies and Substances - The International Challenge, 1989, 63 et seq.

certain dangerous chemicals. But national and regional efforts to regulate the export issue lag behind the overwhelming interests of international organizations in pushing for some form of harmonized regulation on the export and import of banned and severely restricted chemcials and pesticides. Most notably, reference should be made to the:

OECD Recommendation C (84) 37 Information Exchange related to Export of Banned or Severely Restricted Chemicals, 1984;

OECD Guiding Principles on Information Exchange related to Export of Banned or Severely Restricted Chemicals, 1984;

UNEP amended London Guidelines for the Exchange of Information on Chemicals in International Trade, 1989;

the FAO International Code of Conduct on the Distribution and Use of Pesticides, 1986, as amended in 1989;

the UNEP Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, 1989.

1. Concept, definition and role of international organisations

Export and import of banned and severely restricted chemicals and pesticides has become and still is an *international* issue. The very first initiative to develop **international** rules notably within the OECD derives from the Unites States' policy in the late '70s and early '80s to regulate the export and import under a human rights perspective[124]. But national efforts to get a grip on the export/import issue slackened down and have more or less been substituted by attempts of different international regulations in finding some form of harmonized procedure. Differing approaches of the industrialized nations to regulate the export of banned and severely restricted chemicals and pesticides were seen as a kind of technical barrier to trade requiring a process of harmonization on the international floor. The interest and the impact of such an understanding, however, is

123 OJ L 155, 22.6.1988, 2 et seq.; thereto M. Pallemaerts, Export Notification, The Draft EC Regulation in an International Perspective, European Environment Review, Vol. 1 No. 2, 1987.

limited. The original intention to come to some form of harmonized export/import rules world-wide was to bridge the gap between differences in nation states' efforts to protect their citizens and the environment against risks resulting from pesticides and chemicals. Nevertheless, differences subsist even among industrialized nations, differences which lead to a situation where one industrialized country bans or restricts certain pesticides or chemicals whereas another still allows the production and marketing of the very same chemical and pesticide. But the main impetus for an international rule does not derive from these differences between industrialized nations. Developing countries who were the primary addressee of the imports of banned and severely restricted chemicals and pesticides raised their voice already in the late '70s that there were no national legislation to protect these countries against exports from banned and severely restricted chemicals. So the overall perspective in the early '80s has never been to harmonize the international rules on the production, use and marketing of chemicals and pesticides. The issues raised in the '70s and '80s were to find international rules bridging the gap betwen the differences of extensive chemicals and pesticides regulation in industrialized countries and the mere lack of comparable rules in importing countries. One might even go so far as to conclude that the original intention was not to regulate the trade of banned and severely restricted chemicals and pesticides but to find rules under which the trade with these incriminated categories of products should and could be legitimated.

It is in this period where the OECD once more played a key role in international efforts to get a grip on the export/import issue. The OECD adopted already in 1984 its Recommendation on the Information Exchange related to Export of Banned or Severely Restricted Chemicals, and the Guiding Principles. The consensus found within the OECD countries determined for a number of years the discussion in the broader forums like UNEP and FAO. The regulatory model, based on a clear distinction between

124 Cf. Hazardous Products from a Human Rights Perspective, 14, (1983) S.W.U.L. Rev. 81 et seq.; Nayar, Human Rights: The United Nations and United States Foreign Policy, 19 (1978) Harv.Int'l.L.J. 813 et seq.

information exchange on the one hand and export notification on the other, were overcome in the last few years, when under the pressure of developing countries supported by non-governmental organizations these regulatory models of the OECD were further developed and supplemented by the so-called PIC procedure.

The Prior Informed Consent procedure indicates an important shift in the perspective of regulating hazardous, not only banned and severely restricted, chemicals and pesticides. These rules might be the starting point for the development of international rules on the production, use and marketing of chemicals and pesticides. This is true for two reasons: first of all, the PIC procedure establishes a mechanism under which it is guaranteed that all actions taken by countries to restrict or ban chemicals or pesticides can be integrated. Secondly, the rules on classification, labelling and on technical assistance integrated within the UNEP amended London Guidelines not only back the scope of the more narrow rules on banned and severely restricted chemicals and pesticides, but must be understood as an effort to lay down world-wide minimum standards, applicable for all chemicals and pesticides. The Basle Convention providing for PIC has considerably facilitated the adoption of the Amended London Guidelines[125].

Such a perspective of the further development of the international rules on the export of banned and severely restricted pesticides and chemicals are considerably strengthened by the fact that GATT has put the issue on the Uruguay-Round. GATT had already laid down notification and information exchange mechanisms in the early '80s. This effort was more or less initiated by the strong engagement by OECD, FAO and UNEP. GATT felt that something should be done and stepped into the field[126]. The

125 Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal, Environmental Policy and Law, 19/2 (1989), 68 et seq.; cf. for the EEC's committment in implementing the convention, proposal 90/C 289 05 OJ C 289, 17.11.1990, 9 et seq.

126 Cf. E.Rehbinder, Environmental Protection and the Law of International Trade (with particular reference to the export of hazardous chemicals and transfrontier disposal of wastes) in: The Future of the International Law of the Environment, Hague Academy of International Law 1984, R.J.Dupuy 1985, 357 et seq.

discussions and negotiations on the rules, however, took place within OECD, FAO and UNEP. With the establishment of the working group on trade and of domesticly prohibited goods and other hazardous substances, the international scenario has changed dramatically. GATT's involvement makes clear that rules are needed at the international floor bringing together the original GATT idea of guaranteeing free trade worldwide with the necessity to have international rules protecting health and safety and guaranteeing environmental protection. GATT's committment could well constitute the beginning of the development of an international order on regulating product safety and environmental protection.

2. *Information exchange, export notification and prior informed consent procedure*

The OECD Recommendation on information exchange and the Guiding Principles, all adopted in 1984 have introduced a two tier-procedure, which is still valid and executed worldwide. The procedure is based on the distinction between the exchange of information on regulatory action and the notification of the export which takes place once the export occurs. Information exchange simply means that countries which have taken action to ban or severely restrict a chemical or pesticide notify the very same decision to all member states of the international organizations concerned. Such an information exchange should guarantee that the designated authorities of the member states concerned are kept abreast on what kind of action has been taken within the network. The establishment of such an information exchange mechanism entails the necessity to define what kind of action should be notified[127]:

> "only final action as promoted by the industrialized countries or already provisional and intermediary actions,
>
> a definition of what is to be understood by hazardous chemicals, only banned or severely restricted, or at the same time unregistered or voluntarily withdrawn, chemicals and pesticides,

127 Cf. OECD Guiding Principles, 1094 loc.cit.

last, but not least, it requires the complicated determination of the category "severely restricted".

The OECD Guiding Principles have taken a narrow approach, covering only final actions and limiting the scope to banned and severely restricted products by excluding informal activities of manufacturers and the "never-registered". It is an approach which still determines the scope of each and every international mechanism currently under discussion. The mere information exchange of final regulatory actions of limited product categories constituted the original offer by the industrialized countries to guarantee some minimum protection to the developing countries. Mere information exchange between designated authorities all over the world seemed to be quite moderate. But information exchange gains substantially once the information is compiled and filed in a separate document, i.e. the Consolidated List[128].

From the mere information exchange on regulatory actions, the **export notification** has to be clearly distinguished. Export notification means that the respective exporter notifies his intention to export chemicals or pesticides either to the exporting authorities and/or the importing authorities. The OECD Guiding Principles first blocked efforts of developing countries to use the export notification as an instrument to impede the international trade with chemicals and pesticides by promoting the idea of prior informed consent. Prior informed consent in relation to export notification would mean that the exporter is obliged to notify his intention to export and wait for the consent of the addressee, the importing country, before he is allowed to ship the products out. Numerous variations have been discussed within the last years, ranging from stop shipment notification to a much more flexible approach where notification would be necessary only once a year. The same is true for the role of exporting and importing authorities. Developing countries pushed for a model where exporters would be obliged to notify statutory authorities in the exporting and importing countries and where the notification is transmitted from one

128 Cf. References in M.Pallemaerts, loc.cit. and L.Gündling, loc.cit.

statutory authority to the other. Manufacturers on the other hand promoted the idea of organizing the export notification between the exporter and the importer and of setting aside any engagement of statutory authorities, from the exporting as well as from the importing country.

The still prevailing export notification mechanism as fostered by the OECD Guiding Principles leaves much space for interpretation. It merely states that if the export of a chemical banned or severely restricted in the state of export occurs, the state of export should ensure that necessary steps are taken to provide the designated national authority of the state of import with relevant information. The purpose of the export notification is in the language of OECD and the original London Guidelines "to remind the state of the import of the original notification regarding control action (information exchange) and to alert it to the fact that an export will occur or is occurring[129]". There are some minor differences between the OECD Guiding Principles, the original UNEP Guidelines and Art. 9 in the FAO Code of Conduct. But whatever these differences are, no stop shipment notification, not even notification prior to export is mandatory. The role of exporters and importers on the one hand and exporting and importing authorities on the other is still not clearly defined. There is much space for interpretation and variation in shaping the national model.

Within that regulatory frame, however, one might conclude that information exchange and export notification, as originally promoted by the OECD Guiding Principles, has become part of the national regulatory systems of most industrialized nations. This is true for the United States, where the respective provisions of chemical and pesticides control cover the information exchange and notification procedure as provided for under the OECD Guiding Principles, and this is also true for the European Community where the regulation 1734/88[130] makes the international consensus found within OECD, UNEP and FAO mandatory. The EEC regulation avoids a number of conflicts in the exact shaping of the scope by listing 21 chemicals

129 Cf. London Guidelines, loc.cit. under 8. (b).

and pesticides which fall into the ambit of the exchange and notification mechanism.

The PIC procedure in the amended London Guidelines and integrated now in the FAO Code of Conduct constitutes a considerable step towards a more sophisticated regulatory scheme on the regulation with export and import of banned and severely restricted pesticides. The final adoption of the PIC procedure should be understood as the response of the developing countries to the efforts of OECD countries to impose the agreement on information exchange and export notification upon developing countries. The compromise now found between industrialized nations and developing countries, the one defending the OECD system as being sufficient to deal with banned and severely restricted pesticides, and the other promoting the idea of a mechanism which would guarantee that the importing countries are informed on the export of banned and severely restricted countries prior to export, led to the development of what has been phrased the "red flag approach".

The PIC procedure is based on the idea that an alert list can be set up in negotiations between exporting and importing countries and that the importing countries have to make a decision as to whether they refuse the import of chemicals and pesticides being part of the list or whether they agree to the import of those products, perhaps even under specific restrictions. This regulatory model is discussed as "control action-related Prior Informed Consent Procedure", control action-related because prior informed consent is bound to the control action and not to the concrete export. The crucial point of this system seems to be what kind of products under what conditions are to be put on the alert list. The solution appears quite pragmatic. It was agreed that chemicals banned or severely restricted by ten or more countries will be automatically placed on the list while those banned or severely restricted by five or more countries but less than ten will be subject to an "informal consultative process," to determine whether they

130 Cf. Regulation 1734/88 is now under revision, OJ C 17, 25.1.1991, 16 et seq.

meet the definitions of banned or severely restricted for health or environmental reasons as laid down in the London Guidelines and the FAO Code. Those meeting the definitions will be placed on the list. This system will apply to chemicals which have already been the subject of control actions before the implementation of the PIC scheme and will lead to the establishment of an initial "red flag" list.

For chemicals banned or severely restricted **after** the circulation of the initial list, a different system will apply. These chemicals will automatically become subject to PIC requirements when a control action "meeting the definitions of the London Guidelines" is taken and notified by a single government. Thus, action by any one government will be sufficient to make a chemical subject to PIC procedures internationally. However, reference is made here to "an informal consultative process" to "assist UNEP and FAO in determining whether the control action meets the definition". This places a certain amount of discretion on the UNEP, the FAO secretariates, the consulted competent national authorities and the experts. For the first time, a worldwide mechanism has been set up world-wide to constantly review chemicals and pesticides whether they should be put on the "red flag list" because they are so dangerous that international trade needs to be regulated.

The PIC procedure confers a key role to IRPTC. The latter has to ensure that the control action is disseminated to all participating countries and has to varify whether they agree to possible exports or refuse to receive them. The introduction of the PIC procedure has redefined the responsibilities of importing and exporting countries. Whereas the OECD model is largely based on the idea that primary responsibility lies with the importing country when deciding what to do with the information received, the PIC procedures now explicitly starts from the concept of shared responsibility between exporting and importing countries. The London amended Guidelines clearly state:

> It should be the function of designate national authorities with regard to export of banned or severely restricted chemicals "to implement appropriate procedures, within their authority, designed to ensure that exports do not occur contrary to the PIC decisions or participating importing countries".

Although the exact meaning of the reference seems to be far from being clear[131], exporting countries have accepted their responsibility to contribute to the implementation of the amended London Guidelines.

3. Classification, packaging, labelling and technical assistance

The PIC procedure does not provide for explicit classification, packaging and labelling rules. It deals more with fundamental principles. The states should recognize that chemicals exported from their territories are subject to no less stringent requirements of classification, packaging and labelling than comparable products designated for use in the state of export. A similar rule has been introduced in the EEC regulation 1734/88[132]. But the amended London Guidelines go one step further in asking states to take into account the special circumstances surrounding the management of chemicals in developing countries, in the process of elaborating and implementing already existing or future internationally harmonized procedures for the classifcation, packaging, and labelling of chemicals in international trade.

The reference made to technical assistance shows that the implementation of the PIC procedure, the information exchange and the notification system is only possible if specific resources are made available by European countries to build up the necessary infrastructure in developing countries. This reference has initiated a number of activities of national development aid institutions and international organizations aimed at

131 Cf. My paper for the Ad Hoc Working Group of Experts on the Implementation of the Amended London Guidelines, First Session, Nairobi, 15-19 October 1990, Proposals on draft model national legislation on managment of chemicals for the implementation of the amended London Guidelines, UNEP/PIC.WG.3/Inf.3, 11 October 1990.

establishing the prerequisites for some kind of import control by evaluating and assessing the incoming data on banned or severely restricted pesticides[133].

4. The regulations on banned and severely restricted products within UNEP and FAO and the GATT

The message which can be taken from existing GATT rules seems to be quite clear: any form of restricting the export of hazardous chemicals runs counter to the idea of GATT to guarantee free trade worldwide, Art. XI[134]. There does not seem to exist a mechanism to allow states having signed the GATT Protocol to restrict the export for foreign policy reasons. Quite the contrary is true for importing countries, wishing to restrict the import of specifically hazardous products. Art. XX of the GATT allows for import restrictions if the importing country is of the conviction that the goods endanger the health and the environment. The only question here is to distinguish legitimate interests from protectionist considerations. The GATT Agreement on Technical Barriers to Trade tries to balance out conflicting interests here by asking signatory states of the agreement to notify GATT of their wish to restrict the import of certain products for health, safety and environmental reasons[135]. GATT has obviously no rules at its disposal to come to grips with the problem of deviating standards on health, safety and environmental protection. That lack of competences might well be the background for the interest of GATT to develop its own rules now[136].

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132 Cf. Loc.cit.

133 Cf. Most notably, Implementation of the International Code of Conduct on the Distribution and Use of Pesticides, Technical Assistance Project Financed throught a Trust Fund Provided by the Government of Japan, Bangkok Thailand, 14-25 November 1988, Workshop on Pesticides Regulatory Principles and Procedures for the Asian and the Pacific Region.

134 Cf. M.Rom, Export Controls in GATT, Journal of World Trade Law, 1984, 125 et seq.

135 Cf. P.Merciai, Safeguard Measures in GATT, Journal of World Trade Law 1981, 41 et seq.

136 Cf. J.Sankey, Domestically Prohibited Goods and Hazardous Substances - A New GATT Working Group is established, JWTL 1989, 99 et seq; cf. in a broader context

C. Factors determining the process of internationalization of chemical and pesticide regulation

For the further development of the international regulation of chemicals and pesticides, it could be of interest to determine the factors which determine the process of internationalization. The conclusion, therefore, should be read as the preface for the ongoing debate regarding the feasibility of an international convention on the production and use of chemicals and pesticides. UNEP has in mind to elaborate such a convention in the years to come. But this intention has not yet been explictly voiced, for UNEP fears strong and immediate objections from the industrialized countries[137].

I. Economic and political incentives

The most important impetus for the development of international regulatory mechanisms seem to be the fear of the industrialized countries that divergent national standards lead to new barriers to trade[138]. The prevention of barriers to trade were behind coordinated efforts of OECD and EEC to come to a joint solution on the regulatory frame for the control of chemicals. The same is more or less true for the area of pesticides. The FAO Code of Conduct on the Distribution and Use of Pesticides aims at the development of a worldwide regulatory frame which guarantees the free flow of pesticides.

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the very helpful discussions on the relationship between US/EEC chemical regulation and GATT, in International Regulation of Toxic Substances, loc.cit. 92 et seq. 101 et seq.

137 One might understand "The Draft Model National Legislation on the Management of Chemicals for the Implementation of the Amended London Guidelines", elaborated by the Ad Hoc Working Group of Experts on the Implementation of the Amended London Guidelines, First session Nairobi, 15-19 October 1990, UNEP/PIC.WG. 3/3 as a preparatory document for an international convention.

138 This assumption is underscored by the most recent initiative of OECD to organise a workshop on "Economic Effects of PIC", 17-20 September 1991.

The overwhelming importance of the economic incentives for the prevention of technical barriers to trade resulting form divergent national control legislation does not mean that health, safety and environmental policy objectives are set aside. They may be pursued alongside the trade policy objectives, in some kind of a "pick-a-pack procedure". Although the impetus for the prevention of technical barriers to trade improves the perspectives of international regulation of chemicals and pesticides considerably, it restricts, at the same time, the goals which can be achieved. It is never health, safety and environmental protection as such which is subject to the regulatory concept; social protective objectives are inherently bound to the predominating free flow of chemical and pesticide policy.

The different philosophies become clear when the question arises whether international rules should be developed for the protection of health and safety at work. There was no opportunity to integrate the protection of health and safety at work when the frame of an international regulation on chemicals was discussed within the OECD and EEC. Ten years later the negative effects of differing standards on the protection of health and safety at work can no longer be denied. The United States have already introduced in 1974, rules in their Trade Act providing for sanctions against importing countries which benefit from lower production costs because the health and safety at work standards are far below the standards of the United States[139]. Defense strategies against unfair imports can easily be combined with health, safety and environmental objectives. Finland has just adopted a regulation imposing a charge per ton on oil delivered to its ports by tankers without double bottoms[140]. It is in the context of the steadily growing

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139 Cf. J.M. Zimmermann, Extraterritorial Application of Federal Labor Laws: Congress's Flawed Extension of the ADEA, 21, Cornell International Law Journal 1988, 103 et seq; I.Ch.Ballon, The Implications of Making the Denial of Internationally Recognized Worker Rights Actionable Under Section 301 of the Trade Act of 1974, "8, Virginia Journal of International Law, 1987, 73 et seq. For a background analysis cf. R.R.Kerton, Double Standards, Consumer and worker protection in an unequal world, 1990.

140 In January 1990 Finland imposed a charge of 2.20 markka a tonne on oil delivered to its ports by tankers without double bottoms, the Economist, 21-27 April 1990, 31.

importance of differing standards for the health and safety at work that the ILO convention must be seen.

Despite the decisive role of economic incentives the importance of political incentives should not be underestimated. The striking example for the power of the political incentives is the development of rules on the regulation of banned and severely restriced pesticides and chemicals, most notably the adoption of the PIC procedure. Extensive pressure from different sides have lead to a regulatory mechanism which challenges GATT, in order to bring the free trade philosophy of the GATT rules close to that of UNEP which is more orientated towards safety and environmental protection.

II. Unilateral action versus international action to control pesticides and chemicals

The analysis of the regulatory mechanisms on the control of pesticides and chemicals makes clear that unilateral action is needed to legitimate and justify international action. The most striking example is the development of the regulation of banned and severely restricted chemicals and pesticides. Without the United States taking the lead in the late seventies there would have been no incentive for the international organisations like OECD, UNEP and FAO to internationalize the export/import issue. The same might be true for the development of international rules on the control of chemicals. Here, the close cooperation of the United States and the European Countries through OECD and EEC underscore the necessity for the development of genuine international rules which are not only adapted to the needs of the industrialized countries but take into consideration the developing countries as well.

The key role for the development of international rules on the control of chemicals will be incombent upon the UNEP. The history of the development of the rules on banned and severely restricted chemicals illustrates how the rule-making machinary could work. Here the OECD had defined the precedents for the international debate and it took a number of

years and extensive pressure to transform the OECD Guiding Principles aiming at serving the needs of the industrialized countries into a regulatory concept which fits into a world where developing countries play an ever-increasing role. That is why the compromise found between the United States and the EEC member states could form the basis for the drafting of an international convention. Any effort of UNEP, however, has to take care of the effects on the international trade. A solution will be found only in coordination with GATT. The implications are far-reaching. It might well be that the appearance of GATT requires a broader approach integrating not only chemicals but also pesticides, in order to come to an international order on the control of pesticides and chemicals.

III. National involvement in the control of chemicals and pesticides and international perspectives of action

The relatively fast compromise between the United States and the European Community on the regulation of chemicals has been made possible by the mere fact that new regulatory models and new administrative procedures had to be built up to cope with chemicals. It is far easier to come to an international solution on the control of dangerous substances if there is no necessity to overcome national administrative structures and traditions. The same is true for the regulation of banned and severely restricted chemicals and pesticides. The PIC procedure constitutes a novelty, it is a genuine international instrument. There are no national traditions to be changed. An international convention on chemicals could benefit from the relatively young legal infrastructure. It could step into the vacuum which exists in the field of consumer and environmental protection, leaving space for the introduction of regulatory concepts which go beyong the pre-market control mechanism established in the industrialized countries.

The development of international regulation of pesticides and medicines shows that it is very difficult, almost impossible to aim at a common solution to the control mechanism. Although the FAO Code

provides for a registration procedure, a number of industrialized countries have introduced prior approval procedures which go far beyond the FAO compromise. The philosophy of the FAO Code sets the tone for the future regulation of chemicals. International rules could and should never be more that a common platform for the nation states. They remain free in leaving the platform and setting tighter standards for the protection of man and the environment.

IV. Trends in the control of chemicals and pesticides

From an analysis of the national, regional and international rules, it is possible to conclude that there is an overall trend to establish pre-market control procedures. Pre-market control is widely accepted in the field of pesticides but a consensus has almost been reached for the regulation of chemicals, too. The best perspectives for an international regulation seems to be an approach which would rely on a notification procedure, on a concept of shared responsibility between the manufacturers on the one hand and the competent control authorities on the other.

But concentration on the pre-market control of chemicals and pesticides suffers from a major deficiency: it focuses too much on the control of the newly introduced chemicals and pesticides and neglects the dangers of all those chemicals and pesticides which have been or still are circulating without being effectively controlled before marketing or in cases where the risks become evident at a later date although they have been subject to some form of pre-market control. The most advanced industrialized countries are discovering the necessity to establish effective post market control mechanisms. Deviating market restrictions, however, close the markets and run counter to the idea of a free trade without technical barriers to trade. Harmonizing the access to the world market by introducing common pre-market control mechanisms is one side of the coin, harmonizing post market control is the other. The international regulation on banned and severely restricted chemicals and pesticides mainly in form of the PIC procedure constitutes an important step towards the development of international post market control management. But so far it is based on final

regulatory action. What is needed, however, is a mechanism which guarentees the collection and dissemination of risks in order to decide at an international level, which products should be subject to market restrictions. The PIC procedure constitutes a remarkable step forward in that direction, as it provides for the review of products which are not yet on the "red flag list". But it should be accomplished by a joint program of FAO and UNEP in cooperation with OECD to determine the most dangerous chemicals and pesticides which are still on the market and to formulate common criteria for testing the products and for making decisions. Nonetheless even such a joint approach at an international level needs unilateral action to keep progress moving.