

Mentor Group Paper
Proposal for a Case Study on Risk Assessment
in Europe

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(A) Introduction: Risk Assessment and Approaches
to Regulatory Controls: the North American
lessons for Europe

1. Last year Judge Stephen Breyer's incisive paper pointed out that regulatory protection involves an assessment of the risk involved. That assessment may be based on objective assessment of risks and the economic costs of avoiding them or it may be not. Judge Breyer drew attention to the problems of *tunnel vision* (page 7 of his paper), *random agenda selection* (page 11) and *inconsistency* (page 13) and the *vicious circle* (pages 15 to 28). Judge Breyer characterised the source of American regulatory failure as follows:-

"Risk regulation is plagued by problems of public perception, legislative action and reaction, and technical regulatory methodology, and these problems reinforce each other. This vicious circle diminishes public trust in regulatory institutions and thereby inhibits more rational regulation." (pages 15 to 16; also note the conclusion to this part of his paper at pages 27 to 28).

2. Judge Breyer's paper illustrated the problem of the *vicious circle* from a memorable case he heard: US v

Ottawi & Goss (paper page 7): "spending \$9.3 million to protect non-existent dirt-eating children".

3. Judge Breyer concluded his paper by suggesting that the American predicament can provide "*lessons for European Risk Regulation*" (pages 28 to 37):-

"when designing regulatory institutions, one can more fruitfully consider principles such as subsidiarity, proportionality, consistency, and communication in the context of particular regulatory programs studied in depth, than in the abstract" (page 37).

(B) The relevance of these issues in assessing proposals for regulatory controls under EU/EEA legislation.

4. Europe, of course, faces risk regulation issues comparable to those faced in the US and other developed societies. The topics for session III of this year's Mentor Group accordingly build on Judge Breyer's paper and consider the issues he raised from various European perspectives. It is my intention here to support this proposal in the European context, to identify certain judicial precautions needed, to consider other restraints which apply and should be applied especially in considering freedom of speech in a commercial context.

5. As Director General Perissich's paper frankly acknowledges there is no reason to believe that individual European countries will fail to provide "striking examples of incoherence in the regulatory policy" of the kind graphically identified in the United States by Judge Breyer. Furthermore, Mr Perissich notes that one should not be surprised:-

"that the co-ordination, or management, deficit should be even more pronounced when moving to the Community level and one considers the extreme complexity and fragility of the political and institutional structure" (at page 106).

6. In their papers for this year's Mentor Group, both Judge Breyer and Mr Perissich discuss possible mechanisms for "attacking the vicious circle at its weakest point, the regulatory link, and to change the circle dynamics" (Judge Breyer at page 59). Judge Breyer suggests creating an "administrative group" with five features, including that of a *specified risk-related mission*. The mission would not be that of "total safety" or "zero risk" but that:-

"of building an improved, coherent risk regulation system, adaptable for use in several different risk-related programs; the mission of helping to create priorities within as well as among programs; and the mission of comparing programs to determine how better to allocate resources to reduce risks". (page 63)

Others features that Judge Breyer proposes a risk assessment administrative group should possess are "interagency jurisdiction", "political insulation", "prestige" and "authority". For his part, Director

General Perissich draws attention to the model of the Court of Auditors, which supervises the orthodoxy of the Community's financial management and asks the interesting question "whether an independent authority with appropriate powers should not have a supervisory role with regard to the drawing up of new regulatory instruments" (page 113).

7. Last year, Judge Breyer expressed the view that it is most fruitful to be specific and to look at a particular regulatory programme in depth. With this invitation in mind, I would like to consider a particular regulatory programme of professional interest to me. The issue is the regulation of tobacco advertising on which a proposal was made for an EC wide ban. This proposal was rejected, I gather, as lacking a proper legal base. With this in mind, it may not be inappropriate to use this dead proposal as an example for a case study. I propose that a fuller paper should be prepared for next year's session assessing the theoretical issues and possible risk assessment mechanisms against the specific issue of a tobacco advertising ban, on which there is a wealth of relevant experience from several jurisdictions. Let me now outline some of the key points as I see them.

(C) A case study in Risk Assessment, Approaches to
Regulatory Controls in the EU/EEA

(i) The experience of other jurisdictions

8. A number of developed countries provide experience against which risk assessment of the effects of a total ban on tobacco advertising can and should be made. In Norway, a ban has been in force since 1975, one has existed in Canada since 1989, bans have existed in a number of Australian States and one came into force, at Federal level, in mid-1993.

9. The data from these jurisdictions, particularly Norway, has been the subject of analysis and study. While itself supporting a ban, the 1992 UK Department of Health "Smee" Report examined the Norwegian experience and found that "advertising does not have a statistically significant effect in any form" on consumption and noted the absence of any causal relationship between consumption and advertising bans. The pro-ban conclusion of the Smee Report was subjected to careful criticism in a major study conducted by distinguished experts for the Canadian Niagara Institute. Their Report "Do Tobacco Advertising Bans Really Work?" concludes that the Smee Report's conclusion favouring a ban:-

"is both theoretically and empirically suspect in that it fails to meet the necessary tests for ethically credible public policy, namely it fails

first to ask the crucial question of whether its considered policy option is consistent with the core values that inform democratic society, something that should precede an examination of the alleged benefits of the policy and second it fails to advance compelling evidence that its option actually works". (page 102)

10. From Canada, the evidence in support of a tobacco advertising ban was extensively considered in the legal proceedings brought to challenge the 1988 Tobacco Products Control Act ("TPCA"). At first instance, Mr Justice Chabot heard the parties and evidence for over a year. In his 1991 judgment, the learned trial Judge found that:-

"The virtual totality of the scientific documents in the State's possession at the time the Act was passed do not demonstrate that a ban on advertising would affect consumption" (page 127 of the transcript).

Applying the Canadian Charter, the Judge concluded that the advertising ban was a "type of social engineering" that:-

"constitutes an extremely serious impairment of the principles inherent in a free and democratic society which is disproportionate to the objective of the TPCA" (page 138).

11. On appeal, the judgment of Chabot J. was reversed by a majority decision in the Court of Appeal (Rothman & LeBel JA's with Brossard JA dissenting). The different approaches amongst the Canadian Judges are particularly relevant to the risk regulation discussion. The majority of the Court of Appeal criticised the Trial judge for

considering the evidence "as if it were an ordinary civil trial" (page 33 of the transcript of LeBel JA):-

"[The trial Judge] analyzed the evidence and determined the issues essentially as if he were hearing an ordinary civil trial and not a constitutional challenge involving governmental choices. The [Attorney General] was not required in this case to prove, on the civil balance of probabilities, either that tobacco truly caused any particular illnesses or that the limitations imposed on tobacco advertising would in fact diminish consumption...what was necessary was to identify the existence of a reasonable basis for the governmental action and to determine whether that action involved the use of means which respect the minimal impairment test..."(pages 50-51).

12. LeBel JA did not place weight on the refusal by the Attorney General to disclose in Court another legislative option, developed by the civil service. In reaching the conclusion that the total advertising ban satisfied the "minimal impairment test" of the Charter, LeBel JA noted that:-

"...it is true that the evidence of certain experiments in countries where tobacco advertising was banned is not conclusive. There was no decline in tobacco consumption. At times, it has even increased.

Further, civil servants in the Federal Ministry of Health viewed the prohibition unfavourably and doubted its utility...No matter how important, this opinion remains an opinion. It indicates the existence of controversy with respect to the usefulness of a measure. It does not mean that a government is bound by the opinion of its civil servants. In the Canadian political system, ultimate responsibility for legislative choices belongs to those elected, to the Ministers and to the Parliaments. The disagreement of bureaucrats must not be a bar to adopting a given legislative orientation, provided that a rational basis for its adoption can be found.

On the whole, it seems to me that we are faced with a legislative measure the utility of which is certainly debatable. It represents a policy choice and involves an experiment the effects of which will only be known in the future." (pages 59-60)

13. Views may differ as to the proper role of courts and judges when reviewing policy decisions of governments but, by any standard, the approach of LeBel JA accorded the Canadian government wide discretion over risk assessment and the imposition of unproven regulatory constraints. [The case is now being appealed to the Canadian Supreme Court.]

14. Would the majority approach in the Canadian Court of Appeal be acceptable for courts in Europe or would the requirements of EU law call for a stricter approach, such as that taken by Chabot J and Brossard JA in the Canadian case? For reasons outlined below, my view is that stricter supervision is required. More fundamental in the light of the Canadian experience, however, since our discussion is one of policy, is the policy question what might be the proper regulatory restraints which might be developed in the EU (where the Commission has the exclusive power to propose legislation). Certainly, given the facts on the efficacy of an advertising ban accepted by all the judges, it does appear that the Canadian advertising ban provides a text book example of what Director General Perissich called "incoherence in regulatory policy" and what Judge Breyer has termed the

"vicious circle". It is an object lesson of what the EU/EEA should strive to avoid.

15. We might assume that the studied opinion of a risk assessment administrative group as proposed by Judge Breyer, with the authority and other qualities described, would generally be followed. Presumably, this group would be able to make the very type of assessment for the Commission, the absence of which was noted by the ECJ in the Angelopharm case¹.

16. If we assume that the institutional framework develops to include risk assessment authority and also assume that obtaining its reasoned opinion on proposed legislation would be mandatory, then two cases seem to arise for consideration:-

(i) What, if in the face of an opinion of the authority to the contrary, the Commission nevertheless proposed legislation (which was subsequently adopted) affecting the rights of citizens, including corporate citizens?

(ii) What if the reasoned opinion of the authority is insufficiently based on or is otherwise incompatible with a fair assessment of all the

¹ See footnote 3 to Director General Perissich's paper.

(including corporate citizens) that the Courts should have and recognise an inherent power in themselves to provide a forum for judicial review of the appropriateness of any administrative measure of any authority, including a risk assessment authority, and of any regulation or legislation which is insufficiently based, even if it meets other requirements of apparent proportionality.

(ii) The EU Proposal

18. The EU Council considered a proposal for a Directive which, if enacted, would have:

- (a) banned all forms of tobacco advertising in the Community, except that Member States may authorise advertising in tobacco sales outlets which is not visible from the exterior of the premises;
- (b) banned indirect advertising of tobacco, such as sports sponsorship;
- (c) banned the use of established trademarks or brand names for new tobacco products;
- (d) banned the free distribution of tobacco products; and
- (e) required Member States to provide means by which individuals or organisations can take legal action against tobacco advertising or complain to a monitoring body².

² Information on the proposal down-loaded from the DTI database Spearhead: COM(91) 111 (OJ C 167 of 27/6/1991) as amended by COM(92) 196 (OJ C 129 of 21/5/1992).

19. I do not propose to discuss this particular proposal, except to note that there are comprehensive regulations, different in different countries, governing the tobacco industry and its ability to advertise. At EU/EEA level, there is the threshold issue of how and where should risk assessment for regulatory proposals be conducted. Indeed is there not a question whether there should be the same risk assessment authority for both primary and subordinate regulation? Questions arise about the substantive justification for regulatory action and about whether action should be at national or European level. Institutionally the discussion of appropriate approach merges with that on subsidiarity, the role of the EU/EEA institutions and questions of legality, including legal base.

20. Addressing the ISBA Policy Conference in 1993, John Mogg, Deputy Director General for Internal Market with the EC Commission repeated President Jaques Delor's statement that subsidiarity "is simply a question of common sense". Mr Mogg went on to identify two principles to be applied when assessing the need for EU/EEA action:-

"Firstly necessity in the strict sense of the principle of subsidiarity. The need for a specific European (balancing) action impacting on the Commercial Communication sector can only be justified on the grounds that there is no existing or potential national measure that can or could address the relevant problem.

Secondly, when necessity has been demonstrated, - the principle of proportionality has to be ensured ie the least restrictive course of action is taken.

This includes considering the feasibility of mutual recognition of existing national measures. Where this does not suffice the resulting harmonisation measure must be tailored such that it is the least obtrusive to the operation of the relevant market" (page 9 of his paper).

In theory, the above principles sound fine. In practice, the reality is often different and betrays the same incoherences as have been identified in the United States. Director General Perissich has acknowledged that the management deficit is contributed to at the Community level by "the extreme complexity and fragility of the political and institutional structure" and that:-

"It is highly likely that it is above all because of this structure, with watertight compartments and parallel networks, that it is becoming very difficult for the European regulatory process to follow coherent criteria in defining the limits of its scope with respect to that of national legislation (the *subsidiarity* principle)" (page 105).

21. In the absence of a risk assessment authority which might assist in restraining or in influencing the direction being taken by improperly based regulation or legislation, what are the current restraints which apply at the EU level to ensure freedom of speech?

(iii) Freedom of Expression

22. Respect for fundamental rights as evidenced in particular by the European Convention on Human Rights ("ECHR") forms

an integral part of EU/EEA law³. Judge Mancini of the ECJ has spoken of how the ECJ fundamental rights "case law has progressed enormously" and that regulations that derogate from fundamental rights are, in his words, intimately "bound up with fundamental notions governing the relationship between States and their citizens"⁴.

23. Article 10(1) of the ECHR states:-

" Everyone has the right to freedom of expression. This right shall include freedom to hold opinions and to receive and impart information and ideas without interference by public authority and regardless of frontiers..."

24. Paragraph 2 of Article 10 recognises that limitations may be placed on these rights when "prescribed by law" and "necessary in a democratic society" for one of the legitimate purposes listed therein, which includes "the protection of health". The Court of Human Rights has frequently affirmed that under Article 10:-

"freedom of expression is.. applicable to "information" or "ideas" that offend, shock or disturb the State or any sector of the population. Such are the demands of that pluralism, tolerance and broadmindedness without which there is no "democratic society"" (paragraph 71 of the judgment in Open Door v Ireland 15 EHRR 244).

³ See, for example, Article F(2) of the Treaty, the ECJ case law recently summarised in Case C-260/89 ERT [1991] ECR I-2925 and see the article by Judge Mancini and David Keeling "From CILFIT to ERT".

⁴ Judge Macini and David Keeling: "From CILFIT to ERT: The Constitutional Challenge facing the European Court" (1991) 11 Yearbook of European law, page 1 at page 12.

25. The passage just quoted comes from the judgment in which the Court condemned the Irish ban on advertising and information about abortion services that were available lawfully in the UK but prohibited under the Irish Constitution. In condemning the ban on advertising and the provision of information, the Court said it "was struck" by "the sweeping nature" of the restriction (paragraph 74) which it found was "largely ineffective" (paragraph 76). The Open Door case itself concerned a restriction imposed to protect health, but which the Court held to be "overbroad and disproportionate" (paragraph 74).

26. Article 10 applies to commercial companies and information. In a recent case on commercial broadcasting, the Court said, in relation to Article 10(2), that:-

"The Contracting States enjoy a margin of appreciation in assessing the need for an interference, but this margin goes hand in hand with European supervision...In cases such as the present one, where there has been an interference with the exercise of the rights and freedoms guaranteed in Article 10(1), the supervision must be strict because of the importance - frequently stressed by the Court - of the rights in question. The necessity for any restriction must be convincingly demonstrated". (Informationsverein Lentia v Austria 17 EHRR 93, paragraph 35 of the judgment).

27. Accordingly, it can be seen that their necessity must be "convincingly demonstrated" for the restrictive measures in the proposed Directive to be found compatible with

respect for free speech and freedom of information under European law.

(iv) Other legal interests

28. The conclusion on freedom of information means that I can be brief on the restrictions on property rights, including the intellectual property rights in the use of trade marks, intra-brand competition and consumer choice that the proposals entail. Suffice it at this stage to state simply that each of these legal interests also provides reason why any proposal requires convincing justification not least through an adequate risk assessment process based on a objective basis of fact.

29. Let me just note, in passing, that recently the ECJ confirmed the importance of the Commission acting on a sufficiently rigorous basis of fact when adopting restrictions based on assessments of health risks. In Case C-212/91 Angelopharm [1994] ECR I-171, the Court held illegal a ban on cosmetic products for inadequacy of risk assessment by the Commission. Such prohibitions, the ECJ indicated, are to be:-

"founded on scientific and technical assessments which must themselves be based on the results of the latest international research and which are frequently complex. This is particularly the case where it is a question of assessing whether or not a substance is injurious to human health" (paragraph 31 of the ruling).

30. It is to be hoped and anticipated that the ECJ will be willing to exercise its review powers described above in assessing the proper basis of proposed regulations and legislation, whether or not a risk regulation authority is created.

(v) The legal base and its implications

31. As is well known, EU/EEA institutions must act within the limits of the powers given to them by the Treaties. The European Courts control the legality of the bases under which legislation is adopted. Consider, for example, the bases on which regulations are proposed that purportedly concern health (the sector on which Judge Breyer's paper focused).

32. Article 100a (internal market) was the legal base proposed for the tobacco advertising ban. This proposed legal base has been subjected to trenchant criticism from Professors Brunno Simma and Joseph Weiler, two well known and respected experts on European law. They put the matter as follows:-

"In our view the total ban exceeds the level of harmonization which is necessary to ensure a proper functioning of the internal market as an area without internal frontiers in which the free movement of goods persons services and capital is ensured in accordance with the provisions of the Treaty and thus is *ultra vires* and illegal. In the field of health, where the Community has no original jurisdiction and unlike the field of Environmental protection where it does, it can act to the extent and only to the extent that market

conditions so demand."(page 9 of their opinion dated October 1992).

33. Since Professors Simma and Weiler gave their opinion, the Treaty on European Union has come into force and the EU/EEA has acquired relevant limited jurisdiction over health and consumer protection. The terms of Articles 129 and 129a of the amended EC Treaty need to be mentioned; they point decisively against Article 100a being an acceptable legal base for what purports primarily to be a health protection proposal.

34. Underlying both provisions is the concept of EU/EEA action as supportive of but not replacing action and co-operation amongst Member States. Article 129(1) speaks of the Community:-

"contributing towards ensuring a high level of human health protection by encouraging co-operation between the Member States and, if necessary, lending support to their action."

Whilst Article 129a(1)(b) indicates that the Community shall contribute to the attainment of a high level of consumer protection through:-

"specific action which supports and supplements the policy pursued by the Member States to protect the health, safety and economic interests of consumers and to provide adequate information to consumers."

With the entry into force of the above provisions, there is a powerful case that the general base of Article 100a can no longer be used for predominantly health protection measures, quite apart from and in addition to, the

critique of using Article 100a made by Professors Simma and Weiler.

35. When Articles 129 and 129a are examined, however, it becomes clear that those provisions cannot be used to justify the draft Directive. The proposed measures stopping tobacco advertising patently go beyond encouraging co-operation or lending support (Article 129) or supporting and supplementing (Article 129a) the action or policies of Member States. Nor can the proposals be brought within the second sentence of Article 129(1) which authorises "Community action...directed towards the prevention of diseases, in particular the major health scourges, including drug dependency" since the provision specifies the forms of action that the EU/EEA is permitted to undertake as limited to:-

"promoting research into their causes and transmission, as well as health information and education".

36. If indeed the proposed restrictions on tobacco advertising can be lawfully justified under EU/EEA law, which is highly questionable (see above), the appropriate legal basis must be Article 235. Article 235 allows the Council acting unanimously on a Commission proposal and after consulting the Parliament to legislate when necessary to attain an objective of the Community and the Treaty has not provided the necessary powers.

37. It would distort the decision making scheme of the Treaty and the balance between the powers of national legislatures and EU institutions for such intrusive measures as those in the proposed Directive to be adopted by qualified majority (whether under Article 129 or 129a(1)(b) or 100a), instead of requiring unanimity under Article 235 thus giving each Member State a veto over adoption of measures.

(vi) Relevance of Subsidiarity

38. Reference has already been made to the principle of subsidiarity above so I can be brief here. It is worth, however, noting that the proposed Directive is one that falls squarely under Article 3b of the Treaty (as amended):-

"The Community shall act within the limits of the powers conferred upon it by this Treaty and of the objectives assigned to it therein. In areas which do not fall within its exclusive competence, the Community shall take action in accordance with the principle of subsidiarity, only if and in so far as the objectives of the proposed measure cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale or effects of the proposed action, be better achieved by the Community.

Any action by the Community shall not go beyond what is necessary to achieve the objectives of this Treaty".

39. For reasons already outlined, the health and consumer protection powers conferred by the Treaty do not cover the proposed Directive. Treaty Articles 129 and 129a

explicitly indicates that "health" and "consumer protection" are not "areas of exclusive Community competence" to use the language of Article 3b. Accordingly, to comply with Article 3b, the measures in the proposed Directive should be adopted:-

"only if and in so far as [the measure] cannot be sufficiently achieved by the Member States and can therefore, by reason of scale or effects of the proposed action, be better achieved by the Community".

40. For reasons already given, it is difficult to see how any of the measures in the proposed Directive can be thought to satisfy the above requirement.
41. Can it sensibly be contended that an EU/EEA wide ban on sports sponsorship satisfies the "better achieved by the Community" than the national or regional authority standard? The simple answer is that it cannot. Consideration of subsidiarity re-enforces the case against such over-broad measures being adopted by majority voting.
42. It has yet to be settled whether Article 3b can have direct effect and be relied upon in a challenge to the legality of EU/EEA acts. Views differ on this matter, although some weight should surely be placed on the provision being put in that part of the Treaty of Union which is subject to the jurisdiction of the European Court of Justice particularly when so much of the

Maastricht provisions were explicitly excluded from the Court's jurisdiction by virtue of Article L.

43. However this may be, Article 3b and the principle of subsidiarity are of significance to the EU Council when considering whether proposed legislation is appropriate. Guidelines were adopted at the Edinburgh Summit of December 1992, including:-

"The Community should only take action involving harmonisation of national legislation, norms or standards, where this is necessary to achieve the objectives of the Treaty. (Guideline II(iii))

The reasons for concluding that a Community objective cannot be sufficiently achieved by the Member States but can be better achieved by the Community must be substantiated by qualitative or, wherever possible, quantitative indicators. (Guideline II(v))."

Again it is perplexing how either of these tests could reasonably be considered fulfilled by the proposed measures before the EU Council. It is not surprising that the measures have proved controversial and not so far been approved.

(vii) Proportionality & Conclusions

44. Some references to this principle have already been made. Article 3b of the Treaty requires proportionality to be respected as do the Guidelines of the EU Council just quoted. Last year, Judge Breyer said that proportionality "seems to be a polite way of describing the need to avoid "overkill" (page 34 of his paper). As his paper also pointed out there is the institutional issue of which body should control "overkill" or "proportionality" to use the more correct European vocabulary.
45. When, as with the proposed measures under discussion, we are considering proposals pending before the Council, Judge Breyer's questions on the appropriate role of the Courts can be side-stepped or at least postponed. It is clear that the bodies first called on to respect proportionality are the Community Institutions, which participate in legislation.
46. One of the concrete focuses for next year's fuller paper for the Mentor group could be to study concretely how far the elaboration of the measures in the proposed Directive on tobacco advertising has avoided or alternatively fallen into the problems of *tunnel vision*, *random agenda selection* and *inconsistency* which Judge Breyer described as the *vicious circle* in his paper. If such problems have arisen, a fuller paper may help inform our continuing

Mentor Group discussions on how to produce "optimizing" of the policy objectives of risk assessment and regulatory action. This includes consideration of the proposals for introducing changes in the risk assessment machinery of the types raised in this year's papers by Judge Breyer and Director General Perissich.

relevant facts but is nevertheless adopted as legislation affecting the rights of citizens including corporate citizens?

It should also be noted that these two possibilities , far from being theoretical or contrived, are based in experience:-

(a) In Australia, the Federal Government's regulation watchdog, the Office of Regulation Review, wrote to the Department of Health informing the Department that certain proposed regulations should be reviewed as a need for the new regulations had not been demonstrated adequately nor had the benefits, drawbacks and costs of the regulations been identified (as required). Despite this opinion, the Department is pressing on with its initial proposals without further review.

(b) In the USA, the administrative agencies (including the FDA) have faced successful challenges in Court to the scientific basis of proposed rule making.

17. Quite apart from any other legal or conventional restraint on regulation, in my opinion, it is indispensable to the protection of the rights of citizens