The difficulties of Regulating Markets and Risks in Europe through Notified Bodies

*Jean-Pierre Galland**

Although scholars have described and commented on the European New Approach to standardisation principles, they have paid much less attention to the ways in which this innovative process and its follow-on, i.e. the Global Approach, have been implemented. In many cases, this comes through the day-to-day activity of a very specific population of European experts, the notified bodies. Notified bodies, whose role it is to certify that products, for a given sector, comply with the essential safety requirements set out in the corresponding directive, originate from the Member States, but also compete against each other within a European certification market. This article examines the technical and political difficulties encountered by the Commission and the Member States in ensuring both the independence and the competences of these certifiers. It describes and questions the organisational architecture devised in response to these problems.

I. Introduction

At the official creation of the European Economic Community, by the Treaty of Rome in 1957, it was quite clear that sovereign concerns about safety, along with other "sensitive" questions, could only remain the exclusive prerogative of each of the Member States. Given the different parties' reservations with regard to anything that might undermine the traditional entitlements of each of the nations concerned, the promoters of Europe were content to assign a single goal to their project, the liberalisation of trade relations between Member States leading to the creation of a Common Market, although some saw this objective as a means to achieve wider political ambitions[1]. Curiously, however, it was precisely when the liberalisation of trade in each domain between the first Member States became a concrete reality that the awareness of "small differences" in the respective ways in which each State had previously maintained the safety of its own nationals with regard to various risks, began to cause a problem. The goal of liberalising trade within an emerging Europe revealed that the safety of products circulating on the markets of each Member State had previously depended, country by country, on national normative systems, which were themselves built on a country by country basis. Consequently, these normative systems were sufficiently disparate for the emergence of differences, and often conflicts, between Member States, as to the best way to ensure the safety of their respective nationals.

It is on the basis of this paradox – that, politically, safety issues can only fall within the competence of the Member States, but that maintenance of the status quo automatically prevents the actual realisation of the Common, Single or Internal Market – that the promoters of Europe gradually sought to harmonise the practices of the different members, in particular with regard to technical standards. To achieve this, the Commission, stepping outside its initially restricted framework of responsibility[2], and following a long and arduous process, finally succeeded in persuading the Council to accept an entirely new method of technical harmonisation and standardisation, the New Approach[3]. The successive methods employed by the Commission, which finally led to the adoption of the New Approach, whether the initial plan for a total harmonisation of standards between Member

* Senior Lecturer, Ecole des Ponts ParisTech, Marne la Vallée. This article is a shorter and English version of my article "La difficile construction d'une expertise européenne indépendante. Le cas des organismes notifiés", 7, 1, *Revue d'Anthropologie des Connaissances* (2013), pp 223–246.

1 Nicolas Jabko, *L'Europe par le marché.Histoire d'une stratégie improbable*, (Paris: Presses de Science Po, 2009).

2 Mark A. Pollack, "Creeping competence : the expanding agenda of the European Community", 14, 2, *JEPP* (1994) pp 95–145.

3 Council Resolution 85/C 136/01 of May 7, 1985 on a new approach to technical harmonisation and standardisation.

States, then the "invention" of the principle of mutual recognition, following the judgement in the *Cassis de Dijon* case, has been extensively covered in the international literature[4]. And the new forms of standardisation in Europe, with the distinction between "essential safety requirements" formulated in directives – now mandatory for the distribution of products at European level – and the non-compulsory application of so-called "harmonised standards", have also been widely investigated by scholars.[5] By contrast, some of the further developments of the New Approach, in particular relating to problems encountered by the Commission on the evaluation of compliance with the essential requirements stipulated in the directives, have received much less attention from the academic community.

The intention of the New Approach was that, for the large majority of products intended for sale on the European market, evaluation of compliance with the essential requirements laid down in the different directives should be the sole prerogative of the producers themselves. However, with regard to certain products or risks covered by some directives, in particular when compliance with a given essential safety requirement required testing or trials, it demanded that a certificate of compliance with those essential requirements should be issued by a third party possessing technical competences in the domain.

Yet this is the issue that would now generate tensions between the Member States: in practice, and following the implementation of the first New Approach directives, a particular Member State would require a particular manufacturer, which had conducted tests and trials on a product in its country of origin, to repeat those tests, using the Member State's own national assessment bodies, when the said product was sold within its borders. In a way, the initial debate on the reciprocal nonrecognition of each of the Member States' national systems of standards had merely been displaced: the Member States now had only limited confidence in the competence of the other Member States' testing laboratories and refused to open up their own markets to products whose compliance with essential safety requirements had been certified by foreign laboratories or institutions.[6] Of course, the founding text of the New Approach had introduced the principle of information sharing with regard to these bodies. This text stipulates that each Member State should draw up a list, for each directive, of the institutions present in its territory that it considers competent to certify that products comply with the essential requirements stipulated in the corresponding directive, and adds that "The national bodies authorised to issue marks or certificates of conformity are notified by the Member State to the Commission and to the other Member States" [7]; hence the expression "notified body", which would soon take on a life of its own. In 1985, however, no stable framework had yet been established for how these bodies should carry out the tasks assigned to them.

This article, mainly based on a review of European official documents, will begin (Part 1) by summarising how the category of notified bodies was constructed, from its start in the New Approach to European standardisation, which incorporates the so-called Global Approach, which specifies the scope and context of acts of assessment expected of the said bodies. Then, we will give (Part 2) a few remarks and reflections on the somewhat discrete nature of the appraisals conducted by notified bodies, compared with other rather more visible forms of assessment, provided for example within the European agencies responsible for evaluating risks in certain particular sectors. At last we will consider (Part 3) the recurrent questions of both the independence and the competences of the notified bodies by showing to what extent these questions depend on the very mode of construction of this particular category of technical experts. In this third part, we will draw more on European *soft law* documents, such as certain guides to good practices, and on a short number of interviews.[8]

4 Christian Joerges, Josef Falke, Hans-W Micklitz, Gert Brüggemeier, *European Product Safety Internal Market Policy and the New Approach to Technical harmonisation and Standards*, (European University Institute Working Papers Law, 1991); Christian Joerges, Karl H. Ladeur, Elen Vos (eds.), *Integrating Scientific Expertise into Regulatory Decision Making, National Traditions and European Innovations* (Nomos Verlagsgesellschaft, 1997); Torben Bundgaard-Pedersen, "States and EU technical standardization:Denmark, the Netherlands and Norway managing polycentric policy-making 1985-95", 4, 2 *JEPP,* (1997), pp 206–224; Kalypso Nicolaïdis, Michelle Egan, « Transnational market governance and regional policy externality:why recognize foreign standards?", 8, 3 *JEPP* (2001), pp 454–473.

5 Michelle Egan, "Regulation strategies, delegation and European market integration", 5 *JEPP* (1998), pp 485–506; Harm Schepel, *The Constitution of Private Governance; Product Standards in the regulation of Integrating Markets*.(Oxford and Portland:Hart Publishing, 2005).

6 Michelle Egan, *Constructing a European Market; Standards, Regulation, and Governance* (Oxford University Press, 2001).

7 Council Resolution 85/C 136/01, Annex 2.B.VIII, §3.

8 The author conducted a series of interviews (6) in June 2012 with notified bodies and other actors of European standardisation.

II. Notified bodies: Building a new category

1. The global approach

Although it soon came to be perceived as the appropriate solution to the difficulties of harmonising the different normative standards of Member State, the New Approach came up against a new problem. In many sectors, the New Approach directives required independent or third-party certifiers to approve products intended for distribution on the European market as compliant with certain safety requirements laid down in the directives[9]; and one Member State or another balked at allowing into its territory products whose conformity with the essential requirements had been certified by expert bodies other than its own. In order to tackle this new obstacle to the genuine opening up of the European market, and to attempt to increase trust between Member States regarding their structures for assessing conformity with the safety requirements, the Commission went on to devise a series of additional solutions, this time expressed in the "Global Approach" [10]. This approach began by dividing the question of assessing the compliance of products with essential safety requirements into sub-questions which, in the vocabulary devised for the purpose, would give rise to corresponding "modules": a distinction was thus made between a module dedicated to the assessment of the "type" product, and another module dedicated to the assessment of mass produced products, and of any divergences in these from the "type" product. Other basic modules were also introduced, relating to the quality of production or of products. On the one hand, therefore, assessing product conformity with safety requirements now required several sequences and entailed a product by product examination of different modules, whose precise content could vary slightly from one Directive to another. On the other hand, the Global Approach above all constituted an innovation in one specific respect, relating this time to the integration of the "notified bodies" into the new standards landscape. On this issue, the Commission had a twofold objective: its aim, on the one hand, was to minimise the costs and procedures imposed on industries before their products could be traded on the European market, and therefore to ensure that they were not required to carry out the same tests several times; on the other hand, if a single series of trials and tests was to be sufficient, they had to restore the mutual confidence of Member States in each other's appraisal capacity. With regard to these two objectives, the Commission's response was to impose – this time for the notified bodies themselves – the simple principle of mutual recognition, but in return to establish the strongest possible framework for the methods of approving and monitoring the notified bodies, first by standards designed to assess their own competences[11], and to suggest a certain number of methods of coordination, which we will consider later.

We should add that "CE" marking was devised within the context of the Global Approach. Any product that complied with the essential requirements laid down in the directive relevant to it could now be marked "CE" by its producer. In the simplest cases, and for products presenting no apparent dangers, CE marking would rely on self-declaration by the manufacturer. However, for products requiring tests or trials, a producer could only apply CE marking to a product following certification issued by one (or more) notified body or bodies that the said product was in conformity with the relevant essential requirements. In other words, a product with CE marking is deemed to be compliant with the essential safety requirements relevant to it; it can then be allowed onto the internal market and, in principle, no Member State can oppose its distribution.

2. The Notified Bodies markets

The general architecture of European standards has scarcely changed in the last twenty years or so: with each new directive that requires it, each Member State draws up a list of bodies within its territory competent to carry out the checks required to verify the conformity of products to the essential requirements laid down in the relevant directive. The Commission collects the lists drawn up by each Member State for each directive, and compiles them to produce the global European lists, on the basis of mutu-

9 This was the case from the first New Approach Directives ("Toys", 1988; "Pressure equipments", 1987; "Construction products", 1989)

10 Council resolution of May 28, 1989 on a global approach to assessing conformity, OJ 1990, 010, pp 0001-0002.

11 It is thus desired that notified bodies should themselves be accredited under international standard ISO 45000, which assesses the quality of inspection bodies.

al recognition, of "notified bodies" applicable to each directive. However, the consequence of this process was to establish one (or more) market(s), this time amongst the notified bodies themselves.

Indeed, under the Global Approach, a company that wanted to put a new product on the market could now approach any European notified body to assess and certify its product's conformity with the essential safety requirements stipulated in the corresponding directive. Of course, "a German certifier who wants to offer services to French companies must be notified under German legal criteria. However, this does not prevent French manufacturers from using it if it is cheaper"[12]. From the Commission's perspective, this arrangement had several advantages. The emergence of competition on this new market in certification of conformity to the essential requirements would promote a reduction in business costs and, subject to monitoring, an improvement in the services provided by these bodies through a pooling of "best practices". In parallel, the result of mutual recognition between inspection bodies was to break the possible links between Member States and the notified bodies based within their borders, and thus to prevent a long history of protectionism based on standards being replaced by protectionism through laboratories that traditionally represent the interests of the Member States. It also meant, however, that the notified bodies appeared both as protectors of the safety of a certain number of products circulating on the European market and as actors in a very specific new market (or rather a series of markets) [13], in the certification of conformity to the essential safety requirements laid down in the "New Approach" directives[14].

In this way, following long years of fruitless attempts, the promoters of Europe, and in particular the Commission, succeeded in persuading the Member States to adopt an entirely new way of ensuring the safety of citizens and consumers, within the framework and from the perspective of the opening up of the "internal market". The "political" expression of safety requirements, expressed for each major domain and each directive, was reflected in the creation of a market of technical experts responsible in certain cases for assessing and certifying that products were compliant with the stated requirements. The New Approach and its outcomes were greeted as a success, and have led to numerous directives in the last 25 years. It would seem, however, both generally and with particular pertinence in certain domains ([15]), that the implementation of these directives by the notified bodies has raised, and continues to raise, a certain number of problems.

III. A fragmented and disconnected European certification regime

1. Who are the notified bodies?

In 2010, some 1800 notified bodies were active in Europe. The information available about them is both copious and sparse. On the one hand, the lists of notified bodies are published in the Official Journal of the European Communities and now feature, for each directive and each Member State, on the Commission website[16], which means that the population of active notified bodies is in a sense an entirely known quantity; on the other hand, there is very little general, crosscutting work of analysis of these bodies in terms of their respective legal structures, their public or private status, or indeed their revenues or the number of people they employ. We will therefore confine ourselves, on the basis of the only scientific publication to our knowledge devoted to these issues[17], to stating that notified bodies may be private, public, or mixed bodies. Based on research on the main 4 "providers" of notified bodies in Europe (the UK, Germany, France and the Netherlands), the author of the cited article estimates that around 33% of notified bodies are public entities linked with their respective home Member States, that conversely 27%

12 Fabienne Péraldi-Leneuf, "Le cadre juridique de la notification des organismes habilités", *Réalités industrielles* (november, 2002), pp 63–68.

13 Competition at the level of the services provided by the notified bodies applies to each sector and each directive. The result is the emergence of a market based on the directive(s) governing a sector.

14 Emmanuel Kessous, "L'objectivation des qualités industrielles en discussion.Les acteurs du marché européen confrontés à l'élaboration de normes communes", 102 *Réseaux* (2000), pp 93–117.

15 For a focus on the case of the medical devices sector, see my article (supra, note 1) and Bernhard Lobmayr, "An Assessment of the EU Approach to Medical Device Regulation against the Backdrop of the US System", 2(1) *EJRR* (2010), pp 137–149.

16 The European Commission's NANDO (New Approach Notified and Designated Organisations) website, <http://ec.europa.eu/enterprise/newapproach/nando> (last accessed on 5 August 2013).

17 Mehmet Cetik, "The Business Forms and Controlling Sharehoders of 'Notified Bodies' under the New Approach Regulations:A Preliminary Assessment to Implement the Statute of "European Company", Tilburg University, the Netherlands, Spring 2010, available on internet at <http://ssrn.com/abstract=1674209> (last accessed on 5 August 2013)

of them are entirely private bodies, in the sense that they originate with producer groups in the sectors concerned, whereas the remaining 40% are private and family enterprises or associations[18]. However, it is in fact extremely difficult to classify all notified bodies on the basis of a simple distinction between private and public, for example, because these bodies arise from very disparate legal traditions in different Member States, and certain national characteristics in fact give rise to all sorts of configurations in this respect[19]. Moreover, despite the organisational standards imposed on them, it would seem that there is little information on their actual working procedures (e.g. the frequent recourse to outsourcing). Notified bodies thus present the oddity of being both perfectly identified (the Commission allocates a number to each one) and little known in both their diversity and their day-to-day activities.

2. Discreet evaluation procedures

The function of notified bodies is to certify that products comply with certain essential safety requirements. This function, which requires testing, inspection or trials, is carried out on behalf of and in a two-way relationship with the producer. This means that the activities by which notified bodies carry out their evaluation are discreet, because at this stage in the implementation of the New Approach, the notified body only deals directly with the producer that had called for its services. Obviously, the users or consumers of the products in question are not present for these technical verification procedures. The inclusion of a minimum degree of "technical democracy" in the processes of certifying compliance with essential safety requirements can only, if ever, be assessed at meetings of the sectorial Groups of Notified Bodies[20], or in occasional consultations with the "parties concerned" to assess the quality of implementation of a given New Approach directive. Under these circumstances, it is true that, in addition to the producers and notified bodies themselves, consumer associations and practitioners interested in the use of the products in question (e.g. doctors for medical devices) are invited to put across their views, but there is nothing mandatory about this and it may vary from one sectorial Group to another. On the other hand, we might expect greater "public" involvement in the debates on the drafting of the essential requirements themselves, for each directive, which was in fact the wish of the Commission. However, it was not supported on this issue by the Council and the Parliament[21]. As regards the development and implementation of the New Approach directive, there is decidedly little room for the non governmental parties which could be interested. On the one hand, the upstream phase of the development and drafting of the essential safety requirements is perceived as "political" and moreover restricted to national representatives of the Council and the Parliament, possibly assisted by their respective standardisation bodies. On the other hand, the downstream phase of certification of product conformity, on a case-by-case basis, by notified bodies, is considered as purely technical and a matter of a simple series of face-to-face meetings between producers and experts.

III. Independence and competences of notified bodies

1. Two contradictory demands?

The rules leading to the attribution of "CE" conformity marking on a product require the production process for the said product to be broken down into modules (generally eight), notably comprising internal production control, a "type" examination, tests on the conformity of mass production with the "type", and various examinations of production quality. Depending on the directive governing the product in question, and depending on the degree of danger it potentially poses to consumers, the producer will or will not need to call on a certain number of notified bodies to certify, module by module, that the said product is in conformity with the essential safety requirements stipulated in the directive [22].

Under this procedure, therefore, the notified bodies, at least with respect to certain directives, play a

18 *Ibid*. (appendix)
19 Thus in France, many notified bodies have "association 1901" (non-profit) status, which says nothing about the nature of the associates.
20 *Infra*, part 3.
21 Olivier Borraz, "Governing standards: the rise of standardization processes in France and in the EU", 20(1), *Governance* (2007), pp 57–84.
22 Council decision regarding the modules relating to the different phases of the procedures for evaluating conformity and the rules for placing and using "CE" conformity marking, intended for use in technical harmonisation directives, 93/465/CEE.

determining role in the different stages of examination and testing that lead to the application of "CE" marking by the producer. In these circumstances, those responsible for the Global Approach at European level, are concerned not just with the independence of the notified bodies, both from producers and Member States, but also with their competence.

With regard to the first concern – that the notified body should be independent of producers in the sector where they operate – the European authorities will never go further than to stress certain minimum principles, in which a certain awareness based on experience is nevertheless implicit. "A conformity assessment body shall be a third-party body independent of the organisation or product it assesses".[23] But "a body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of products which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body".[24] The restrictions are that "a conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing installation, use or maintenance of those products, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services" [25].

However that may be, in the last twenty years or so, the main focus of the Commission's work has been much more to tackle the two other concerns, i.e. the independence of notified bodies from their home Member States, and a general improvement in the competences of these bodies.

Yet these two concerns are both linked and in tension, because of the reasons behind and the manner in which the entire edifice has been built. From the numerous texts, normative or otherwise, emanating mainly from the Commission since the 1990s, on the general manner in which the notified bodies operate, it would seem that many tensions arising from this particular method of constructing an independent European system of appraisal have not yet been resolved.

These tensions between the parties involved in the procedure can be broadly outlined as follows. It is to the advantage of producers to go through the cheapest or fastest notified bodies in Europe in order to obtain the certificate of conformity they need and to be able to place CE marking on their products; the notified bodies have every reason to lower their prices, to impose their own methods of evaluating products and their risks, and thereby to extend their share in the market for certifying conformity; Member States are officially permanently responsible for the competence of the bodies that they have personally notified, but continue to focus rather on the quality of notified bodies based in other Member States, and on the level of safety of certain products with CE marking that enter their own borders. The Commission, for its part, continually sought to reduce these contradictions, despite its limited scope, by trying to work more through persuasion than through coercive methods that it is structurally and politically incapable of imposing.

Broadly speaking, with the aim of reducing disparities between notified bodies in terms both of competence and differences in the methods used by the different entities, the Commission long argued in favour of a "framework for coordination and cooperation between notified bodies, Member States and the European Commission under the community harmonisation directives based on the New Approach and the Global Approach"[26]. The approach at this stage was essentially to organise the operation of (sectoral) Groups of Notified Bodies into forums, whose main tasks relate to information sharing and "to share experience and exchange views on application of the conformity assessment procedures with the aim of contributing to a better understanding and consistent application of requirements and procedures"[27].The aim was also to "pinpoint difficulties, propose possible solutions and agree a common solution or several equivalent solutions"[28], and perhaps

23 Decision of the European Parliament and Council on a common framework for the sale of products, replacing Council decision 93/465, Annex 1, Article R17, Requirements applicable to notified bodies, 768/2008/CE.
24 *Ibid*.
25 *Ibid*.
26 EC, Framework for coordination and cooperation between notified bodies, Member States and the European Commission under the community harmonisation Directives based on the New Approach and the Global Approach, CERTIF 94/6 Rev.6, February 20, 1998.
27 *Ibid*.
28 *Ibid*.

thereby to contribute to the work of the European standardisation bodies and the Commission itself in monitoring the actual implementation of directives. To this end, the Commission sought to persuade Member States to encourage "their" respective notified bodies to take part in the work of these sectoral groups. In the same spirit, in the late 1990s the Commission proposed both to the "Notifying Authorities" (simply put, the Member States) and to the notified bodies, that they should agree to a code of ethics that would establish the latter's rights and obligations[29]. With regard in particular to the ability of the notified bodies "to intervene on behalf of the public authorities", they were asked under this Code to submit regular activity reports both to their Notifying Authority and to the Commission, to inform producers of the existence of recommendations that arise from the coordination efforts of the notified bodies themselves, and to implement these recommendations in practice; to set out their terms of service precisely, by detailing the services associated with them, so that producers could make competitive assessments on a like-for-like basis; and finally (emphasised in the Commission's text) to "take part, directly or be represented, in the tasks of European standards bodies and in those of the relevant group of notified bodies coordination in charge of the drawing up of recommendations, in order to ensure a coherent implementation of these provisions ".

Despite these recommendations put forward in the 1990s, the same concerns are present in a new Commission text issued a few years later.[30] Beginning with a reminder of the general background, the Commission notes and regrets that "since the inception of New Approach directives, there has been no systematic exchange of information between Member States concerning the criteria and procedures applied at national level for the assessment and surveillance of notified bodies". At a time when the total number of notified bodies had reached around a thousand (end 2002), "this lack of transparency has encouraged suspicions about uneven levels of implementation which, in turn, undermine the confidence that is essential if the mutual recognition and acceptance of certificates issued by notified bodies is to function smoothly". Under these circumstances, the text continues, both "to ensure the safety of products and to avoid restrictions on the free movement of goods that could arise due to shortcomings in relation to the competence, impartiality, etc. of notified bodies" and "to allow notified bodies to compete on a level playing field, while ensuring that competition does not lead to a reduction in the quality of the service they offer",then comes again that "efforts of Member States and the Commission towards reaching a homogeneous designation system must be intensified".[31]

2. The accreditation solution

This communication by the Commission to the Council and the Parliament, the outcome notably of an e-mail survey of the interested parties (2001), and in particular of companies, began to steer the debate towards a new solution: if the Member States were not capable of exchanging and harmonising the procedures whereby they appointed and monitored the activities of their respective notified bodies, it would be desirable to create an additional level that would take more interest in these exchanges. A certain number of States had already commissioned independent accreditation bodies to verify the competence of their notified bodies, at the time of their approval and subsequently. The idea of this practice being more or less imposed by the Commission on the Member States would take a few years.

Following a Commission proposal[32], it would be a regulation introduced by the Parliament and the Council [33] that would (temporarily) bring the final touch to the edifice. The wish of the European authorities was that, in each individual State, the procedures for approving bodies for assessing the conformity of products with essential safety requirements, should require the said bodies, again in each individual Member State, to be approved by a national accreditation body independent of the State. Since these accreditation bodies would, both as entities and in their activities, be subject to standards (ISO/CEI 17000), this should contribute to harmonising the

29 EC, Code of Conduct for the functioning of the system of notified bodies, CERTIF 97/1 Rev. 3, July 17, 1998.
30 Communication from the Commission to the Council and European Parliament. Enhancing the Implementation of New Approach Directives, 7/05/2003, COM (2003) 240 final
31 *Ibid*.
32 Draft regulation by the Parliament and Council, 14/02/2007, COM (2007) 37 final.
33 Regulation (EC) of the European Parliament and Council setting out the requirements for the accreditation and market surveillance relating to the marketing of products and repealing Council regulation (CE) No. 339/93, July 9, 2008, 765/2008.

practices of the notified bodies accredited by them. In a word "a system of accreditation which functions by reference to binding rules helps to strengthen mutual confidence between Member States as regards the competence of conformity assessment bodies and consequently the certificates and test reports issued by them". Finally, it would be decided that "each Member State shall appoint a single national accreditation body" [34], which would be responsible both for approving and monitoring "its" notified bodies and for discussing these issues with its alter-egos [35]. It remains to be seen whether the introduction of this additional and, it would seem in the eyes of the promoters of the Global approach, ultimate layer, would really be capable of significantly reducing the difficulties so far encountered.

IV. Conclusion

With the New Approach and its subsequent phases, the European Commission devised a means of regulating the European market which ultimately consists in examining "risks more than products"[36], or in any case in making the free circulation of goods subject to compliance with the essential safety requirements set out in the directives. True, the fields covered by the "New Approach" directives relate to products or services that are in principle less dangerous to the health or safety of European citizens than those in more sensitive domains, which are covered by another method of market and risk regulation, through networks of public agencies, a model that applies particularly to pharmaceutical products[37] or food products[38]. That being said, amongst the New Approach directives, the regulations call for the use of third-party assessment and hence notified bodies in the case of products or domains sufficiently dangerous for the authorities not to be content to base the procedure for certification of conformity with essential safety requirements on a simple self-declaration by the producers.

With regard to these "medium sensitivity" sectors, either because of its own lack of resources[39] or political constraints, the Commission therefore devised an original method of extracting the accumulated expertise of its Member States' different national laboratories and qualified bodies to give rise to a European assessment system designed to give equal treatment to producers in the certification of their products as compliant with the essential safety requirements stipulated in the directives. However, the process that leads to this particular form of transnational governance [40], which seeks to separate notified bodies from the influence not only of producers but also of their respective home States, in other words to make them independent in the European sense of the term [41], is packed with multiple procedures and incentives, which do not automatically seem to guarantee a corresponding competence in the bodies in question, or at least the overall effectiveness of the system in meeting its multiple objectives.

Finally, the method of regulating markets and risks described in this article, which concerns a section of the products on sale within Europe, suffers from a dual deficit in comparison with the European governance of certain other products conducted by networks of public agencies. First, a democratic deficit, in the sense that the multiple procedures that punctuate the implementation of the New Approach and its outcomes are practically never opened up to the scrutiny of non governmental associations : from the upstream "political" phase of drafting essential safety requirements appropriate to a particular directive, through to the downstream "technical" phase, in which the notified bodies certify the conformity of a given product to the said requirements on a case-by-case basis, the public is at best consulted only during surveys conducted by informal groupings incorporating some of the notified bodies.

Second, a deficit of attention from the social science community: whereas the construction and op-

34 Article 4. In France for example, COFRAC, the French Accreditation Committee, had been set up in 1994, and similar committees or bodies had also been set up in other Member States in the 1990s and 2000s. On this question, it would seem that the European contribution was essentially to extend this innovation to all the Member States.

35 For this purpose, moreover, a European cooperation for Accreditation (EA) was set up.

36 Jacques McMillan, "La 'certification', la reconnaissance mutuelle et le marché unique", *Revue du Marché Européen* (1991), pp. 181–211.

37 Boris Hauray, *L'Europe du médicament*, (Paris: Presses de Science Po, 2006)

38 Elen Vos, Frank Wendler (eds.), *Food Safety in Europe.A Comparative Institutional Analysis*. (Antwerpen-Oxford: Intersentia, 2006).

39 Giandomenico Majone, *La Communauté Européenne:un Etat régulateur* (Paris: Montchrestien, 1996).

40 Christian Joerges, Free trade with hazardous products?The Emergence of Transnational Governance with Eroding State Government, (EUI Working Papers Law 05/2006).

41 Martin Shapiro, "The problems of independant agencies in the United States and in the European Union", 4 *JEPP* (1997), pp 276–291.

eration of the European agencies has long attracted relatively significant levels of interest, both from both European and North American researchers [42], the implementation of the Global Approach by the notified bodies has so far received little academic attention. It is true that a certain number of studies focus on the recent development of national standardisation bodies[43] or more generally on the growing role of standards in market regulation [44], but within these general trends, there is little research specifically exploring the category of notified bodies and the way in which these bodies perform the functions assigned to them.

Yet these discreet and diffuse procedures constitute a threefold challenge: a public health and safety challenge arising first of all from the fact that, despite a wide variety of precautions and recommendations, it would seem that there are still deficiencies in the way in which the safety of certain products sold on the European market is ensured; then a scientific challenge in the sense that the case of the notified bodies constitutes a particularly symptomatic example of the difficulty of building a European certification system; and finally, a democratic challenge in the sense that a deeper awareness of the actual implementation of the New Approach and its outcomes would perhaps contribute to the establishment of formal consultation processes for the consumers' and practitioners' concerned associations.

42 Renaud Dehousse,"Regulation by networks in the European Community:the role of European agencies", 4, *JEPP* (1997), 246–261; Shapiro, *ibid*.

43 Egan M., *supra* note 5; Christian Frankel, Eric Hojbjerg, "The Constitution of a Transnational Policy Field:Negociating the EU Internal Markets for Products", 14 *JEPP* (2007), pp 96–114.

44 Harm Schepel, *supra* note 5.