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ORGANISATIONAL STRUCTURES OF PRODUCT SAFETY REGULATION

I. MODELS OF FEDERAL SAFETY REGULATION

Christian Joerges has recently attempted to harness the Europeanisation of regulatory policies to the discussion on the economic constitution of the EEC.[1] He identifies three starting points in legal integration theory: neo-liberalism (Ordnungspolitik) as the foundation of the European economic constitution (*Ernst Joachim Mestmaecker*), the Community as a special purpose association (Zweckverband) of functional integration (*Hans Peter Ipsen*) and legal structures and decision-making processes (*Joseph H. H. Weiler*) and couples them with Europeanisation options: from competitive democracy to competition between democracies, regulatory centralism and finally co-operative federalism.

The description of the organisational structures is interwoven with the theoretical discussion and a set of regulatory options. It is designed as a means to identify the paths which the Commission and the Community pursue in order to promote the Europeanisation of product safety policies.

Many of the models of product safety regulation developed by the EEC may be identified with the categories of regulatory centralism, more specifically co-operative federalism. The EEC has placed a clear veto on competition between systems of regulation. With this statement, however, the limits of a clear policy are reached. The process of safety regulation is characterised by an inventive richness on the part of the Commission, which always has as its goal the compatibility of social regulation with economic integration. To achieve this the EEC follows many tangled paths, which may only be reconstructed in the light of the history and peculiarities of each product. The following attempt to categorise the related models can then be but a simplification. It describes the politics of the Community. The process continues and the legal structures remain to be settled.

[1] Markt ohne Staat ? Die Wirtschaftsverfassung der Gemeinschaft und die Renaissance der regulativen Politik, forthcoming *in* WILDENMANN R. (ed), Staatswerdung Europas. Optionen einer europäischen Union, Baden-Baden 1991.

1. STANDARDISATION AND CERTIFICATION - EUROPEANISATION THROUGH CENTRALISATION AND DECENTRALISATION

The regulation of product safety rests upon the premise that the State merely lays down fundamental safety requirements which are then elaborated by private standardisation organisations. The Commission has, in its New Approach,[2] based the Europeanisation of consumer goods safety upon the German model, i.e. legislative requirements are laid down by the EEC in directives related to products, the European standardisation organisations CEN/CENELEC particularise the details of these requirements and transform them into technical standards. The relationship between the Commission on the one hand and the standardisation organisations on the other, is regulated in the so-called "Memorandum of Agreement".[3] Central to this is a division of labour. CEN/CENELEC take on the elaboration of standards, the EEC guarantees their financial status. The privatisation of product safety, at the level of standard setting is legitimised by a democratisation of the procedural rules for the particularisation of standards. The standardisation organisations are open to pluralist participation, particularly on the part of consumers.[4]

The elaboration of standards is decentralised. CEN/CENELEC merely have a co-ordinatory function, the real work is undertaken by national standardisation organisations. Input from interest groups such as industry, business and consumers occurs at the national level. The pertinent technical committees co-ordinate the work of the national standardisation organisations and oversee agreement procedures. In so far as consumer interest groups are financed by the EEC, are co-ordinated at and have direct input into the technical committees at Community level, they have an organisational advantage over industry.[5] At present they have an observer status on Community committees.

The EEC has, however, recently thrown this type of co-ordination model into doubt in its Green Paper on standardisation.[6] The EEC strives for a consistent Europeanisation of standardisation. Industry should have a direct input into technical committees at the Community level. The consequences of such a re-orientation are far reaching. If industry is involved on the EEC level, then national standardisation loses its substance. National standardisation organisations will become mere agents for the transformation of European standards into national laws. Both organisationally and institutionally the EEC has taken note of the experiences of ETSI (European Telecommunications Institutions), responsible

[2] Council resolution of 7.5.1985, O.J. C 136/1 et seq. of 4.6.1985, cf. JOERGES C./FALKE J./MICKLITZ H.-W./BRÜGGEMEIER G., Die Sicherheit von Konsumgütern und die Entwicklung der Europäischen Gemeinschaft, ZERP Schriftenreihe Band 2, Baden-Baden 1988.

[3] Cf. DIN-Mitteilungen 64 (1985), 1 et seq.

[4] MICKLITZ H.-W., Produktsicherheit und technische Normung in der Europäischen Gemeinschaft *in* PAETOW H./TONNER K. (eds), Wirtschaftsregulierung in der Krise. Jahrbuch für Sozialökonomie und Gesellschaftstheorie, 1986, 109 et seq.

[5] The work is carried out in the "secretariat for co-ordination" attached to the consumer organisation BEUC.

[6] Green Paper on the Development of European Standardisation: Action for faster technological convergence in Europe, COM (90) 456 final of 16.10.1990, O.J. C 20/1 et seq. of 28.1.1991.

for standardisation in this economic sector.[7] Here Europeanisation has been realised. It is foreseen that three standardisation organisations, CEN/CENELEC and ETSI will be combined to form the "European Standardisation Board". The counterpart of the European Standardisation Board is the "European Standardisation Committee", which comprises industry, consumers, users, trade unions, the EEC Commission and the EFTA Secretariat. Although the particulars remain obscure - should the Council provide political advice in the sense of the "French superior standardisation council",[8] should it organise technical inputs into standardisation, or do both - the Green Paper contains a strong tendency for the displacement of decentralised standardisation by a stronger centrally organised standardisation. The Commission has promised that this will lead to an acceleration of standardisation and increased competitiveness in the European economy especially in the area of new technologies.

Certification presents a completely different picture.[9] Here Europeanisation is not centralised, but on the contrary decentralised. Certification documents the conformity of the product to essential safety requirements. Put another way, it shows that the producer has observed the minimum legal requirements, namely essential safety requirements. A single "conformity mark" should certify this accordance, the "CE-mark". In its New Approach the Commission recognises the need for a Europeanisation of certification, but does not adequately tackle the difficulties involved. This task was reserved for the so-called "Global Concept".[10] The Commission faced two problems. On the one hand there is no common certification model in the Member States; it is organised partly privately, partly by the States and partly semi-stately. This fact alone leads to great diversity. But far more problematic for the EEC is the lack of national structures upon which the EEC can base the process of Europeanisation. To concretise, there are no authorities for the testing of standards analagous to the national standardisation organisations. There are also no contractually guaranteed relationships between the State and the standard testing authorities.[11]

A Europeanisation strategy must perform on two fronts. On the one hand, promote a centralisation process in the Member States themselves, to give the Commission an inter-

[7] Conformance testing and certification in information technology and telecommunication, CENELEC, Amsterdam IOS PRESS, 1990.

[8] Cf. MICKLITZ H.-W. *in* JOERGES C. et al. (FN 2), p. 85 et seq.

[9] Cf. BURFEIND H., Die gegenseitige Anerkennung von Produktregelungen und Produktzertifizierung im Europäischen Recht, ZERP DP 4/90; cf. for the function of certification within the regulation of product safety, JOERGES C., Product Safety Law, Internal Market Policy and the proposal for a Directive on General Product Safety, EUI working paper, EPU No. 90/3: more comprehensively MICKLITZ H.-W., The Global Concept on Certification, the New Approach and Consumer Protection, Bremen/ Florence October 1990.

[10] O.J. C 231/3 et seq. of 8.9.1990; Commission communication of 15.6.1989, O.J. C 267/3 et seq. of 19.10.1989.

[11] Cf. The Federal Republic of Germany has a "State Contract" with DIN, Great Britain a "Memorandum of Agreement" with the BSI and France has recently created a "Co-operation Arrangement" with AFNOR, cf. MICKLITZ H.-W., Perspectives on a European directive on the safety of technical consumer goods, Common Market Law Review 1986, 617 et seq. A parallel development would require the Member States to take responsibility for certification.

locutor in each nation.[12] A tried and tested method is the accreditation of testing places. On the other hand, comparable foundations for the work of testing places must be laid. A degree of homogeneity in testing decisions can only then arise, where all testing places work with comparable standards. The Commission makes use of the strategy of the New Approach. It wants to lay down new essential requirements - relating to the form of certification (self-certification or certification by an independent third person); to the equipping and structure of testing places (here the apportionment of responsibility has yet to be settled) and to the supervision of testing places - which may then be elaborated into harmonised technical standards. To date, however, there is not an adequate common working framework to guarantee the Europeanisation process. Only a continuous exchange of experience between the testing systems will enable the testing organisations of the Member States to agree upon a common practice. The Commission has undertaken the task of organising this exchange of information and expertise between testing authorities. For this purpose it established the European Organisation for Testing and Certification (EOTC). For a transitional period the European standardisation organisations CEN/CENELEC will perform this function. Again co-operation is based upon a "Memorandum of Agreement".[13]

The policy of the "Global Concept" places a certain organisational pressure on national testing authorities. To prepare for Europeanisation these systems must create national organisational structures. These authorities are in competition with the national standardisation organisations. Coupling EOTC with CEN/CENELEC may thus prove troublesome. In this area, however, the lack of national and European representation in certification becomes apparent. A further centralisation may cause problems, it will in any case, be harder than in the sphere of standardisation. The centralisation foreseen by the Green Paper is designed to open up markets. In contrast to this testing structures for pharmaceutical and chemical supervision have the role of State authorities. This function was traditionally exercised decentrally in the areas of technical consumer goods and foodstuffs.[14] The centralised supervision of technical consumer goods would therefore prove "conditio sine qua non" for the centralisation of testing structures at the national level. It is possible that the standardisation of the work, when taken together with an accreditation system will stimulate such a process.

[12] German testing institutions, however, are getting together. They have set up a "Zentralstelle der Länder für Sicherheitstechnik".

[13] Memorandum of Understanding between the Commission of the European Communities, the European Free Trade Association (EFTA) and CEN/CENELEC for the Setting-up of the European Organisation for Testing and Certification.

[14] An organisational form bearing no relation to the present governmental structures of the Member States.

2. THE MANAGEMENT OF "NORMAL" RISK IN PHARMACEUTICAL, CHEMICAL AND TECHNICAL CONSUMER GOODS - THE PRINCIPLE OF THE FUNCTIONAL DIVISION OF LABOUR AND CO-OPERATION BETWEEN THE COMMUNITY AND THE MEMBER STATES[15]

Community policy aims to harmonise market entry conditions through secondary Community law. It aims to create common central conditions for the marketing of these categories of product. The enforcement of secondary Community law on the management of normal risk should, however, remain in the hands of the Member States. This division of labour between the Community and the Member States leads to federalist enforcement in Europe.[16] This federalist enforcement can only be diluted if Member States co-operate vertically with the Community and horizontally amongst themselves. The principle of a division of labour must therefore be enriched by the mechanisms of co-operation and co-ordination.[17]

It remains only to explain the meaning of the management of "normal" risk. Here we restrict ourselves to the thesis, that the management of "normal" risk legitimises State intervention in the market. It relates to those risks which are inherent to the product and the maintenance of the minimum State controls necessary for the protection of the public. These risks cannot, however, be eliminated.[18] The category of normal risks gains importance when comparison is made with crisis management, which will be dealt with later.[19]

The policies of the Community have been realised to very different extents, even if their aim has remained constant. The Community has for many years striven to open the market. Common standards have been established for the marketing of chemicals;[20] similarly for consumer goods, insofar as directives have been released under the New Approach,[21] and for pharmaceuticals inasmuch as producers submit themselves to a multi-state authorisation procedure should they wish to market pharmaceuticals in more than

[15] Cf. MAYNTZ R., Föderalismus und die Gesellschaft der Gegenwart, Archiv für Völkerrecht 1989, 232 et seq.

[16] Cf. FROWEIN J. A., Integration and the Federal Experience in Germany and Switzerland *in* CAPPELLETTI M./SECCOMBE M./WEILER J. H. H. (eds), Integration through Law, Berlin/New York 1986, 586, 587.

[17] Cf. LENAERTS K., Constitutionalism and the Many Faces of Federalism, AJCL 1990, 205 et seq., 230 has as its starting point: "The principle of federalist enforcement has found its way from German constitutional law into the Community legal order".

[18] Literature on the nature of risk is comprehensive. A common examination of the form of risk in each product category does not, however, exist. In relation to this area JOERGES C. et al. (FN 2), 35 may suffice. The questions posed here may be applied to the supervision of pharmaceuticals and foodstuffs.

[19] Cf. p. 55 et seq.

[20] Council directive 79/831/EEC of 18.9.1979, O.J. L 259/10 et seq. of 15.10.1979; to the present state of harmonisation REHBINDER E., 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, München 1986, 79-139.

[21] FALKE J., Normungspolitik der Europäischen Gemeinschaften zum Schutz von Verbraucher und Arbeitnehmer *in* ELLWEIN Th./HESSE J. J./MAYNTZ R./SCHARPF F. W., Jahrbuch zur Staats- und Verwaltungswissenschaft, Band 3, 1989, 217 et seq, gives an overview of the present state of Europeanisation.

one Member State.[22] An authorisation from one Member State does not yet guarantee the right to market in all other States. The authorisation of biotechnological pharmaceuticals provides the exception to the rule with a centralised authorisation procedure.[23] The Commission wishes to extend the centralised procedure and is attempting to restrict the future application of national authorisation control mechanisms to pharmaceuticals.[24] A common standard in the area of consumer goods will be set should the EEC enact the directive on product safety, currently being prepared.[25] The directive would then cover in those areas not yet affected by product-related directives under the New Approach. It remains to clarify whether the directive lays down common safety standards, i.e. not either it is to be applied only as a subsidiary instrument or can, at the very least, be used to supplement the directives in the light of the new programme.[26]

Whilst the principle of the division of labour is relatively far advanced the same cannot be said for the principle of co-operation and co-ordination. It is, however, precisely the two mechanisms of co-operation and co-ordination which have the last word on whether the market remains open, more specifically whether it can be closed retrospectively. This is relevant as further decisions must often be taken about risks once authorisation has been given. Standards laid down at the outset do not guarantee that those markets opened up will remain open. An examination of the distinction between pre- and post-market controls gives the following picture. The Community wishes to use the newly established agreement procedures between the Member States and the EEC, to guarantee the existence of common EEC standards - more precisely the conditions for market entry. This occurs through the creation of committees in which the representatives of the Member States supervise the Europeanisation of market entry conditions. Thus the committees in their functions and structures reflect the present state of the harmonisation of marketing standards.

The situation in the area of post-market control is far more complex. Federalist enforcement necessarily leads to divergence between the decisions of the Member States. Cohesion can only be achieved through procedural instruments. The Community first attempted, with the help of communication and reporting duties to secure a minimum of

[22] Cf. to this more comprehensively, HART D./REICH N., Integration und Regulierung des Arzneimittelmarktes in der EG, ZERP Schriftenreihe Band 13, Baden-Baden 1990; in brief: HANCHER L., The European Pharmaceutical Market: problems of partial harmonisation, European Law Review, 1990, 9 et seq.

[23] Council directive 87/22/EEC of 22.12.1986, O.J. L 15/40 et seq. of 17.1.1987; Council directive 90/220/EEC of 23.4.1990, O.J. L 117/15 et seq. of 8.5.1990..

[24] HART D./REICH N. (FN 22), Pt. 26.a.

[25] Commission proposal of 11.6.1990, O.J. C 156/8 et seq. of 27.6.1990; to this JOERGES C. (FN 9); comprehensively HOFFMANN D. *in* FALLON M./MANIET F. (eds), Product safety and control processes in the European Community, Brussels 1990, 63 et seq.

[26] It is not yet clear whether the planned directive lays down a common standard for all products, i.e. inclusive of those regulated in directives released under the New Approach, or whether it should only be applied where regulatory lacunae arise. At the present it appears that the Commission is following a complementary programme, it remains unclear which practical consequences this will have; cf. FRIELE R., Stellungnahme zur Richtlinie über Produktsicherheit, Stellungnahme für die Arbeitsgemeinschaft der Verbraucherverbände, Typescript, Bremen Autumn 1990.

cohesion in the supply of mutual information. This follows the style of international organisations. The sovereignty of the Member States is not questioned. The constituent principle of a division of labour is safeguarded. It was and remains the policy of the Community to act as a central co-ordinator and disseminator of information in order to minimise the risk that Europeanisation will fall victim to intergovernmental co-ordination. This policy has met with protest on the part of the Member States, since it is supposed that the centralisation of information leads to the centralisation of decision-making.

Recently the Commission has increased its attempts to give co-operation and co-ordination in the area of post-market control a firm legal framework. The mechanisms are well known. The EEC attempts to find a centralised interlocutor in each Member State to collate national information and pass it to the EEC. The constant use of this mechanism[27] has a legal background. The addressees of the EEC are the Member States, not merely the legislatures but also administrations and the courts. The EEC, however, can interact only with the central instance of the Member States. If, due to the federal structure of a Member State, there is no central instance the Community must foster centralisation to promote Europeanisation within the structure foreseen by the Treaty. To a degree the Member States have created central national supervision agencies, especially in the areas of pharmaceuticals and biochemicals. It is well known that this was not done solely with consumer protection in mind, but also owes to the interests of industry in wishing to promote the legitimate marketing of potentially dangerous goods on the basis of homogenous state decision-making. Centralisation in the Member States facilitates the creation of Europeanised post-market control. Such instances are lacking in the areas of consumer goods and foodstuffs. The Netherlands, with the Europeanisation process in mind, have introduced a centralisation of these national organisations.[28] The Federal Republic of Germany faces an operational difficulty. More concretely it is concerned that the national co-ordination and endorsement procedure will bind the supervision authorities (Gewerbeaufsichtsämter) more closely together. In reality a decentrally organised enforcement of Community standards strengthens the national instance and weakens the regions (Länder).

The EEC does not, however, bow to the pressure to create central national agencies. To an ever greater extent it pursues a policy of harmonisation of national enforcement instruments. In this economic perspective - post-market control. In the areas of pharmaceuticals,[29] chemicals,[30] consumer goods and foodstuffs,[31] the Commission has prepared

[27] Cf. The accreditation system of testing facilities, infra p. 65 et seq.

[28] Cf. GESTEL M. C./SNIJDERS C. M. F., Product Safety in Emergency Situations. The Netherlands, Country Report in the frame of the research project on the management of emergency situations in the Member States of the European Community, conducted by ZERP for the Commission of the European Community under the direction of H.-W. Micklitz.

[29] EEC-Commission proposal Doc. III/3603/90-EN, February 1990, Future systems for the free movement of medicinal products within the European Community (four preliminary draft proposals): Draft explanatory memorandum; proposal for a Council regulation (EEC); proposals for three Council directives (EEC) amending directives 65/65/EEC, 75/318/EEC, 75/319/EEC, 81/851/EEC, 81/852/EEC, 87/22/EEC, COM (90) 283 final-SYN 309 to 312 of 14.11.1990; O.J. C 330/1 et seq. of 31.12.1990. Cf. HART D., Harmonisierung der Marktüberwachungsinstrumente für Arzneimittel in der EG, Pharm. Ind. 52, Nr. 9 (1990), 1072 et seq.

proposals which are directed at a harmonisation of the supervision provisions of the Member States. The decision-making authority of the Member States is not infringed upon. Instead comparable ground rules are laid in the Member States. An exception to this is pharmaceuticals as the Commission feels that post-market control of biotechnological, high tech and new medicinal goods (all authorised centrally) should be fully Europeanised.[32] In this case a supranational authority would usurp national competences, the Member States would merely act as agents.

It is clear that a harmonisation of post-market controls, including the supervision of pharmaceuticals, does not adequately guard against the closure of markets due to the divergent decisions of the Member States. This can be traced to those provisions in secondary Community law with a "general" nature. Thus even where instruments are identical, decisions taken may diverge. Therefore communication between national agencies and the Community is necessitated. The appropriate method of securing agreement is the creation of committees. A slight simplification allows a distinction to be made between "scientific-technical committees" and "political-administrative committees". Scientific-technical committees are designed to promote consensus between experts on the potential risks of a product. The composition of these committees is dictated by scientific ability. They thus include, in addition to the representatives of the Member States, independent scientific experts.[33] The political-administrative committees[34] do not merely advise on conditions of market entry but should also exert influence on post-market control. This mechanism has, in essence, an advisory nature and does not concretise post-market control.[35] The new political-administrative committees are mostly overstretched by their new competences, as they were not designed to exercise them.[36] They were created and have grown in the tradi-

[30] Proposal for a Council regulation on the evaluation and the control of environmental risks of existing substances, COM (90) 227 final-SYN 276 of 5.10.1990; O.J. C 276/1 et seq. of 5.11.1990.

[31] Cf. in relation to the proposed directive on general product safety, COM (90) 256 final - SYN 192 of 11.6.1990, O.J. C 156/8 et seq. of 27.6.1990; to this MICKLITZ H.-W., (ed), Post Market Control of Consumer Goods, ZERP-Schriftenreihe Band 11, Baden-Baden 1990, with comparative country reports from certain Member States of the EEC, Australia, Sweden, the USA in addition to an analysis of the post-market control instruments of the proposed directive.

[32] Cf. HART D. (FN 29).

[33] Such committees exist for pharmaceuticals - the "Pharmaceutical Committee" - and for chemicals - the "Advisory Committee for Toxicity and Ecological Toxicity". There is no such committee for technical consumer goods. The Commission is considering the creation of a committee for product safety and has commissioned research from ZERP under the direction of FALKE J. This study examines the Committee for Technical Appliances and its possible transposition to the Community level. H. Bentlage is a member of ZERP. A parallel study is underway in France under the direction of TEMPLE H., at the Centre de Droit de la Consommation, Université de Montpellier. A first draft is now underway: Projet de décision de la Commission relative à la création d'un comité consultatif de la sécurité des produits et des services, SPC/DCC/1, 7.1.1991.

[34] For pharmaceuticals the "Committee for Pharmaceutical Specialities", Council directive 87/19/EEC of 22.12.1986, O.J. L 15/31 et seq. of 4.6.1985; for chemicals the committee in Council directive 79/831/EEC of 18.9.1979, O.J. L 259/10 of 15.10.1979, Art. 20; for technical consumer goods the Standing Committee for Standardisation under the information, Council directive 83/189/EEC of 28.3.1983, O.J. L 109/8 et seq. of 26.4.1983.

[35] With the exception of pharmaceuticals and emergency controls for consumer goods and foodstuffs.

[36] For pharmaceuticals, HART D./REICH N. (FN 22), section 1, I 2a (notes 7-11); for technical consu-

tion of the opening of markets. It is possible that, even without explicit competences, these committees have created their own Europeanisation momentum. This was not, however, planned and linked to concrete procedures, but is a spontaneous evolution.[37]

In relation to the federalist movement, the most decisive factor is the "centralisation" pressure which the organisation of post-market controls creates. Only the representatives of the central national authorities may sit on the political-administrative committees.

3. MANAGEMENT IN THE CASE OF INCREASED RISK - CENTRALISATION TENDENCIES

Community policy aims to increase the concentration of the management of product safety in its own hands. The Community, however, treads cautiously and pays due regard to the peculiarities of each product category. This may explain the difficulty in identifying one common policy. The development is still underway and the EEC applies disparate models, best understood in relation to the overall concept, in order to use the peculiarities of each product as a vehicle for Europeanisation.

The management of increased risk is, to a certain extent, suited to a centralisation of product safety policies in the hands of the Community. This in practice relates to the combating of grave and immediate risk to consumers arising from technical consumer goods and the binding decisions, which the Commission should take.[38] At present, research into management of crisis situations in the Member States is underway.[39]

In the area of pharmaceuticals, more specifically with the introduction of Europe-wide rules for biotechnological products, the Commission has achieved a break-through in the Europeanisation of market entry conditions. The fact that risks arising from biotechnological medicinal products arouse great public interest greatly aids the successful harmonisation of standards. This holds true, even though the pharmaceutical industry accepted EEC supervision as industry goals could be better pursued at the EEC level. The Community also strives for the centralisation of post-market control of biotechnological products. A specific example is provided by the regulation of "undesired side-effects". Doubts about a product must be communicated to the Commission and the Member States within 15 days.[40] In contrast to consumer goods and foodstuffs, however, no special procedure is planned at the EEC level in order to accelerate Community-wide decision making. Responsibility for post-market control is dependant upon the type of authorisation procedure. If this is centralised, the Commission is ultimately responsible. If it remains decentralised, the Member States are competent.[41]

mer goods, JOERGES C. et al. (FN 2), 389 et seq.

[37] The consequences of this will be dealt with infra p. 62 et seq.

[38] Art. 11 of the general product safety directive (FN 31).

[39] The Management of Emergency Situations in the area of Consumer Goods in the Member States of the Community (FN 28).

[40] Art. 22 para. 1 of the draft directive, the unpublished version provided for a mere 48 hours!

[41] Cf. HART D. (FN 29) and HART D./REICH N. (FN 22), pt. 24 et seq. (26b).

The situation is different for chemicals. In its planned regulation, the Commission is primarily concerned with the problem of the so-called "old-burdens", i.e the circa 100000 chemicals which were in circulation at the time of the enactment of the sixth amendment directive. The planned regulation does not aim to Europeanise decision-making but to Europeanise the premises upon which decisions rest. The possible consequences of a judgment on the dangers of each chemical should be seen in the light of directive 76/769/EEC.[42] This is the lowest level of Europeanisation as a decision on marketing must be taken in accordance with Article 100.[43] The planned regulation, however, represents an entry into the post-market supervision of chemicals. It will be shown that the Commission uses exactly those mechanisms designed to lead to Europeanisation in the post-market supervision of consumer goods and foodstuffs, as the basis for a decision on possible dangers. Clearly the "old-burdens" do not present an "emergency situation", but rather a situation in which increased risk is subject to Community-wide evaluation.

If one wishes to evaluate the degree of planned Europeanisation in each product category, it is necessary to differentiate between the degree of delegation in each decision-making process. The most far-reaching Europeanisation would entail the placing of decision making in the hands of an agency with regulatory competences. This approach is apparent in pharmaceutical law. The Commission is planning the creation of a "European Evaluation Authority for Pharmaceuticals".[44] This will be responsible for the authorisation and supervision of all biotechnological medicines and for those medicines authorised under the multi-state procedures. It should be composed of technical working groups, an administrative council (representatives of the Member States, the Commission and the Parliament) under the control of a director and served by an administrative and technical apparatus. The most important actor is the reconstituted "Pharmaceutical Committee". It has the brief to co-ordinate action with the relevant national authorities in relation to the suspension or withdrawal of authorisation. The Commission and not the Pharmaceutical Committee, however, takes decisions.

Europeanisation in the area of environmental protection has progressed to the extent that the Member States have agreed to the creation of an Environmental Agency.[45] The Environmental Agency, however, does not have a regulatory competence. It is not even allowed to publicise its work, public exposure, as experience has shown, being the mechanism most likely to forward a European decision-making process in the area of "crisis control" in emergency situations.[46] The agency should collate information and evaluate risks to the environment. This is the preparatory work forming the basis of decisions, which are then taken by the Community. Insofar, the Community is true to its policy of Europeanisation in the evaluation of environmental risk. The Environmental Agency is

[42] Council directive 76/769/EEC of 27.7.1976, O.J. L 262/201 et seq. of 27.9.1976.

[43] It is foreseeable that Art. 100 will be replaced by Art. 100a.

[44] Cf. FN 29.

[45] O.J. L 120/1 et seq. of 11.5.1990.

[46] As proof of this, the situation in France, where the "Commission de la sécurité des consommateurs" has had great success with this type of regulatory instrument. Cf. MICKLITZ H.-W. *in* JOERGES C. et al. (FN 2), 72 et seq.

merely one other facet of the evaluation procedures for "old-burdens". In short, the political-administrative decisions remain in the hands of the Member States.

In contrast to the framework adopted for pharmaceuticals, the Europeanisation of the management of emergency situations in the spheres of consumer goods and foodstuffs is not based on the delegation of the decision-making process to a particular working group. The creation of a European Consumer Authority has neither been planned, nor discussed. Management, even in crisis situations should be carried through with the aid of the Commission.

If any similarity can be identified in all the planned models, it is the "two-tier" procedure. The first tier encompasses the technical-scientific evaluation of risk, the second the political evaluation of the results of the first tier. The first stages are coupled with and interrelated to each other in many different ways. That the Member States can contribute their technical-scientific knowledge in the first stage is important for the management of risk situations. Thus, the first tier fills the technical-scientific gap at the base of the Community and dispenses with the need for large numbers of agencies as in the national-European or American dimensions. Thus the Commission has attempted to restrict the initial numbers of the Pharmaceutical Authority to 100. This first stage procedure is, however, Europeanised, insofar as the Member States are active in the name of the Community as simple agents.[47]

In pharmaceutical law the reconstituted "Committee for Pharmaceutical Specialities" is expected to organise the technical endorsement procedures within the envisaged European Pharmaceutical Agency.[48] The solution to the "old-burdens" of chemicals appears different insofar as the Commission wishes to make use of the principle of the "lead country", borrowed from international organisations. In the preparatory stage each country undertakes the evaluation of and work on particular chemical risks. If the "lead country" concludes that a Community-wide decision on further marketing should be taken, it turns to the Commission with the requisite ballot, which then activates the Management Committee. To date there is no advisory Committee for Product Safety in consumer goods and foodstuffs.[49] The functional equivalent is an information and consultation procedure, which is preparatory to the decision taken in the Management Committee. The execution process is not detailed. The placing of this procedure in the hands of the Member States, however, guarantees that they can introduce the requisite technical knowledge to the process. Although these "first stages" are very diverse in structure, they all serve the same purpose, the evaluation of the risk.

Decision-making and endorsement are identical for chemicals, technical consumer goods and foodstuffs. In the case of chemicals a simple decision on the existence of a risk

[47] The provisions in pharmaceutical law (FN 29) and in chemical (p. 7 of the Council regulation, FN 30) explicitly make reference to "in the name of the Community". The general product safety directive (FN 31) is formulated as follows: "The Commission may decide to initiate a consultation and investigation procedure with the Member States" (Art. 9).

[48] Cf. HART D. (FN 29).

[49] Cf. supra p. 56 FN 33.

and the desirability of European regulation is made. Management Committee proceedings end with a request to the Commission to introduce marketing restrictions in accordance with directive 76/769/EEC.[50] On the other hand decisions on technical consumer goods and foodstuffs are concerned with the continued marketing of goods recognised to be dangerous. It follows the "Management Committee" variant of "comitology", i.e. in each Management Committee the national representatives gather to make a political decision upon the results of the first stage investigation. These committees provide the arena for a practical Europeanisation of national administrative law. In accordance with the Management Committee variant, the Commission enacts measures, which are directly applicable. Should voices be raised in protest against Commission measures (but not against the committee's findings), then the measures are notified to the Council. In this case the Commission may - emphasis is placed on may - postpone the measures for five days in the case of consumer goods and foodstuffs and for one month in the case of chemicals. To make this clear: the Commission decides. The Council may, on the basis of a qualified majority and within the time limits, overturn the decision. This procedure arises directly from the structure of the committee, as the Member States are represented on it.

The situation is different again for pharmaceuticals. The reconstituted Committee for Pharmaceutical Specialities is composed of technical experts. Votes are taken on the basis of a scientific technical understanding of the material. Should a Member State make a written protest, the Commission must decide within 30 days. If such a protest is made the Commission may re-activate committee proceedings. If the differences cannot be bridged, the Commission passes the matter to the "Standing Committee on Medicinal Products for Human Use".[51] This is in principle a repeat of Management Committee processes. This committee, comprising representatives of the Commission and the Member States, must take a decision on the basis of a qualified majority.[52] If the Commission is in agreement with the vote it must enact the necessary measures. If the Commission withdraws, the Council must decide. The Commission can, however, only take provisional measures. An exceptional regulation for emergency situations "where action is urgently necessary to protect public health" arises insofar as the decision within the Committee for Pharmaceutical Specialities must be taken within 15 days.[53]

It is impossible to foresee whether the Member States will agree to the planned Europeanisation of decision making. It is possible that the Commission will apply the American model of "grants in aid" to purchase support. In reality the centralisation of the management of increased risk leads to a tendential reduction in the power of national regulatory instances. The Member States can formally give validity to their influences on decision-making in the Management Committees. It remains to be seen, however, how practice will evolve. The question is: will the mixture of EEC and national competences reduce the authority of local and regional instances? "The knives are drawn", - the call for a "Solan-

[50] Cf. FN 42.
[51] Cf. draft directive 90/C 330/01, Art.10.4.
[52] Council directive 87/19/EEC of 22.12.1986, O.J. L 14/31 et seq. of 17.1.1987.
[53] Draft directive (FN 51), Art. 18 para. 3 and 18 para. 4.

ge III" is prepared.[54] The problem is not, however, restricted to Germany. Spain also has powerful regions, which strongly defend their recently won competences from central State incursions.[55] In addition all forms of centralised management of increased risk situations alienate the decision-making level from the problem to be addressed.[56] This lack of connection can only be avoided through procedural "re-referals". The hands of the EEC are tied as they cannot include the regions or local instances in the management process.[57]

4. INTERGOVERNMENTAL OR INTERREGIONAL CO-OPERATION AS AN ALTERNATIVE TO CENTRALISATION

An increasing tendency to intensify "horizontal co-operation" in the management of normal risk is justified by the theory that a centralisation of competences in the hands of the EEC increases room for operation at the local and regional level. The most recent example is the transposition of the British risk information system to the Netherlands. This system was set up in Britain with the introduction of Standard Trading Offices under the Consumer Product Safety Act and Safety at Work Act.[58] It creates a horizontal network of some 126 offices, who continuously interact providing information on the appearance of risk, completed investigations and decisions taken. The local decision-making authority of Standard Trading Officers is preserved. The Netherlands have mirrored this system with their "Keuringsdiensten".[59] It is also clear that both countries wish to make use of these co-operation arrangements. In practice a competition model could develop between the existing rapid exchange system[60] and the information network planned by the product safety directive. The users of this system claim it to be superior and more effective, since they have an on-line system which provides them with greater information.

[54] SCHOLZ R., Wie lange bis "Solange III" ?, NJW 1990, 941, to this EVERLING U., Brauchen wir "Solange III" ? On the requests for a revision of the case law of the Federal Constitutional Court, EuR 1990, 195 et seq.

[55] Cf. in relation to consumer protection, which has led to constitutional conflicts in Spain, LOPEZ SANCHEZ M. A., La tutela del Consummatore in Spagna, Rivista Trimestriale Di Diritto e Procedura Civile 1986, 960 et seq.; GERLACH J. W., Die moderne Privatrechtsentwicklung in Spanien, ZVglRW 85 (1986), 247 et seq.

[56] For pharmaceutical law, HART D. (FN 29), for consumer goods see, MICKLITZ H.-W. (FN 28), Abschlussbericht Management von Notfallsituationen bei Konsumgütern.

[57] Cf. the first programmes for the inclusion of the regions. Commission decision for the creation of a Council of regional and local bodies 88/487/EEC of 6.9.1988, O.J L 247/23 et seq. of 24.6.1988; also PERNICE I., Kompetenzordnung und Handlungbefugnisse der Europäischen Gemeinschaft auf dem Gebiet des Umwelt- und Technikrechts, Die Verwaltung 1989, 43.

[58] Cf. WOODROFFE C./WEATHERILL S., Post Market Control of Technical Consumer Goods in the UK *in* MICKLITZ H.-W. (ed), Post Market Control (FN 31), 259 et seq.

[59] GESTEL M. C./SNIJDERS C. M. F., Product Safety in Emergency Situations: The Netherlands (FN 28).

[60] Cf. Council decision 84/133/EEC of 2.3.1984, O.J. L 70/16 et seq. of 13.3.1984.

II. FURTHER PROBLEMS FOR THE ORGANISATIONAL STRUCTURE OF PRODUCT SAFETY LAW

The restructuring of product safety law creates a series of legal problems which sooner or later must be addressed. The debate focuses upon the constituent principles of the organisation of product safety law: the centrally designed opening up of the market and the decentral, or possibly central enforcement of standards which are created at the centre.

1. LEGAL QUESTIONS ARISING FROM A CENTRALISED OPENING OF THE MARKET

The realisation of the Internal Market is only possible if all markets are truly opened. The Single European Act is designed to achieve this goal. The Community, however, in its attempts to create the Internal Market, becomes increasingly entangled in the regulation of product safety.[61] The underlying logic is comparatively simple: pharmaceuticals, foodstuffs, technical consumer goods and chemicals pose, per se, a health hazard. If the EEC wishes to secure a free flow of trade in the Community by harmonising market entry conditions, it concurrently intervenes, or better still must intervene in product safety law.

Steindorff[62] has recently questioned the ability of the Community to pursue an "active and positive creation of social policies" and asked whether the Community should not restrict itself to those "connected social policies", inextricably linked to the opening of the market. This relates to jurisdiction. A centralised creation of standards would, given this perspective, only then be legitimate if it were aimed at the opening of the market. According to this, the proposed product safety directive does not fall within the competences of the Community. Even more complex, when seen in this light, would be the attempts of the Commission to harmonise, or even centralises legal enforcement. This process, so it is argued, ensures by the harmonisation of post-market control, that markets are not retrospectively closed by divergent decision-making.[63] This does not relate to the opening of markets, but to the maintenance of open markets. It is exactly this type of post-market control which is most important in product safety policies.[64] *Norbert Reich*[65] considers the distinction between "original social policies" and "annexed social policies" to be irrelevant as it is based on too restricted a concept of the Internal Market. Product safety, whether as an "independent" policy or an "annex" is part of the Internal Market. Such a concept of the Internal Market, containing socio-political elements, avoids the dichotomy identified by *Steindorff*. As a consequence *Reich* must place the regulation of product safety within the ambit of Article 100a, as anchoring it to Article 130r would, on the contrary, establish the

[61] Cf. to this MICKLITZ H.-W., Consumer Rights *in* CASSESE A./CLAPHAM A./WEILER J. H. H., (eds), Human Rights and the European Community: The Substantive Law, 1991 (forthcoming), 53 et seq. Comments by PIPKORN J., 113 et seq.

[62] Grenzen der EG-Kompetenz, Heidelberg 1990, 32.

[63] We pursued this theory in our study, JOERGES C. et al. (FN 2).

[64] Cf. MICKLITZ H.-W. (ed), Post Market Control of Consumer Goods (FN 31).

[65] REICH N., Binnenmarkt als Rechtsbegriff, EuZW 1991, 203 et seq.

competence of the Member States. He therefore adheres to the doctrine which places product safety under Article 100a and procedural regulation under Article 130r.[66]

This interpretation leads *Reich* to take the step, explicitly laid down in Article 130r of the Single European Act; that is a movement away from a purely business oriented concept of the Internal Market.[67] Article 130r requires a re-orientation of the Internal Market. There is, however, no corollary to Article 130r in consumer protection policy. Whilst the Council has proclaimed that consumer protection and product safety are to be integrated into the other policies,[68] there is no explicit mention of consumer protection in the Single European Act. A socio-political concept of the Internal Market gives the same result. Article 100a rubs shoulders with Article 130r. Added legal validity may be gleaned from the case law of the ECJ, which has declared the "Consumer Protection Programme" to have legal effect.[69]

Where a socio-political concept of the Internal Market is applied, Article 100a must be understood as a competence-detailing provision. *Kai Hailbronner* regards Article 100a as a mere procedural norm,[70] given substance by Article 130r. A noteworthy position is taken by *Verloren van Themat* who considers the Commission's proposed product safety directive to be ultra vires as the Single European Act has not altered the jurisdictional boundaries.[71] The final conclusion would be the inability of the Commission and the Community to introduce product safety policies under Article 100a; if this is to be done at all it must be under Article 235.[72] We would take a different approach. Discussion in Germany is primarily concerned with the division of competences.[73] Who has the power to include social policies within the realisation of the Internal Market: merely the Member States or also the Community? We would go further and state that this is not merely a question of power, but also of "the acceptance of responsibility". Two paths are open: if Article 100a is a competence detailing provision, then the Community must take responsibilty for the health and safety of citizens throughout the EEC. If this path is not chosen one is left with a "tranference of duties" in the sense of delegation. This entails the recognition by the Member States of their responsibilities and the tranference of these, either explicitly or implicitly, to the Community within measures for the realisation of the Internal Market. If

[66] Cf. an overview of the state the discussion *in* JOERGES C./FALKE J. (FN 2); cf. especially HAILBRONNER K., Der "nationale Alleingang" im Gemeinschaftsrecht am Beispiel der Abgasstandards für PKW, EuGRZ 1989, 101 et seq.; SCHEUING D. H., Umweltschutz auf der Grundlage der Einheitlichen Europäischen Akte, EuR 1989, 152 et seq.

[67] Cf. similarly in relation to this HAILBRONNER K. (FN 66), 114.

[68] O.J. C 3, 15.12.1986, 1 et seq.

[69] ECJ of 7.3.1990, Case N° 362/88, not yet published in English, in German in EuZW 1990, 222 et seq.

[70] Cf. FN 66, 105/106.

[71] Cf. some comments of a former advocate general at the Court of Justice of the EEC *in* FALLON M./MANIET F. (eds) (FN 25), 129 et seq.; STEINDORFF E. (FN 65), is forced to the same conclusion.

[72] There is increased conflict between the Commission, Council and Parliament over the appropriate legal basis. To this PERNICE I. (FN 57), 1 et seq., who gives an overview.

[73] It is apparent that competences are not the subject of such vehement discussion in the other Member States. Cf. an overview *in* LAENERTS K. (FN 17), 223.

one pursues this path further, the consequences prove far more troublesome; namely with the delegation of duties related to the completion of the Internal Market to the Community, responsibility for action also passes to the Community. It must be decided at the outset whether Article 100a is a competence-detailing or a simple procedural norm. It is a fact that the Community in its attempts to realise the Internal Market has entangled itself in the regulation of product safety. It must then take the health and safety of the public into account. It is impossible, and in this *Reich* is correct, to uncouple product safety from the Internal Market. The regulation of product safety and the realisation of the Internal Market are inextricably linked.[74] To distinguish between the competence norm or the procedural norm leads to error, as the final question remains whether the Member States can claim any residual competence in areas covered by Community action.

The relevance of such a line of investigation becomes apparent in cases of conflict, more precisely, what happens when the Community fully harmonises an area, on the basis of Article 100a, but the levels of protection which it establishes are lower than those of a Member State overruled during the voting procedure? The problem is no longer theoretical, as it was in the debate on German petrol emission standards,[75] where, with hindsight the protests of the Federal Government went off like a damp squib. The Community wants to implement a common "conformity mark" for the marketing of technical consumer goods. In the opinion of the Commission the German safety mark, the GS (Geprüfte Sicherheit) is not compatible with this.[76] Another example of even greater importance: the Federal Republic of Germany, under great pressure from the public, has completely banned the marketing of pentachlorphenol.[77] The Community did not introduce a ban and allowed marketing to continue, only reducing the permitted concentration levels. Can the Federal Republic of Germany maintain its higher standards (GS-Zeichen) and/or introduce a complete ban in reliance on Article 100a para. 4?[78]

1. OPTION

The everything or nothing solution: the Commission has, with the adoption of the proposed measures, taken the regulation of product safety onto its own shoulders. Article 36, in the sense given to it by the ECJ,[79] points to this approach. Article 36 is not to be understood as a competence-detailing norm. On the contrary, the Member States may maintain measures for the protection of health and safety only if they are legitimate and not hidden protectionism mechanisms. Legitimate national measures can only be standardised through harmonisation. With harmonisation, however, the Member States lose the right to

[74] EVERLING N. may also be interpreted in this way (FN 54), 204/205.

[75] Cf. comprehensively, HAILBRONNER K. (FN 66).

[76] Cf. Global Concept (FN 9).

[77] BGBl. 1989 I 2235 et seq.

[78] Cf. for a discussion on the importance of Art. 100a para. 4, ZULEEG M., Vorbehaltene Kompetenzen der Mitgliedstaaten, NVwZ 1987, 279 et seq.; HAILBRONNER K. (FN 66); SCHEUING E. U. (FN 66).

[79] Corroboration to be found *in* LAENERTS K. (FN 17), 221 et seq.

set their own product safety goals. Article 36 is not watertight, as Article 100a para. 4 allows the Member States to diverge from majority decisions of the Community. The emergent German position sees in Article 100a para. 4 the right of a nation to follow its own path.[80] If one does not take this position, and much remains speculation, the importance of Article 100a para. 3 in the context of product safety policies becomes decisive. Is it a simple "operational instruction"[81] or on the contrary a "legal rule"? What is the meaning of a "high level of protection"? Does Community law have a basic standard that the public be afforded the "best possible protection" from product risks.[82] Such a ground rule could compensate for the lack of competence of the Member States, which arises when a narrow interpretation is given to Article 100a para. 4. Article 100a para. 3 must then, however, be regarded as a legal rule which the Parliament safeguards.[83] The case law of the ECJ would not disagree with this approach as Article 100a para. 3 would, in this context, also be considered a procedural norm. A failure to observe this norm would infringe the rights of Parliament.[84] The institutional balance, both vertically and horizontally, would in any case support an increase in the competences of Parliament.

2. OPTION - THE RE-DELEGATION SOLUTION

This imputes that the Commission in its adoption of the planned directives in product safety, has accepted both competence and responsibility. Such a move would be in tune with the case law of the ECJ. The planned measures for the organisation of product safety law, however, show that the Commission is not (any longer) able to fulfill all its tasks. It has to redelegate competences to the Member States. This move is obvious in standardisation and even clearer in certification. The Commission wants to entrust the first stage evaluation of the risk to the Member States, who should perform this function "in the name of the Community". The action of the Commission is undoubtedly wise politically and in view of the optimal use of the aggregate resources of the Member States is also practical. But is it legally legitimate? The re-delegation of competences waters down the pre-emption doctrine.[85] The ECJ appears prepared to accept this conclusion in the Common Commercial Policy.[86] Whether this case law is applicable to the completion of the Internal Market,

[80] Cf. ground-breaking ZULEEG M. (FN 78) and HAILBRONNER K. (FN 66).

[81] Cf. ZULEEG M. (FN 78), 284.

[82] ZULEEG M. (FN 78), has attempted just this in the area of environmental protection. Article 130r provides the starting point, but this is lacking in product safety.

[83] This argument is made by KRÄMER L., Grundrecht auf Umweltschutz, EuGRZ 1988, 285 et seq., 289; also PERNICE I. (FN 57), 9.

[84] Cf. ECR, 1990, 269 et seq., to this HILF M., Das Klagerecht des Europäischen Parlaments im Organstreit, EuR 1990, 273 et seq.

[85] Cf. DOMINIK M., "EEC-Israel Agreement and the Common Commercial Policy", ELR 1986, 466 et seq., 470.

[86] Cf. to this discussion, WALBROECK M., The Emergent Doctrine of Community Pre-emption - Consent and Re-Delegation *in* SANDELOW T./STEIN E., (eds), The Courts and the Free Markets; Perspectives from the United States and Europe, 1982, 584 et seq.; LAENERTS K. (FN 17), 228; MICKLITZ H.-W./REICH N., Legal Aspects of European Space Activities, ZERP-Schriftenreihe Band 9, 1989, pts.

in particular to the relationship between Articles 30/36 and 100a[87] is, however open to debate. Re-delegation would allow Member States to challenge the "acquis communautaire". Is the Community now so strongly "federalist", that it could make political use of this lever, developed by the ECJ, in the Council - and not in a fully fledged democratic parliament?[88]

3. OPTION - SHARED COMPETENCES BETWEEN THE COMMUNITY AND THE MEMBER STATES?

The starting point here is a certain scepticism as to whether the annexed regulation of product safety within the Internal Market programme has really lead to a delegation of all the competences and responsibilities of the Member States, within the field of product safety, to the Community. Questions may arise which cannot be answered by EEC regulation. Whether this is or must be related to independent policies not linked to the Internal Market Programme, seems to us difficult of definition. Shared responsibilities should not be linked to a perception of product safety which exists "outside" the Internal Market - that is a conception of product safety which transcends the Internal Market. Such a differentiation would soon be lost in borderline cases. It is also academic insofar as national product safety law is integrated in national markets. It seems more important to us to ask whether there is a residual national competence which can assert itself above the exclusive claim of Community law.

Community law contrary to federal constitutions knows no shared competences and responsibilities. The case law of the ECJ states that where the Community becomes active it automatically inherits competence. This concept does not answer the difficulties of a delegation and redelegation of competences. On the other hand it should not be overlooked that the concept of shared responsibility also places the pre-emption doctrine in doubt and thus causes problems for the foundations of Community law.[89]

It may be possible and fruitful to seek a basic norm for the minimum character of market entry regulation in Community law. This is laid down explicitly for environmental protection in Article 130t and for social policies in Article 118a. The proportionality principle may provide a starting point, in any case this will be so when it is applied to the relationship between the Community and the Member States.[90] It seems to us, however, that the proportionality principle is not alone a sufficient base for such a basic principle. The

94, 114 et seq.

87 To the legal effects of the "New Approach", LAUWAARS R., The Model Directive on Technical Harmonization *in* BIEBER R./DEHOUSSE R./PINDER J./WEILER J. H. H. (eds), 1992: One European Market? A Critical Analysis of the Commission's market strategy, Baden-Baden 1988, 151 et seq., 165.

88 Cf. LAENERTS K. (FN 17), 259.

89 To this point see discussions upon environmental and technology law in the European Community - Antrieb oder Hemmnis, 4. Trierer Kolloqium zum Umwelt- und Technikrecht vom 21. bis 23. September 1988, Düsseldorf 1989, 165 et seq.

90 Cf. with examples from case law, REICH N. (FN 65), who, however, rejects the creation of a subsidiarity rule.

foundation must be sought in the desired institutional balance between Member States and the central organ in a federal constitution.[91] This would secure against the danger that the Member State with the lowest standards dictates the tempo of the convoy. If, however, a divergence from the harmonised entry conditions is not only tolerated, but also desired, then a mechanism is needed to secure the constant revision of the harmonised standards and their adaptation to higher "natural" standards. The Community and remaining Member States could take on board an "improvement duty". This would a least ensure the possibility of a revision of standards once they have been set and harmonised. If Article 100a para. 4 secures the right to "go it alone" in pursuit of an improvement in product safety within the Community, then this provision offers the basic foundation stone on which the co-operation duty between the State with higher standards and the Community and remaining States may be built. In the final analysis this requires the development of a procedure[92] which ensures a constant improvement and at the same time impedes each Member State from finding its own path instead of encouraging them to remain true to the search for a worthwhile common European standard.

2. LEGAL QUESTIONS ARISING FROM DECENTRALISED OR CENTRALISED ENFORCEMENT

The Commission still follows two paths but with one ever stronger motif. Two approaches remain: on the one hand the management of normal risk by the Member States, on the other, the management of increased risk situations by the Community. But the tendency appears to be towards centralistion.

A decentralise enforcement can only avoid the danger of closure of markets if the decentralised authorities are required to observe each others decisions. The Federal Constitutional Court has declared this to be the case for German Industry Supervisory Authorities[93] (Gewerbeaufsichtsämter). This decision corresponds to the doctrine of mutual recognition. The Commission has, however, given up its attempts to achieve harmonisation of law enforcement by promoting mutual recognition.[94] Where the Commission feels that it can live with diversity it entrusts the development of co-ordination and co-operation to the Member States; on the other hand, where a common decision is required, i.e. in the evaluation of emergency situations and cases of increased risk, it desires centralised decision-making. Primary Community law perhaps provides more chances for the realisation of mutual recognition than the Commission now accepts. Much has been written on the importance of Article 100b.[95] It is nevertheless impossible to predict the restrictions which the ECJ will place on this Article.

[91] Cf. MOTT R. N., Federal State Regulations in U.S. Environmental Law: Implications for the European Community, EPU No 90/2.

[92] Cf. REICH N. (FN 65), comes to this conclusion and uses this argument to combat the Competences discussion.

[93] Cf. BVerfGE 11, 1 et seq., 6.

[94] This is explicit in the area of pharmaceuticals where the Member States are clearly addressed in these terms; this is not the case for certification. The conditions are not, however, comparable.

[95] Cf. EHLERMANN C. D., The internal market following the Single Act, CMLR 1987, 361 et seq.;

The EEC Treaty only recognises a centralised enforcement competence in competition law. Can the Member States use secondary Community law to transfer enough competences to the Community to give it full enforcement authority?[96] Or is the Commission, once again acting ultra vires? The core of the committee proposals is the formal retention of power by the Member States. But an increasing tendency is apparent, especially in the management of emergency situations, to restrict the operational room of the Member States. This could lead to a de facto centralisation of decision-making in the hands of the Commission.

Protests are made about the Europeanisation of management, both in its centralised and in its decentralised form, where it creates an almost autarkical system, which is no longer subject to legal control. This is situated outside the sphere of national law, but not yet within the ambit of Community law. At the present the committees are not even subject to reporting duties, and even should such a duty arise, reports are often late or not completed. The composition of the working groups, both the scientific-technical and the political-administrative committees, is not transparent. If procedural rules exist at all, they are not made public. The continuing discussion on the democratisation of administration within the western industrial world apparent since the 1970s has fallen victim to the integration process. The committees have furnished the administrations of the Member States with a niche into which they may withdraw and direct product safety policies without fear of legal interference. The question should, however, be addressed. Must the committees be subject to democratic control, does existing Community law demand a reporting duty and transparency? Finally the composition of the working groups is called into question. Consumers are active on the technical-scientific level in the areas of standardisation and certification. Here they are used to legitimise the privatisation of product safety. Should they also be represented on the reconstituted Pharmaceutical Specialities Committee?[97]

A centralisation of the decision-making process in the hands of the Commission requires one to identify the degree of legal protection given to any affected undertaking. The proposed model already gives the Commission sole discretion as to when it accepts the majority decision of the scientific-technical committee. The proposed regulation for the creation of a Medicinal Products Authority plans to give producers a direct action against the Commission.[98] Product safety should be regulated by means of a directive and not a regulation. The same is true for decision making in emergency situations. Whilst Member States are bound to observe the decision of the Commission, legal protection for national actors must be guaranteed before national courts. Should not a way be found to

MATTHIES H., Zur Anerkennung gleichwertiger Regelungen im Binnenmarkt der EG (Art. 100b EWG-Vertrag) *in* Festschrift E. Steindorff, Berlin 1990, 1287 et seq.; EVERLING U., Probleme der Rechtsangleichung zur Verwirklichung des europäischen Binnenmarktes *in* Festschrift E. Steindorff, Berlin 1990, 1155 et seq.

[96] Comprehensively to this problem, HILF M., Die Organisationsstruktur der Europäischen Gemeinschaft, Berlin/Heidelberg/New York 1982, 310 et seq.

[97] Cf. HART D./REICH N. (FN 22).

[98] Cf. HART D./REICH N. (FN 22). This would also create a new precedent, that is the release of a regulation under Art. 100a.

enable undertakings thus affected to challenge Commission decisions in the ECJ, even if they have been implemented by the Member States, especially as the actions of the Member States are mere interpretations of Community decisions?

III. CONCLUSION

The discussion on the legal questions of organisational structures demonstrates the organisational difficulty of integrating product safety within Community policies. Despite an inventive richness it appears that the present structures are not adequate to allow a realisation of the Internal Market. The Internal Market, achievable only at the cost of an integrated product safety policy, requires a re-assessment of organisational principles. The discussion on the organisation of product safety regulation is inextricably linked with the revision of the European economic constitution.