

Multiple Use of Test Evidence under EC Chemicals Legislation and EC Basic Rights: Is there Intellectual Property in Administrative Information?

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INTRODUCTION

Within the European Community (EC), manufacturers and importers of chemical substances wishing to place a substance on the market are required to submit certain records on the basis of which the competent authorities assess the hazards associated with the substance and lay down the marketing rules as appropriate. In the case of 'new substances' placed on the market since 19 September 1981, the data have been and still are submitted in connection with the duty to give notification of the substance to a competent authority before placing it on the market.¹ The substance must not be marketed until the records have been submitted in full. In the case of 'existing substances' already on the market before that date, there has been, and still is, a concurrent procurement obligation, which is divided into certain stages. If the records are not submitted, sanctions under administrative law may be applied; the substance may however continue to be marketed.²

This system is to be restructured on the basis of the European Commission's White Paper on Strategy for a Future Chemicals Policy.³ A major element of this reform is the aspect of speeding up the procurement of data. Although the connection with the notification requirement for new substances has largely proved successful, the White Paper proposes to effect certain

simplifications.⁴ In the case of existing substances, the submission of data has been a failure because it has benefited manufacturers and importers to keep Member State authorities in the dark. Changes of a more fundamental nature can be expected here.

One special aspect of the reform proposed in the White Paper relates to the fact that many substances are marketed by more than one manufacturer or importer. Under existing law, each manufacturer or importer has a separate obligation to submit records. This may be described as multiple submissions. A distinction must be made here between consecutive and simultaneous multiple submissions. The former occurs mainly in the case of new substances, namely where notification of a substance is first made by an initial notifier and later made again by a second notifier (and possibly by further subsequent notifiers).⁵ On the other hand, a simultaneous multiple submission occurs primarily in the case of existing substances, since a substance is not infrequently marketed simultaneously by multiple manufacturers or importers.⁶

It is logical that each individual manufacturer and importer is subject to a separate obligation in cases where the information varies although it applies to the same substances. This is relevant to the identity of the manufacturer or importer, the identity of the substances manufactured or imported by the manufacturer or importer, the manufacturing process, the

¹ Council Directive 67/548 of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, [1967] OJ L196 (as amended) (hereinafter 'Directive 67/548'), Article 7.

² The scope of the data to be supplied depends on the quantity to be placed on the market. In general, the 'tonnage philosophy' applies, i.e. the larger the quantity, the more hazard dimensions are encompassed by the data and especially the test evidence relating to the hazards. For an overview see G. Winter, 'Maßstäbe der Chemikalienkontrolle', in G. Winter (ed.), *Risikoanalyse und Risikoabwehr im Chemikalienrecht* (Werner, 1995).

³ European Commission White Paper of 13 February 2001 on Strategy for a Future Chemicals Policy, COM (2001) 88.

⁴ *Ibid.*, at 4.4 for targeted risk assessments in the context of accelerated risk assessments.

⁵ In the cases of existing substances, the testing requirement applies simultaneously to all manufacturers who market the substance; Council Regulation 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances, [1993] OJ L84 (as amended) (hereinafter 'Regulation 793/93'), Article 3(1). If they have fulfilled their obligation and further marketers of the substance then come upon the scene, the submission of data by the latter is also a case of consecutive multiple submission.

⁶ In the case of new substances, it is also possible (though rare in practice) that two or more manufacturers or importers may wish to place a substance on the market at the same time.

proposed and actual methods of use, the expected and known exposure, the quantity manufactured or imported, the predicted or known waste quantities and types, and means of reusing the substance and of rendering it harmless.⁷ (These items of information will be referred to in this article as 'supplier-specific data'.) The situation is different in the case of test evidence (data obtained by means of certain tests about the chemical and technical properties, health hazards and environmental hazards of a substance).⁸ If the tests are performed precisely, the resulting evidence can only be the same, no matter which manufacturer or importer the substance comes from. The reason why every single manufacturer and importer has a basic duty to procure the evidence is due to the fact that procuring the data can in some cases be very costly, and the intention is to prevent subsequent notifiers free-riding at the expense of prior notifiers.

On the other hand, it is not economically efficient for each individual manufacturer and importer to produce test evidence afresh. In particular, high costs make it more difficult for small and medium enterprises (SMEs) to enter the market. In addition, it is very complicated for the authorities and represents a barrier to the establishment of over-arching assessment expertise, if they have to store test evidence for each individual procedure separately and have to pretend not to know existing information when assessing the risks for a subsequently notified substance. Above all, multiple submissions in the case of test data requiring animal tests involves unnecessary suffering and wastage of animals.

For reasons arising from various combinations of the aspects just described, the existing law provides for certain simplifications. In the case of consecutive multiple submissions, existing law allows a subsequent notifier to make reference to the test evidence of the prior notifier; accordingly the authority may, when assessing the risks arising from the substance, make use of the prior notifier's test evidence in the procedure for the subsequent notifier. In the case of simultaneous multiple submissions, the parties concerned may request a jointly elected consortium leader to submit the documentation and may make reference to it in their own submission; correspondingly the authority may make use of the test evidence in the procedures for all parties concerned. This article suggests that these cases be referred to as consecutive reference and consecutive multiple utilization on the one hand, and simultaneous reference and simultaneous multiple utilization on the other.

This article first describes the present tools used to simplify the procedures that exist in EC law (taking examples of its implementation in Germany) and the new arrangements envisaged in the course of the reform of European chemicals legislation. The article then examines the requirements of EC constitutional law which should be considered by the new arrangements and appraises issues that arise from competition law points of view.

It may be noted that the constitutional issues raised below have already been the subject of detailed discussion in the drafting of the German Chemicals Act.⁹ In that work, the emphasis has been on compatibility with the national constitution, because the EC provisions gave the Member States freedom in this respect. However, since the problem is now to be solved through EC legislative reforms, the focus must now shift to compatibility with the EC constitution. Precursors are EC provisions on the assessment and monitoring of the environmental risks of existing chemical substances,¹⁰ on the classification, packaging and labelling of hazardous substances,¹¹ on plant protection legislation,¹² on pharmaceuticals legislation,¹³ and on biocide legislation.¹⁴

Using data from one procedure for further procedures has only been regarded as problematic in the EC in the field of product legislation, especially in chemicals law in the broad sense (i.e. including legislation on pesticides, biocides and pharmaceuticals). In all other administrative sectors, it seems to be a matter of course that the authorities may use all information received by them for all procedures within their purview, subject only to compliance with the limits of data

⁷ These items are listed in Annex VII(a), nos 0–2 and 6 of Council Directive 67/548.

⁸ Such test evidence is defined in Annex VII(a), nos 3, 4 and 5 and Annex VIII of Council Directive 67/548.

⁹ For stringent multiple submission, see M. Bullinger, 'Wettbewerbsgerechtigkeit bei präventiver Wirtschaftsaufsicht', 31:43 *Neue Juristische Wochenschrift* (1978), 2173, at 2178; E. Denninger, 'Die Zweitanmelderproblematik im Arzneimittelrecht', 86:9 *Gewerblicher Rechtsschutz und Urheberrecht* (1984), 627, at 631; H.-J. Papier, 'Verfassungs- und verwaltungsrechtliche Probleme der Zweitanmeldung', 3b.1/2 *Neue Juristische Wochenschrift* (1985), 12, at 15. For more flexible solutions see D. Schefold, 'Verfassungsfragen zum Verhältnis von Erst- und Nachanmelder im Zulassungsverfahren von Arzneimitteln', 2 *bga-Berichte* (1983), at 27; M. Zuleeg, 'Rechtsgutachten zur Regelung der Zweitanmelderfrage', 2 *bga-Berichte* (1983), at 3.

¹⁰ Council Regulation 793/93, Articles 6(I) and 12(III).

¹¹ Council Directive 67/548, Article 15.

¹² Council Directive 91/414 of 15 July 1991 concerning the placing of plant protection products on the market, [1991] OJ L230 (as amended), Article 13. In this context see V. Kaus, *Die Zweitanmeldung im Pflanzenschutzrecht* (Lang, 1993); D. Schwarz, *Die Zulassung von Pflanzenschutzmitteln* (Kovac, 2001).

¹³ Implemented in Germany in section 24(a) and (b) of the German Pharmaceuticals Act (Gesetz über den Verkehr mit Arzneimitteln) (hereinafter the 'Pharmaceuticals Act') of 11 December 1998 (Bundesgesetzblatt I, 3585) amended by an Act of 13 December 2001 (Bundesgesetzblatt I, 3586).

¹⁴ Directive 98/8 of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market, [1998] OJ L123, Article 12.

protection, the protection of business and trade secrets, and protection against self-incrimination. Chemicals legislation brings the aspect of exclusive utilization of data into play. It is conceivable that the idea might also be applied to other control procedures, including those relating to installations. For example, the operator of an installation might demand that his safety report or environmental impact assessment should not be evaluated in the authorization procedure for a competitor who uses the same technology or who moves to the same location. If individually produced test evidence must only be used exclusively in product legislation, why should this not be the case in the law of installations too? Or conversely, if in chemicals law one grants a generous monopoly of individual test evidence and rejects moderate solutions, this opens the door to new and problematic obstacles to administrative monitoring activities. This background should be borne in mind throughout the entire debate.

SITUATION AND REFORM IN EC LAW

THE EXISTING SYSTEM

Consecutive Multiple Submission and Utilization of Test Evidence

Principle

Under Article 15(I) of Directive 67/548, each manufacturer or importer has a duty to notify and hence to submit the full records required for his substance, regardless of whether prior notifications exist. At the same time, this means that a new substance does not become an existing substance (not subject to notification) simply because it has been notified at some earlier date by another manufacturer or importer.¹⁵

Exemption after 10 Years

Test evidence submitted in a prior notification dating back more than 10 years does not have to be submitted again. Although the duty to notify continues to exist, it only applies to certain items of information, namely the identifying features of the substance, information on its use, harmful effects during use, the quantity of the substance to be marketed, and the proposed classification, packaging and labelling.¹⁶ The test evidence on the hazards associated with the substance

can now be used for the risk assessment of subsequently notified substances.

According to commentators,¹⁷ the exemption from the requirement to submit test evidence is based on the consideration that a period of 10 years gives the initial notifier sufficient opportunity to take advantage of his innovative lead. It should be noted here that the period would seem to be too long if it is really intended solely as compensation for the lead which the manufacturer or importer has created by procuring the test evidence. In fact, the 10-year period creates a monopoly which favours the exploitation of the invented substance. This represents an abuse of legal concepts, since the possibility of taking out a patent is available for this purpose.¹⁸

Reference by Second Notifier with Permission of Initial Notifier

Even before the 10 years have elapsed, a competent authority may permit the second notifier to make reference to the test evidence submitted by the initial notifier if the latter gives his approval to such reference.¹⁹ This applies regardless of whether the initial notification was made to the same authority or to an authority in another Member State. The approval of the initial notifier must be submitted to the notification authority in writing. It is not possible for the notification authority to take a decision in lieu of such approval.²⁰

The decision on whether to permit such reference is at the discretion of the notification authority. This presupposes that the substances are identical and that the purposes for which the new substances are to be used are comparable to those stated in the first registration.²¹

Reference in Cases of Test Evidence Requiring Animal Tests

In cases of test data requiring tests on vertebrates, German law includes a provision that they may be used even without the approval of the initial notifier. The German Chemicals Act sets out a defined procedure that has to be observed, consisting of the following stages:²²

¹⁵ Cf. M. Reh binder *et al.*, n. 15 above, section 5, marginal no. 26.

¹⁶ Cf. M. Schröder, 'Der Geheimhaltungsschutz im Recht der Umweltchemikalien', 10 *Berichte des Umweltbundesamt* (1980), 20, who however points out that a patent does not provide any protection against disclosure of the substance data. Disclosure is however essential for the State to grant a monopoly like the patent. This exchange of 'monopoly for disclosure' cannot be broken down by over-extending other forms (such as the protection of test evidence) to create additional monopoly rights 'by the back door'.

¹⁹ Council Directive 67/548, Article 15(1); Chemicals Act, section 20(a)(I).

²⁰ See E. Reh binder, *et al.*, n. 15 above, section 7, marginal no. 85.

²¹ *Ibid.*, section 7, marginal no. 88.

²² Chemicals Act, section 20(a)(II)-(IV).

¹⁵ Cf. E. Reh binder *et al.*, *Chemikaliengesetz* (C.F. Müller, 1985), section 7, marginal no. 81.

¹⁶ Council Directive 67/548, Article 9; Act on the Protection Against Hazardous Substances (Gesetz zum Schutz vor gefährlichen Stoffen) (hereinafter the 'Chemicals Act') of 25 July 1994 (Bundesgesetzblatt I, 1703) amended by an Act of 20 June 2002 (Bundesgesetzblatt I, 2090), section 6(III).

- (1) The notification authority establishes contact between the initial notifier and second notifier at the request of the second notifier.
- (2) The initial notifier agrees to such utilization or enters an objection. In the event of an objection, a waiting period equivalent to the time required to procure the test evidence shall apply; the period may on application be determined by the authority.
- (3) The notifying authority utilizes the test evidence.
- (4) The initial notifier has a claim for partial remuneration against the second notifier. If the second notifier fails to pay, the initial notifier may forbid it to market the substance.
- (5) At the same time the second notifier has a claim against the initial notifier for a copy of the test evidence.

Directive 67/548 is more restrained than German law. Article 15 of the Directive prescribes only the first step mentioned above. For the subsequent procedure, it merely requires that the initial notifier and second notifier attempt to reach agreement on joint use of the data. It is left to the Member States to decide whether and how to create provisions governing the utilization of the data by the authorities and the adjustment of costs between the parties concerned.

Simultaneous Multiple Submission and Utilization of Test Evidence

New Substances

Directive 67/548 does not contain any special provision for the event that two or more notifications of the same new substance are received simultaneously. On the other hand, the general rule that each manufacturer or importer is required to submit the data cannot be regarded as exhaustive in the sense that no simplifications to multiple notification procedures can be introduced. To this extent, the Member States can lay down more specific legal provisions.

German law has made use of this facility.²³ The notifiers are given an opportunity to reach agreement, within a period set by the authority, on joint submission of test evidence determined by the authority. If no such agreement is reached, the notification authority selects a manufacturer or importer who is to be solely responsible for the submission of test evidence, while the other parties are obliged to share on an equal basis the expenses incurred for the preparation of documents. The other parties are liable to the primary party under private law and are jointly and severally liable. Unlike the consecutive notification arrangement, the other notifying parties in this case do not have any claim to copies of the test data.²⁴

Existing Substances

Existing substances are by definition already on the market and are frequently sold by manufacturers and importers. As with new substances, however, the basic principle applies here that each individual manufacturer and importer is required to submit records.

The obligation to submit records in EC Regulation 793/93 has two stages. In the first stage, essentially only the existing data are to be submitted.²⁵ Substances to be dealt with on a priority basis are determined on the basis of this stage. The second stage involves preparing more extensive data defined in more detail for the priority substances.²⁶

Unlike Directive 67/548, Regulation 793/93 contains provisions relating to the avoidance of simultaneous multiple submissions. Under Article 6(I) (first stage) and Article 12(III) (second stage) of the Regulation, the manufacturers or importers of a substance may have certain test evidence submitted by one of their number on their behalf and with their consent. This possibility is thus completely voluntary; no pressure of any sort is exerted. For the second stage, Article 12(III) adds that the others must bear an 'appropriate' share of the costs. Thus, the details are left to the agreement between the parties concerned.

APPROACHES TO A NEW SOLUTION

The European Commission is considering introducing further opportunities for utilizing certain test evidence.²⁷ The goals which could be considered here are:

- minimizing tests on vertebrates and possibly on other animal species;
- avoiding economic inefficiency arising from duplication of work by the manufacturers or importers of substances;
- facilitating market entry for SMEs, which can reduce costs by making reference to existing test evidence;

²⁴ In a decision on the parallel system in plant protection legislation (German Plant Protection Act (Gesetz zum Schutz der Kulturpflanzen) (Plant Protection Act) of 14 May 1998 (Bundesgesetzblatt I, 971) amended by an Act of 6 August 2002 (Bundesgesetzblatt I, 3082)), section 14, the Bundesgerichtshof held that it was not even possible to deduce a claim from a tacit agreement between the two parties. This does not, however, preclude the possibility that such a claim might be introduced by legislation on the grounds of public interest such as the dialogue capacity and self-monitoring of the manufacturer or importer – as in the case of consecutive multiple submission under the Chemicals Act, section 20(a)(IV), sentence 1.

²⁵ Council Regulation 793/93, Articles 3 and 4.

²⁶ *Ibid.*, Article 9.

²⁷ See European Commission White Paper, n. 3 above, at 5.5.

²³ Chemicals Act, section 20(a)(V).

- simplifying administrative procedures by no longer requiring that the authorities keep the test evidence separate; and
- improving the quality of work by the authorities by ensuring that all existing data can be used for the risk assessment.

In the case of a *consecutive multiple submission*, one strategy taking account of these objectives might be for certain test evidence already in the possession of the authorities to be used for the benefit of the subsequent registrant without the first registrant having to give its consent.²⁸ In a more limited variant, the test evidence might relate solely to data requiring tests on vertebrates (or conceivably tests on all animal species). However, it would be necessary to ensure that the subsequent registrant observes a pre-marketing waiting period equivalent to the time needed to procure the test data (but which would certainly not have to be as long as the 10 years specified in Article 9 of Directive 67/548). The subsequent registrant would also have to bear a share of the first registrant's costs. The same would apply to further subsequent registrants.

With regard to *simultaneous multiple registration*, a strategy taking account of the above-stated objectives should consist of setting the relevant manufacturers and importers a deadline for forming a consortium for joint procurement of test evidence. In the event of fruitless expiration of the deadline, the competent authority then appoints a primary responsible party.²⁹

The new strategies mentioned raise problems regarding compatibility with primary rights. In particular, basic rights might be affected. They also raise issues of competition law in view of the fact that the new strategies encourage economic agreements.

COMPATIBILITY OF THE NEW STRATEGY FOR CONSECUTIVE MULTIPLE SUBMISSION WITH BASIC RIGHTS

Basic rights that might be affected by the European Commission's proposed approach are the guarantee of property, freedom of occupation and the principle of equal treatment.

²⁸ According to the above-mentioned European Commission White Paper, the term 'notification' is to be replaced by 'registration'. This term is used in this fashion for the remainder of this article.

²⁹ For further variants of the new system, see below in this article.

GUARANTEE OF PROPERTY

Structure in terms of Legal Doctrine In terms of legal doctrine, the EC guarantee of property can be regarded to possess a protected sphere and a protection programme. The protected sphere does not, for example, extend to mere market opportunities. The protection programme prohibits encroachments unless they are justified by a legal arrangement that pursues a goal of the common good which is commensurate with the principle of proportionality – on no account must the essential content of the basic right be infringed.³⁰

This structure is similar to that of the German basic rights. The German *Bundesverfassungsgericht* has however developed an interesting concept that the European Court of Justice (ECJ) has not yet adopted as a term, namely the statutory definition of the content of property (*Inhaltsbestimmung durch Gesetz*).³¹ This means that the legislature can decide what is to form part of the content of the property. Although legal positions acquired through input of capital and labour are recognized as property, even they may be reorganized and in certain circumstances rescinded without this having to be regarded as expropriation and hence being the subject of mandatory compensation. Thus, the German Federal Constitutional Court rejects the natural law concept of property dictated to the State, and attaches considerable scope to the legislature's political freedom to elaborate. However, there are constitutional limits even to content determination. The legislature must observe the principle of proportionality and must, in the event of any modification of acquired property positions, make the consequences thereof tolerable through transitional periods and, if necessary, by means of compensation.³² Furthermore, the institutional guarantee of property must be observed. This includes, in particular, the recognition of the property necessary for the individual to conduct a decent life.³³

Although the ECJ does not use the term 'determination of content', it has made it clear in several judgments that it thinks on very similar lines to the

³⁰ See, for example, ECJ judgment of 5 October 1994, Case C-280/93, *Banana Market*, [1994] ECR I-4973, at 5042, marginal no. 78; cf. I. Pernice, 'Gemeinschaftsverfassung und Grundrechtsschutz-Grundlagen, Bestand und Perspektiven', 43:39 *Neue Juristische Wochenschrift* (1990), 2409, at 2415.

³¹ Federal Constitutional Court, decision of 15 July 1981 (*wet gravel removal*), BVerfGE 58, 300, at 330.

³² For the obligation to compensate, cf. Federal Constitutional Court, decision of 14 July 1981 (*statutory submission of copy*), BVerfGE 58, at 137.

³³ See Federal Constitutional Court, n. 31 above, at 330; Federal Constitutional Court, decision of 18 December 1968, BVerfGE 24, 367, at 389.

Federal Constitutional Court. The ECJ has repeatedly stated that an enterprise cannot claim a vested right to the retention of advantages granted by administrative law. The Court has seen such advantages in the allocation of milk quotas, sugar quotas and customs quotas.³⁴ Curtailment of such advantages cannot be regarded as violations of the basic right to property.³⁵ In connection with permissible restrictions on freedom of trade, the ECJ has recognized industrial property rights as intellectual property within the meaning of Article 30 of the EC Treaty, but at the same time demanded that the relevant national provisions must be designed such that they do not impose excessive restrictions on freedom of trade.³⁶ Such legislative shaping of the allocation, alteration and fleshing-out of market opportunities is, by its nature, a determination of the content of property. Nevertheless, the ECJ also sees limits to the freedom of the legislature. It does not call such limits an institutional guarantee, but a guarantee of the essential content of property.

This doctrinal foundation permits – and indeed demands – a closer delimitation of the following examination of basic rights:

- With regard to the protected sphere of a possible right of property, it is appropriate to confine the examination to establishing whether the new arrangement for multiple utilization of test evidence proposed for the future violates the guarantee of property. This disregards the test evidence already produced at the time that the new arrangement enters into force. This is because the issue of whether such evidence can be recognized as property and, as such, be gradually abolished is a marginal problem (and capable of pragmatic solution).
- As to the protection programme it must be examined whether the first registering party's right to determine the secondary utilization of 'its' test evidence is covered by the protected sphere of the guarantee of property. If it emerges that a valid statutory ruling (i.e. determination of content) confers on a specific advantageous position the character of constitutionally protected legal positions – which is conceivable for copyright protection, for example – it is nevertheless necessary to ask whether the legislature is prevented from changing this conferment in the future.

The statutory determinations of content considered must include arrangements under EC law, because it

is a question of the compatibility of property-related rulings of a secondary legal act with the guarantee of property under EC law. Other relevant provisions are norms of international law which are binding on the EC. Insofar as the EC has not itself fleshed out the details of intellectual property in secondary legislation, but accepts the national provisions, the latter may themselves be taken as examples of what would be determined by secondary legislation if the EC were to impose provisions of its own.

Protected Sphere of Guarantee of Property: Encroachments The protected sphere of the basic right to property can include intellectual achievements ('intellectual property'). Intellectual property of this kind does not exist in each and every idea created with the investment of labour and capital. Such direct deduction of a right from constitutional law could scarcely be handled in a way calculated to provide legal certainty – one only has to think of the invention of a mathematical formula, an organizational plan, or a political ideology. Intellectual property is primarily property determined by laws. Only indispensable aspects of the content of intellectual production may be protected as property rights that can be derived directly from the constitution.

Among the property rights that have been introduced by simple law in relation to intellectual achievements, patent law and copyright law are the most relevant. Another possibility is that test data might be regarded as trade and business secrets and, as such, may enjoy protection under property law. Another possibility is that chemicals legislation itself may create a property position for the initial registrant.

Patent Law

Patent law secures for the patent holder the sole right to utilization of the patented invention. An invention can be patented under the European Patent Convention if it is new, based on an inventive activity and capable of commercial use.³⁷

Test evidence obtained by means of tests by a registrant or by his agents does not in itself constitute an invention. Indeed, the purpose of conducting tests is solely in the scientific discovery of chemical properties and action mechanisms. The invention, by contrast, lies in the new substance itself, its possible uses and its manufacturing process. If the invention also possesses innovative value and commercial applicability, patent protection can be sought for the invention. Thus, test evidence does not constitute a patentable invention. Apparently patent protection has in Europe

³⁴ ECJ 6 December 1984, Case 59/83, *Biovilac*, [1984] ECR 4057, at 4080, marginal no. 23; ECJ 27 September 1979, Case 230/78, *Eridania*, [1979] ECR 2749, at 2768, marginal no. 22; and see *Banana Market*, n. 30 above, marginal no. 80.

³⁵ *Eridania*, *ibid.*, at 2768, marginal no. 22.

³⁶ ECJ 31 October 1974, Case 15/74, *Centrafarm*, [1974] ECR 1147; ECJ 20 January 1981, Cases 55/80 and 57/80, *GEMA*, [1981] ECR 147.

³⁷ European Patent Convention, Article 52. Article 64 provides that the rights of utilization shall be based on national patent legislation.

never even been sought for such test evidence, let alone granted.

Copyright

Test evidence has a closer affinity with copyright law than with patent law. Copyright law secures for the creator of a work the sole right to decide on its use. This presupposes that test evidence is an intellectual creation.³⁸

Routine tests which are performed in accordance with painstakingly detailed rules are not an intellectual achievement. Such an achievement could at most be presumed to exist for the more complicated tests.³⁹ If this is the case for specific test evidence, it is necessary to ask whether the copyright holder's right of use is violated if a competent authority uses test evidence of the first registrant in the second registration procedure without the first registrant's consent. The right of use encompasses the right of dissemination, i.e. the right to offer the work to the public or to place it in circulation.⁴⁰ However, use of test evidence within the same authority for the benefit of the subsequent registrant does not constitute such dissemination. Thus the right of use would not be violated.

In the context of basic rights, this means that although certain test evidence, as copyright-protected work, falls within the protected sphere of the guarantee of property, the protected sphere is itself limited by the rights of use, which are not violated by the second registration system. Thus the secondary utilization by the authority does not constitute an encroachment on property.

The situation might be different if the new concept, as provided in section 20(a)(IV) of the German Chemicals Act, granted to the subsequent registrant (who has complied with a waiting period and borne a share of the costs) a legal claim against the first registrant for delivery of a copy of test evidence used. But disclosure to another company could only be regarded as dissemination on a very broad interpretation of the term.⁴¹ Moreover, test evidence is delivered to the

subsequent registrant not by the authority, but by the first registrant itself, which means that any restriction of the right of use would not be due to an official action.

One can however regard the legal granting of a private-law claim as in itself a derogation from the normal rules of copyright law. The obligation to hand over test evidence would then have to be regarded as a special determination of the content of property for the context of chemicals monitoring. However, this obligation would not affect the essential content of copyright law in terms of constitutional property rights, but would only relate to a peripheral elaboration of the right of use. This is because the basic allocation of the creative intellectual achievement to the copyright holder does not necessarily have to consist of a perfect right of exclusivity from a constitutional rights point of view. If modifying interests of other parties or of the general public exist, it is permissible instead to provide for disclosure to the subsequent registrant.⁴² The fact that the subsequent registrant bears a share of the costs is sufficient reason (although admittedly not a compelling reason) to give him access to the data, co-financed in this way. This also caters for the public interest that if the subsequent registrant has knowledge of test evidence he is in a better position to control the risks of the substance and to provide information and engage in a dialogue in relation to subsequent official supervisory activities.⁴³

In summary, the mere utilization of test evidence for second registrations does not violate the right of use under national copyright law; it does not in itself constitute an encroachment on the protected sphere of property. If the new system involves test evidence having to be handed over to the subsequent registrant, this is admittedly a departure from the normal content of copyright law, but it is nevertheless (given sharing of costs and compliance with a waiting period) a permissible determination of copyright property which does not violate the essential content thereof.

Trade and Business Secrets

A third issue is whether the first registrant's test evidence can be classified as 'trade and business secrets'. Protection of such secrets may be regarded as another type of property right granted by law, besides patent and copyright protection. Article 19 of Directive 67/548 and Article 16 of Regulation 793/93 indeed grant such protection. The manufacturers or importers who have to produce documentation may indicate that certain items of information are of economic value and ask for them to be kept confidential. The competent

³⁸ World Intellectual Property Organization Copyright Treaty, Article 5; revised Berne Convention as amended by the Paris Act of 1971, Article 2.

³⁹ Cf. with regard to German law, U. Loewenheim, in G. Schrickler (ed.), *Urheberrecht-Kommentar* (Beck, 1999), section 2, marginal no. 64, who sees eligibility for protection in the processing of findings and in the selection, coordination, correction, systematization and arrangement of data and findings.

⁴⁰ See, for example, German Copyright Act (Gesetz über Urheberrecht und verwandte Schutzrechte) (Copyright Act) of 9 September 1965 (Bundesgesetzblatt I, 1273), amended by an Act of 23 July 2002 (Bundesgesetzblatt I, 2850), section 17; Directive 96/9 of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases, [1996] OJ L077 (as amended), Article 5.

⁴¹ See the assertion by J.V. Ungern-Sternberg, in G. Schrickler, n. 39 above, section 15, marginal no. 58, who claims that as few as two people are sufficient for the 'dissemination', is not convincing.

⁴² Cf. G. Schrickler, 'Introduction', in *ibid.*, n. 39 above, marginal no. 12, on restrictions on the grounds of public interest.

⁴³ See E. Reh binder, *et al.*, n. 15 above, section 7, marginal no. 80.

authorities then decide whether the information merits protection. However, summaries of the results of toxicological and eco-toxicological tests are not protected ('negative list').⁴⁴ In the case of existing substances, the Regulation also provides for the exclusion of 'any information which, if withheld, might lead to animal experiments being carried out or repeated needlessly'.⁴⁵ Further restrictions in both the Directive and in the Regulation are the provisions that the request may only extend to secrecy 'from all persons other than Member States and the European Commission'.⁴⁶

These provisions may be regarded as the granting of property positions in a constitutional sense. They also limit the scope of such positions, however, in that:

- it is left to the competent authority to assess the question of whether they merit protection;
- a negative list of non-protected information is set up; and
- secrecy is not granted in relation to the competent authorities.

Under this mechanism for the protection of secrets, the result – under the existing substances regime – is that test evidence resulting from animal tests can be disclosed to other substance suppliers, whereas other test evidence (except for the summary of results) is protected. However, an aspect of crucial importance here is that the protection of such test evidence only applies to disclosure to the public. Use of the data within the administrative sphere of national and European risk assessment remains explicitly unrestricted.

The net result, therefore, is that the protection of trade and business secrets in accordance with the legal standards laid down in EC chemicals legislation would not be violated at all by multiple use of test evidence, since this is a matter of processes within the administrative sphere. This result is fully in line with the traditional general understanding of trade and business secrets. The law serves to protect a market position against encroachments by competitors or the public at large, but is not aimed at the organization of the internal administrative sphere. Problems of information handling within the administrative sphere are dealt with by other areas of the law, such as data privacy protection, rules on mutual administrative assistance, and also the relevant rules on multiple utilization of data.

It would however have to be regarded as disclosure to the public and hence as a secrecy problem if EC law,

following the example of section 20(a)(IV) (sentence 1) of the German Chemicals Act, were to provide that the subsequent registrant had a claim to delivery of a copy of the test evidence in return for his contribution to the costs. Even then, however, the property guarantee would not be violated, because EC law on delivery of the documentation would be a determination of the content of the property.

As already mentioned in connection with copyright law, the subsequent registrant itself and the public administration have legitimate interests in ensuring that the subsequent registrant is informed about the risks of the substance manufactured or imported by the latter. By comparison, the interests of the first registrant play a subordinate role, especially since the latter receives financial compensation and enjoys the protection of a waiting period.

A violation of the property guarantee would only occur if the essential content of the property were impaired. The ECJ has not yet developed any clear doctrine on the description of the essential content of property.⁴⁷ Where the field of entrepreneurial activity is concerned, and not that of personal development, this essential content can at most be considered to comprise information about the innermost internal sphere of an enterprise, such as business policy strategies, customer master files and information about production methods. Test evidence, by contrast, provides information about the effects of products on the environment. It therefore relates, not to the internal sphere of the company, but to its contact with the world outside. Consequently, test evidence does not belong to the core area of the company that is protected by the guarantee of essential content. On balance, therefore, one can conclude that even the disclosure of test evidence to a subsequent registrant does not constitute an encroachment on the property guarantee under EC law.

One could also consider whether this conclusion runs counter to Article 39(III) of the World Trade Organization's TRIPS Agreement.⁴⁸ In the context of the protection of business secrets, this Article of the TRIPS Agreement provides that data which are required to be submitted in authorization procedures for pharmaceutical and agrochemical products must be protected from unfair use. Quite apart from the fact that the case considered here is not a pharmaceutical or agrochemical procedure, neither the internal utilization of test evidence within the competent authorities nor the possible delivery of the test evidence to the subsequent registrant would be unfair use.

⁴⁴ Council Directive 67/548, Article 19(1), sentence 3, subsection (e); Council Regulation 793/93, Article 16(1), sentence 3, subsection (4).

⁴⁵ Council Regulation 793/93, Article 16(1), sentence 3, subsection (6).

⁴⁶ Council Directive 67/548, Article 19(1), sentence 1; Council Regulation 793/93, Article 16(1), sentence 1.

⁴⁷ This is the conclusion reached by I. Pernice, n. 30 above, at 2416.

⁴⁸ Agreement on Trade-Related Aspects of Intellectual Property Rights (Marrakesh, 15 April 1994).

Test Evidence as the Subject of an Independent Proprietary Right for Intellectual Property

One could consider regarding the existing second notification system under EC law as a special variant of the granting of proprietary rights. It undoubtedly creates an advantageous situation for the first notifier because, under existing law, a second notifier is bound to produce test evidence itself in cases where the first notifier objects to utilization and where (in those Member States that have introduced provisions on the compulsory utilization of animal test data) the test evidence does not relate to such animal test data. This advantageous situation is, however, a privilege granted by the public authorities, and not a legitimately acquired right. It was created by the EC legislation and can be modified or abolished by the same.

The situation is similar to the cases decided by the ECJ with regard to the granting of market advantages.⁴⁹ A farmer has a right of property in his farm, but does not own the milk quota. The importer of bananas has a right of property in his forwarding business, but does not own the customs quota. Similarly the manufacturer or importer has a right of property in his manufacturing business, and in the design of the substance and the documents containing the test evidence, but he does not own the way that they are used in official procedures.

If the situation were different, it would in future be necessary in administrative procedures for the data submitted to be separated on the basis of property aspects. The authorities would not be in a position to learn from one procedure for others and to accumulate know-how. For example, they would not be allowed to use information from an environmental impact assessment, such as data on an existing local environment, for other procedures. This would seriously affect the supervisory mission of the administrative authorities. However, when shaping the secondary utilization of test evidence, it is necessary for the EC legislature to observe certain limits of discretion, and in particular the principle of equal treatment.

FREEDOM OF BUSINESS ACTIVITY

It is also necessary to investigate a possible violation of the basic right to freedom of occupation, which is also recognized as a basic right under Community law.⁵⁰

Without any doubt, the protected sphere of freedom of occupation includes the right of every entrepreneur to decide whether to manufacture products and which products to manufacture. It is however open to ques-

tion whether an encroachment on the protected sphere is involved. The essential encroachment on the freedom of occupation lies in the fact that the manufacturer or importer is required to prepare and submit test evidence. This encroachment is justified on health and environmental protection grounds, which are recognized by Article 2 and Article 3(I) (letters p and l) of the EC Treaty. Arguably, this very far-reaching encroachment also covers every utilization of test evidence for administrative monitoring activities, including use of such evidence for risk assessment procedures other than the original procedure. In this light, the present arrangement under which use of the documents is not specifically permitted for other risk-assessment procedures (unless the first registrant agrees) can be seen as a concession. The new arrangement, which partly abolishes this concession, thus represents a return to the normal scope of the overall encroachment and, therefore, does not include any independent encroachment. In fact, it is normal practice in the law of monitoring of economic activities that the measured data submitted to the authorities are used by the authorities for all monitoring purposes and are not kept precisely separated in terms of the individual projects monitored.⁵¹ Thus, the submission of test evidence does not give the first registrant an exclusive right that might guarantee him the *de facto* maintenance or improvement of his market position in relation to his competitors.⁵²

If one nevertheless assumes that the multiple use of test evidence on its own constitutes an encroachment on freedom of business activity, this raises the question of possible justifications. Here it is necessary to distinguish between carrying out tests that require animal tests and those for which animal tests are not required.

Insofar as repeated performance of animal tests can be avoided by utilizing test evidence, it is possible to justify the encroachment on the first registrant's freedom of business activity on the grounds of protection of animals.⁵³

In cases where test evidence does not require animal tests, but provision is to be made for secondary use, it is necessary to look into other possible justifications. According to the ECJ,⁵⁴ the legislature must be allowed

⁴⁹ For the multiple use of data by the competent authority as it is allowed by the legislation on industrial installations, cf. R. Lechelt, in H.-J. Koch *et al.*, *GK-BImSchG* (Werner, 2002), section 52, marginal no. 298.

⁵⁰ Cf. M. Zuleeg, n. 9 above, 3, at 11; D. Schefold, *ibid.*, 27, at 48.

⁵¹ According to Article 15(II)–(IV) of Council Directive 67/548 the Member States can in the interest of animal protection introduce provisions which support and even request the first registrant's consent with the subsequent use of his data.

⁵² ECJ 13 December 1994, Case C-306/93, *SMW Winzersekt*, [1994] ECR 5555, marginal no. 24.

⁴⁹ See n. 34 above.

⁵⁰ See *Banana Market*, n. 30 above, marginal no. 78.

freedom here. The EC legislature is not obliged to select the optimum measure, but has a large degree of freedom in assessing the relative merits of the various interests. The Court only objects to patently erroneous assumptions and improper assessments.⁵⁵

As mentioned above, the following may be regarded as goals of a system under which existing test evidence may be used even without the consent of the prior registrant: avoiding economic inefficiency, promoting SMEs, improving administrative monitoring activities and simplifying official administration. These are legitimate objectives of EC law. Only in the case of simplifying official administration might their legitimacy be in some doubt. In German literature, it is argued that mere savings of administrative effort cannot legitimize encroachments on basic rights. In connection with this view, however, it is alleged that secondary use of test evidence amounts to expropriation, which at the same time means that the justifications must carry particular weight.⁵⁶ On the view expounded here, however, there is no encroachment on the protected sphere of property. It is solely a question of the justification for encroachments on the freedom of business activity. For this purpose, grounds that satisfy lower standards are sufficient, and these include simplification of administration.

The extent of the burden on the first registrant is also not unreasonable, because the sharing of costs and the imposition of waiting periods establish a kind of 'equality of arms' between the first and subsequent registrants. On the contrary, it would, from the point of view of the subsequent registrant, be unreasonable to demand test evidence even if the authority already knew (e.g. from prior registrations) that a substance was not dangerous. On the other hand, the principle of equal treatment requires that the burdens must not be borne by one registrant alone. Thus, the real problem of the second registration system is not compatibility with the basic rights of freedom, but compatibility with the principle of equal treatment.

GENERAL PRINCIPLE OF EQUAL TREATMENT

The general principle of equal treatment is also recognized as a basic right under EC law.⁵⁷ This general principle states that identical situations must not be treated differently. Different treatment is not excluded, however, if it can be justified by cogent reasons.⁵⁸

It is obviously a case of unequal treatment if the first registrant's test evidence is utilized for the benefit of the subsequent registrant without compensation. Both registrants want to give notification of substances and both are subject to the same burden of procuring data, but permitting references to the existing test evidence places the subsequent registrant at an advantage in that he saves time and money. This unequal treatment is, however, compensated by the contribution to costs and the waiting period. Any remaining inequality in the treatment of the first registrant can be justified by the above-mentioned interests of protecting animals, ensuring macro-economic efficiency, promoting SMEs, and simplifying and improving the quality of official administration.

COMPATIBILITY OF NEW SIMULTANEOUS MULTIPLE SUBMISSION CONCEPTS WITH BASIC RIGHTS

Whereas in the case of second registration, the multiple submission of test evidence takes place consecutively, the case of multiple submission relates to two or more producers or exporters acting simultaneously. Such a situation can occur in the following cases:

- registration of an existing substance that is placed on the market simultaneously by two or more producers or importers;⁵⁹
- subsequent requests for data on a substance already registered that is placed on the market simultaneously by two or more producers or importers;⁶⁰
- registration of a new substance that is to be placed on the market simultaneously by two or more producers or importers.⁶¹

It is reasonable to suspect that the practical relevance of avoiding simultaneous multiple submission is greatest in relation to the registration of existing substances. This article therefore concentrates on the (most frequent) cases of multiple registration of existing substances. The other cases can however be treated analogously.

⁵⁹ Under the present law, this situation corresponds to first-stage and second-stage requests for data relating to an existing substance that is manufactured and marketed by two or more parties; Council Regulation 793/93, Articles 3 and 4 and also Articles 9 and 12.

⁶⁰ Under existing law this situation corresponds to subsequent requests for data both for new substances and existing substances; Council Directive 67/548, Article 18(II); Council Regulation 793/93, Article 10(II).

⁶¹ Under existing law, this situation corresponds to double notification of a new substance, for which Directive 67/548 does not contain any specific provision. A different situation applies under German law; see Chemicals Act, section 20(a)(V).

⁵⁵ See *Banana Market*, n. 30 above, at 5068.

⁵⁶ See H.-J. Papier, n. 9 above, at 15.

⁵⁷ ECJ 25 November 1986, Cases 201/85 and 202/85, *Klensch*, [1986] ECR 3477.

⁵⁸ T. Oppermann, *Europarecht* (Beck, 1999), marginal no. 492.

VARIANTS OF POSSIBLE MULTIPLE UTILIZATION OF TEST EVIDENCE

Consortium Single Dossier Submissions

One possible new variant of possible multiple utilization of test evidence may be to place concerned parties under an obligation to form a consortium which – on the principle 'one substance/one dossier' – submits for each substance a single dossier that encompasses the test evidence once and for all. This could take place in the following way. In view of the proposed pre-registration of the substances on the market,⁶² it is assumed that the substances marketed and their producers and importers are known. Where substances are marketed by two or more parties, the competent authority informs the pre-registrants known to it that the situation of simultaneous multiple submission exists and that a consortium must therefore be formed. A statutory deadline applies to submission by the consortium. Until the deadline expires, individual submission of supplier-related data and test evidence by the individual marketers is not permissible.

If the deadline expires without a consortium being formed, various options for sanctions are conceivable. The most severe sanction would be that a marketing ban would come into operation for all pre-registered parties until the consortium was finally formed. This variant, however, has the serious consequence that the individual marketer cannot take individual action to avert the ban (i.e. by submitting its own data), but has to rely on the readiness of all the other parties to join forces. This would be a very serious encroachment on an individual party's entrepreneurial freedom of action, which would likely be rejected as unreasonable by the ECJ because other equally effective, but less serious, means are available. This variant of a universal marketing ban will therefore not be pursued further here.

Primary Party Submission A less severe variant would be for the competent authority to appoint a primary responsible party who would have to submit test evidence for itself and all other parties concerned within a further deadline.⁶³ In relation to the other parties concerned, the primary responsible party would have an enforceable private-law claim for a share in the costs. Possible candidates for the primary responsible party might in particular be the market leader or the party who knows the most about the substance. The criteria 'market leadership' and 'knowledge' could be statutorily defined, but they should only

be guiding marks for discretion which should be granted to the authority as a matter of principle, since in practice other criteria may prove to be suitable as well. If the primary responsible party does not submit the test evidence in time, it can be compelled by administrative sanctions or, alternatively, a marketing ban.

It might be regarded as a disadvantage of this system that the appointment of the primary responsible party implies involvement of the competent authority. The administrative burden is however slight, since the criteria and the actual situation (market leadership and knowledge situation) are clearly defined. Since the contribution to costs is left to private compensation, the competent authority would not have to set any cost rates either.

This variant should be designed so that it applies not only to test evidence based on animal tests, but to all test evidence. The reason for this is that it considerably simplifies the entire set of regulations. Admittedly from a constitutional point of view, encroachments on basic rights can be justified particularly in terms of the interest in avoiding animal tests. This has led to the widespread differentiation that still exists between rules for animal test data and rules for other data. However, as noted below, even for other data there are sufficient grounds of public interest to justify rules on the avoidance of multiple submissions.

Partial Consortium Submission A third variant might consist in allowing, after expiration of the deadline for the formation of the consortium, a further deadline for the submission of test evidence by partial consortia or even individual suppliers. Once a partial consortium or an individual submits test evidence, others would be able to make reference to such evidence. The system for consecutive multiple utilization as elaborated above would then apply.

The disadvantage of this variant is its lack of clarity, which could only be avoided by means of official monitoring. What is even more important is that it does not exclude the multiplication of animal tests. This variant too will therefore not be pursued any further.

This article will only examine the constitutionality of the concept, which provides for an obligation to form a consortium and possibly for the subsequent official appointment of a primary responsible party. Separate consideration will also be given to the constitutionality of marketing bans that are imposed as a sanction for failure to comply with data submission obligations. Marketing bans are conceivable as sanctions in a variety of situations, but here they are to be examined – *pars pro toto* – for cases where the primary responsible party fails to submit the specified test evidence.

⁶² This pre-registration will correspond approximately to first-stage data submission pursuant to Council Regulation 793/93, Articles 3 and 4.

⁶³ This would correspond to the German duplicate registration system for new substances pursuant to Chemicals Act, section 20(a).

CONSTITUTIONALITY OF THE VARIANT: OBLIGATION TO FORM A CONSORTIUM/APPOINTMENT OF A PRIMARY RESPONSIBLE PARTY

Guarantee of Property With regard to multiple utilization of test evidence, it is necessary to examine whether there is any violation of the guarantee of property. Unlike multiple utilization in the context of a consecutive multiple submission, multiple utilization in connection with a simultaneous multiple submission does not give rise to any problems of encroachment of intellectual property, for the simple reason that the consortium leader who prepares and submits the test evidence for the consortium has agreed to this procedure.

If the consortium fails to come into being and a primary responsible party is appointed, and if the test evidence submitted by the latter is used with regard to other parties concerned, the legal situation is the same as for consecutive multiple utilization. The property guarantee is not violated, because the EC legislature is free to determine that the use of the data within the administration does not belong to the protected sphere of ownership of the test evidence.

Freedom of Business Activity It is necessary to distinguish several different elements of the variant assumed here that might constitute an encroachment on freedom of occupation, namely the multiple utilization of test evidence, the imposition of the obligation to form a consortium and the appointment of a primary responsible party.

Multiple Utilization of Test Evidence

The parties concerned must declare in the consortium that they agree to test evidence being used for all of them. As a result of this consent by all parties, there is no encroachment on freedom of occupation. Admittedly they are, in the final analysis, compelled to agree, but this is due to the obligation to form a consortium, which has to be examined separately (see below). Multiple utilization of the data is however not an encroachment in its own right.

Obligation to Form a Consortium

The obligation to form a consortium undoubtedly represents an encroachment on the entrepreneurial freedom of the producers and importers. The encroachment is, however, justified by the various public interests mentioned above: it minimizes animal tests, ensures economic efficiency, promotes SMEs, and simplifies and improves the work of the authorities.

Appointment of a Primary Responsible Party

If a primary responsible party is appointed, its position in terms of basic rights must be adjudged in a

similar manner to the case of the first registrant in consecutive multiple utilization. The primary responsible party's freedom of occupation is already restricted by the obligation to submit test evidence. This can be justified on the grounds of environmental and health protection interests. The multiple utilization of the data means the primary responsible party is at the same time called upon to act for the other parties concerned. This does not place the primary responsible party under any additional burden, since it only has to submit the data once. If the multiple use of the data is, however, seen as an additional encroachment, this is justified by the public interests mentioned above.

Principle of Equal Treatment With regard to the formation of consortia, the principle of equal treatment will be observed, since all members are equally obliged to join forces and the costs are shared equitably. When it comes to the appointment of a primary responsible party, there is essentially a case of unequal treatment in relation to the other parties who are not required to submit test evidence. This is alleviated by the cost contributions made by the other parties. The residual inequality of treatment can be justified on material grounds. These once again include the public interests in avoidance of multiple submission that have already been mentioned. They are justification for selecting only one party from the circle of suppliers and placing that party under an obligation. Furthermore, the decisive selection criteria, for instance, in particular, market leadership and knowledge of the risks associated with the substance, offer a guarantee that the selection itself does not take place in an arbitrary manner.

CONSTITUTIONALITY OF A MARKETING BAN ON THE GROUNDS OF FAILURE TO SUBMIT DOCUMENTS

This section first describes the situations in which the imposition of a marketing ban might be considered. Here only marketing bans that the party concerned can avoid by submitting the documents individually are examined. The case where the party cannot individually avert the marketing ban because he is bound to rely on the formation of a consortium has already been excluded above as unreasonable.

The following situations may be considered as possible triggers for marketing bans:

- a producer or importer fails to submit in time the data required for (pre-)registration;
- the primary responsible party appointed by the authority fails to submit in time the test evidence for the existing substance in question;

- a supplier fails to submit in time the supplier-specific and the effect-specific details about his existing substance; or
- a supplier has registered a new substance and is lawfully marketing it. The authority however subsequently demands test evidence that the market participant fails to submit in time.

A marketing ban constitutes an encroachment on the freedom of occupation of the manufacturers and importers. One must ask whether this encroachment can be justified. It is assumed here that hardship rules apply which may delay the onset of the marketing ban in certain cases.

It is crucially important to distinguish between two possible public interests in restrictions on marketing. One of these interests has a purely administrative character: its aim is to obtain risk data. The other interest has a material character: it is concerned with avoiding dangers, or prevention of risks. If one were to demand such material grounds for the marketing restriction under examination here, a marketing restriction would rarely be able to come into play because there would be, at least in a situation where the primary responsible party refuses to provide information, a lack of the necessary information for making a risk assessment.

However, even the mere administrative purpose is sufficient reason for marketing restrictions. Unlike the marketing ban based on material grounds, which continues in force permanently until the competent authority receives information which enables it to give the 'all clear', the marketing ban on formal grounds is only a temporary measure. Upon submission of the documentation, marketing can be resumed again, regardless of whether or not the information gives cause for concern.

If refusal to supply information was not a sufficient reason for the marketing restriction, one could call into question the notification system for new substances. Here too marketing is banned until certain records are submitted. The situation for existing substances is an exact parallel – marketing is banned until the data are submitted. Admittedly one might object that in the case of existing substances, unlike new substances, the marketing ban results in loss of established customers, which means the cost consequences can be particularly serious. This, however, can be countered by the argument that in the case of new substances, the development costs are usually considerable and delays due to the completion of the data to be submitted can therefore be very expensive. For existing substances, the development costs have usually been recovered. The crucial factor for both existing substances and new substances is that it is entirely in the hands of the producer or importer to

ensure, by submitting the required information, that the marketing ban is lifted again.

For existing and new substances alike, the encroachment on basic rights is justified by a basic suspicion that legitimizes the requirement to procure the data. In the cases of new substances, this is seen in the fact that they are 'substances' in the legal sense, i.e. 'chemical elements and their compounds in natural form or manufactured by a production process'.⁶⁴ The suspicion lies in the fact that given the appropriate dose ('*dosis facit venenum*', as Paracelsus said), any chemical substance can become dangerous – through a combination of intrinsic properties and exposure conditions. Before marketing, therefore, it is legitimate to demand information that makes it possible to assess where the dangerous dose lies and whether it will be exceeded by exposure. This approach can similarly be applied to existing substances as well. That it is not unrealistic is clear from assessment practice, according to which some 70% of the new substances notified in the EC are classified in at least one of the hazard categories.⁶⁵ It is reasonable to assume that a similarly large percentage can be expected for the assessment of existing substances.⁶⁶

COMPETITION LAW PROBLEMS OF FORMING CONSORTIA

The formation of consortia to distribute the burdens of data procurement raises questions about compatibility with European competition legislation. In particular, Article 81(I) of the EC Treaty which prohibits 'agreements', 'decisions' and 'concerted practices' which may affect trade between Member States may be violated.

Where the data procurement burdens are distributed among several market participants in a consortium, this is undoubtedly a case of an 'agreement' or 'concerted practice'. Such an agreement has an effect restricting competition if trade between States develops differently as a result of the measure than in a system with undistorted competition.

If, as intended in the new concept assumed here, all market participants are legally bound to form consortia, a restriction of competition can be ruled out simply because of this legal obligation. This is because a restraint of competition presupposes that the actors enjoy freedom of action from a competition point of

⁶⁴ Council Directive 67/548, Article 2(I)(a).

⁶⁵ See European Commission White Paper, n. 3 above, at 7.

⁶⁶ *Ibid.*

view in the first place.⁶⁷ Under the assumed variant, however, the enterprises do not have the freedom to refrain from taking part in a consortium. Expressed in positive terms, the legally prescribed compulsion to form a consortium is specifically intended to prevent any inequality of opportunity between the competitors concerned.

CONCLUSIONS

In the context of developing an improved European system for the regulation of chemicals, the question arises as to how far duplication of work can be avoided in the procurement of test data required for risk assessment purposes in cases where two or more manufacturers or importers place the same substance on the market either consecutively or simultaneously. It is proposed that the two cases be called consecutive and simultaneous multiple submission of test evidence, and the simplifications be known as consecutive and simultaneous multiple utilization of test evidence. This article discusses the compatibility of certain solution variants with primary EC law, in particular basic rights and competition law.

CONSECUTIVE MULTIPLE SUBMISSION AND UTILIZATION OF TEST EVIDENCE

The starting point is a concept that permits multiple utilization of the first registrant's test evidence. Under this system the subsequent registrants may make reference to existing test evidence submitted by a first registrant, and the authorities may use such test evidence in the second registration procedure. The system is intended to apply to all test evidence, regardless of whether or not it is based on animal tests. It is however subject to the condition that the subsequent registrants comply with a waiting period equivalent to the period necessary for procuring the documents and that they bear a share of the first registrant's costs.

Guarantee of Property There is no encroachment on the protected sphere of the property guarantee. Legally elaborated rights of intellectual property such as patent rights, copyrights and trade secret protection rights would not be violated. Test evidence does not constitute an invention and is therefore not patentable. In some cases it is capable of copyright protection, but its multiple utilization is a process internal to the administration and therefore does not

violate the legal owner's exclusive right of dissemination. The protection of trade and business secrets is not violated, because this is intended to prevent the disclosure of documents to the 'outside world', not their utilization in internal operations.

Freedom of Business Activity First, the new concept is not an independent encroachment on the first registrant's freedom of business activity, but is part of the registration requirement, which constitutes the real encroachment that is justified on health and environmental protection grounds. Multiple utilization of test evidence submitted is covered by the legislature's discretion with regard to the details of such encroachment.

Second, if one nevertheless assumes that multiple utilization of test evidence is in its own right an independent encroachment on the protected sphere of the freedom of business activity, this is at any rate justified. The interests of protecting animals, simplifying and improving the quality of administrative procedures, ensuring economic efficiency and safeguarding the interests of SMEs are legitimate objectives which are implemented by means of the waiting period and cost sharing in a manner commensurate with the principle of proportionality.

Principle of Equal Treatment The disadvantage incurred by the first registrant under the new concept is cushioned by the waiting period and cost contribution required of the subsequent registrant. Any residual disadvantage is justified by the factors mentioned in the second part above regarding the freedom of business activity.

SIMULTANEOUS MULTIPLE SUBMISSION AND UTILIZATION OF TEST EVIDENCE

It is assumed here that a new system applies under which the manufacturers or importers of substances are set a deadline for forming a consortium and are required to jointly submit the test evidence on the principle of 'one substance/one dossier'. On fruitless expiration of the deadline, a primary responsible party is appointed with the obligation to submit the dossier. In return, the primary responsible party has a claim on the other suppliers for a share of the costs. If he fails to submit test evidence, he is fined or a marketing ban is imposed on him.

Guarantee of Property If a consortium comes into being, multiple utilization of test evidence does not raise any problems regarding encroachment on

⁶⁷ For the absence of entrepreneurial freedom of action and State-induced measures, cf. H.-J. Bunte, in E. Langen and H.-J. Bunte, *Kommentar zum deutschen und europäischen Kartellrecht Bd.* (Luchterhand, 2001), section 1, marginal nos 144, 199.

intellectual property, for the simple reason that all have agreed. If the consortium fails to come into being and a primary responsible party is appointed, and if the test evidence submitted by the latter is used with regard to other parties concerned, the legal situation is the same as for consecutive multiple utilization. There is no violation of the property guarantee.

Freedom of Business Activity

Multiple Utilization of Test Evidence where a Consortium Exists

In view of the consent by all parties, there is no encroachment on freedom of occupation. Admittedly the parties are in the final analysis compelled to agree, but this is due to the obligation to form a consortium, which has to be examined separately. Multiple utilization of the data is however not an encroachment in its own right.

Obligation to Form a Consortium

The obligation to form a consortium is an encroachment on the freedom of business activity. The encroachment is however justified by the public interest in protection of animals, economic efficiency, promotion of SMEs, and administrative simplification and improvement.

Appointment of a Primary Responsible Party

The obligation to submit test evidence is an encroachment that can be justified on the grounds of the public

interest in environmental and health protection. The fact that multiple utilization of the data means that the primary responsible party is at the same time called upon to act for the other parties concerned does not place it under any additional burden, since it only has to submit the data once. If the multiple use of the data is, however, seen as an additional encroachment, this is at all events justified by the public interests mentioned above.

Principle of Equal Treatment With regard to the formation of consortia, the principle of equal treatment is observed, since all members are equally obliged to join forces and the costs are shared. With regard to the appointment of a primary responsible party, there is indeed inequality of treatment in relation to the other parties who are not obliged to submit test evidence, but this can be justified by the aforementioned public interests in avoiding multiple submission and also by the selection criteria of market leadership and knowledge of the substance risks.

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