A Brief Comment on Science-based Risk Regulation Within the European Union

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Nowadays as political decision making involves such a huge range of complex matters, scientific experts have become more and more involved in European risk regulation. The support by so-called independent experts may, on the one hand, be seen as a guarantee of rational decision making, increasing the quality of decisions as well as the general acceptance of all people affected. On the other hand, the number of expert groups, scientific committees and agencies helping the Commission in fulfilling its duties is vast and confusing.

In addition, scientific advisory bodies often face the burden of unrealizable independence, as well as a lack of transparency and democratic control. This article sums up the central position of science-based risk regulation within the European Union (EU), referring to the necessity for expert opinion as well as to consequent problems concerning the involvement of these experts in risk regulatory actions.

I. Introduction

Currently the EU controls many political decision making processes. Whether this control is seen to be positive or negative, there is of course a need to regulate certain matters.

The EU not only has to be capable of taking action to regulate and correct the single market so that it is a fair and sustainable economy, but it also has to fulfil an important role as a global player, exercising responsibility for security matters in Europe. As a multinational actor it tries to fight not only against the financial crisis and diseases spreading throughout the world, but also against the distribution of counterfeit drugs through the Internet or unsafe ingredients contaminating products like food or animal feed.

In terms of European regulation, in general, it has to be taken into consideration that regulation stands for control and control always pursues a certain purpose. Within the EU, regulation as a controlling measure performs two specific functions. The first function is indeed strongly connected to the main goal the EU originally was and is still working on: the establishment of the Single Market with its freedoms of goods, services, persons and capital.[1] In addition, European regulatory actions often pursue a second aim that is closely related to safety matters, namely the reduction of risks. Hence risk regulation, as a means of preventing dangerous situations from happening, is the other main task European policy is trying to fulfill.

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1 See Giandomenico Majone, "The Rise of the Regulatory State in Europe", 17 *West European Politics* (1994), pp. 77 *et sqq*.

II. Examples of European risk regulation

Regardless of whether the EU should be allowed to regulate certain risks, a question that has already been dealt with exhaustively in academia, the question of the actors playing the leading part within this process of risk regulation seems much more intriguing.

Therefore, if for example the manufacture of polycarbonate feeding bottles containing Bisphenol A (BPA)[2] – a chemical substance that is mainly used in combination with other chemicals to manufacture plastics – has been outlawed by the EU since March 2011[3], it has to be asked why and by whom?

Risk regulation goes hand in hand with the risk analysis process, including risk assessment, risk management and risk communication; hence the question of the relevant actors defining and assessing dangerous situations, products or behavior is at the heart of European risk assessment.

Concerning BPA, the substance has been permitted for use in food contact materials in the EU[4] as well as in the United States and Japan for many years. In fact, it has been suspected of having effects on development, immune response and tumour promotion in humans, especially in infants.[5] The decision to ban the use of BPA for baby feeding bottles is based on this assumption, but who decides that these health effects really should be taken seriously and are not just imaginary or media-driven hysterical reactions?

From 2006 onwards there have been areas of uncertainty[6] concerning BPA, deriving from new studies, which culminated in scientific arguments against the use of BPA. In accordance with its right of initiative, the European Commission responsible for presenting a proposal concerning the prohibition or restriction of BPA requested additional, but above all, independent and objective scientific advice. Therefore, the European Food Safety Authority (EFSA), a European regulatory agency, received an iterated request about BPA that was launched by the Commission. The EFSA´s scientific panel on food contact materials, enzymes, flavourings and processing aids (CEF) then worked on a revised scientific opinion[7] concerning BPA. After months of discussion between the Commission´s service, the EFSA, the Member States (MS) of the EU and the chemical industry, the EU finally outlawed at least the manufacturing of feeding bottles containing BPA from 2011 on and prohibited the import and sale of these bottles beginning June 2011.

Critical decisions concerning European legislation often involve complex technical information where risk analysis procedures are required. The higher the risk, the faster the decision has to be made. As a result, decisions are often linked to intense, expensive and time consuming procedures, i.e. the supply of assessments, the cost-benefit-evaluation and finally protracted negotiations between concerned policymakers, stakeholders and experts. The ban on certain chemical substances like BPA, the registration of medications, the prohibition of genetically modified organisms (GMOs) in human food or, most recently, the reinforced controls on imported food and feed from certain regions of Japan after the nuclear accident at Fukushima are good examples.

III. Scientific experts within the process of European risk regulation

Given that the consequences attached to certain political decisions may be very serious and, in rare cases, even fatal for the people affected, one has to bear in mind that risk analysis might be very often the only objective scientific basis for making rational decisions; even in cases where the risks faced are highly uncertain. In such situations political decisions should be based on objective scientific risk as-

2 For further details see Tessa Fox, Esther Versluis and Marjolein van Asselt, "Regulating the Use of Bisphenol A in Baby and Children's Products in the European Union", 1 *EJRR* (2011), pp. 21 *et sqq*.

3 Commission Regulation 2011/10/EU of 14 January 2011 on plastic materials and articles intended to come into contact with food, OJ 2011 L 12/1.

4 Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs, OJ 2002 L 220/18.

5 For an overview see <http://www.efsa.europa.eu/en/topics/topic/bisphenol.htm?wtrl=01> (last accessed on 16 January 2012).

6 Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the Commission related to BPA, EFSA Journal (2006) 428, 1–75; Scientific Opinion of the Panel on Food additives, Flavourings, Processing aids and Materials in Contact with Food (AFC) on a request from the Commission on the toxicokinetics of BPA, EFSA Journal (2008) 759, 1–10; Statement of EFSA on a study associating BPA with medical disorders prepared by the Unit on food contact materials, enzymes, flavourings and processing aids (CEF) and the Unit on Assessment Methodology (AMU), *EFSA Journal* (2008) 838, pp. 1–3.

7 Scientific Opinion on BPA: evaluation of a study investigating its neurodevelopmental toxicity, review of recent scientific literature on its toxicity and advice on the Danish risk assessment of BPA, 8 *EFSA Journa*l (2010), at p. 1829.

sessments, employing the precautionary principle that is said to cover those specific circumstances "where preliminary objective scientific evaluation, indicates that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the high level of protection"[8] that was chosen by the EU.

Considering the vast number of scientific advisors and advisory bodies that exist, it is important to begin with a brief overview of the scientific actors working within this process of science-based risk regulation in Europe. Science-based risk regulation starts within the European Commission´s own administrative structure. The Commission is responsible for preparing legislative acts that are finally adopted by the Council and the European Parliament and therefore needs to have up-to-date information and evidence on hand. Food safety scandals like the BSE-crisis have triggered the intensified establishment of independent expert bodies since the early 1990s.[9] The sheer impossibility of obtaining all recent scientific information within the ranks of the Commission´s own resources was the main reason why independent expert advice began to play such a significant role within the European decision making process.

1. Commission related experts groups

The Commission itself has established numerous so called expert groups within the structure of its general directorates (GD). These expert groups are consultative entities set up by the Commission or its services, comprising at least six public and/or private-sector members and meeting more than once. When defining the composition of the expert group, the Commission shall aim towards ensuring balanced representation, not only of the relevant areas of expertise and interest, but also concerning gender and demographical criteria. The expert group´s main task is to provide advice and expertise to the Commission concerning the preparation of legislative proposals and policy initiatives. Expert groups prepare scientific opinions and recommendations but never actually decide particular questions, as they are supposed to have an advisory function only. These scientific opinions present the views of the individual committee members and do not necessarily reflect the views of the European Commission. At the end of the risk assessment process opinions are adopted and certain statements may even be published. In fact, the Commission may publish on the Internet any reports, opinions and proceedings that are not confidential in nature.

Depending on the subject the expert group is working on, its members can be representatives of the MS, NGOs, universities or the industry, etc. There is a formal procedure to be followed in order to invite independent experts who are appointed *ad personam* and are not nominated by one of the groups mentioned above. The Commission publishes a call for the expressions of interest including certain requirements for the candidate´s application in the Official Journal of the EU.

In the case of the Directorate General for Health and Consumers (DG SANCO) the Commission established different independent expert groups, i.e. non-food Scientific Committees to provide the Commission with the scientific advice it needs when preparing proposals related to consumer safety, public health and the environment. One of these expert groups, the Scientific Committee on Consumer Safety (SCCS), is currently composed of sixteen independent scientific experts recruited by the Commission through an open call for applications. The committee usually produces its reports in response to a specific request by the Commission and deals with all questions with regard to "all types of health and safety risks (notably chemical, biological, mechanical and other physical risks) of non-food consumer products (for example: cosmetic products and their ingredients, toys, textiles, clothing, personal care and household products such as detergents, etc.) and services (for example: tattooing, artificial sun tanning, etc.)"[10]. In one case, *e.g.* the Commission wanted to know whether the committee had any scientific concern with regard to the use of a certain hair colouring agent in hair dye formulations.[11]

Whereas the Commission´s expert groups are, first and foremost, fora for discussion and brainstorming providing the Commission with a high level expertise, that enjoy a certain degree of autonomy but do not have legal personality or decision making power,

8 COM (2000) 1, *Communication from the Commission on the precautionary principle*, 3.

9 COM (2000) 200 final, *Reforming the Commission – A White Paper – Part II – Action plan*, action 17.

10 SCCS, *Opinion on HC Yellow n° 13*, SCCS/1322/10, 2.

11 SCCS, *Opinion on HC Yellow n° 13*, SCCS/1322/10, 6.

there are other expert bodies marked by different characteristics.

2. Independent agencies

So called policy agencies[12] do not only have legal personality but might as well have genuine decision making power to perform executive functions in order to contribute to the regulation of specific sectors at the European level.[13] Policy agencies are a subgroup of thirty existing European regulatory agencies, which are permanent and relatively independent[14] bodies of secondary EU-law created by the legislator, i.e. the Council or jointly the Council and the European Parliament, whilst the above mentioned Commission related expert groups are created by the Commission´s decision.

Out of the twenty-four policy agencies that handle tasks delegated by the Commission, some policy agencies enjoy a certain level of authority: on the one hand, some, like the European Chemicals Agency (ECHA) or the European Aviation Safety Agency (EASA) have the privilege to adopt legal acts, not of general application but binding on third parties. On the other hand, agencies like the EFSA, draw up non-binding decisions, which may be taken as a binding basis for the subsequent adoption of a Commission´s decision. Ordinary agencies have mere advisory functions[15], like the European Environment Agency (EEA), offering policymakers the objective, reliable and comparable information they need to draw up effective laws and strategies. In fact, the agencies´ predetermined functions may develop over time, as was the case with the European Monitoring Center of Drugs and Drug Addiction (EMCDDA). In regard to new psychoactive substances[16] the EMCDDA´s scientific committee has a central role in the assessment of risks associated with a new psychoactive substance, with the scientific opinion being the basis for the subsequent adoption of a Commission´s decision. With EMCDDA´s help the EU managed, e.g. to prohibit the sale and use of Mephedron[17], a commonly known drug and so called "legal high".

Although the agencies vary in size and purpose, they have similar ways of operating and a common basic structure. Within this structure scientific committees may help the agencies with their scientific expertise, conducting risk assessments and providing high level expertise concerning different matters. These committees are made up of scientific experts specializing in the relevant fields; the experts may be nominated either by the MS or recruited by the Commission through an open call for applications, depending on the different agencies.

It is obvious that what agencies and expert groups have in common, despite all the differences, is their responsibility for formulating an objective scientific basis for European risk regulation. Certainly, the Commission may also count on other instruments to ensure that it obtains the full range of views and expertise on any given matter. International organizations, scientists of non-Member-State countries, international conferences and consultation procedures may help the Commission to broaden its professional knowledge.

IV. The problem of the expert´s independence

Obviously, expertise on certain matters should be provided by independent and objective experts only. However, it is important to understand what is meant by independence. Generally, independence is understood as the absence of pressures from political and industry interests.[18] In fact, no one can guarantee that the experts consulted are absolutely independent, as every expert has to acquire scientific knowledge and ability not only through qualifications but also through practice. Advanced knowledge is based on experience that is gained through practical train-

12 See http://europa.eu/agencies/index_en.htm (last accessed on 16 January 2012).

13 See for example Stefan Griller and Andreas Orator, "Everything under control? The way "forward" for European agencies in the footsteps of the Meroni doctrine", 1 *ELRev* (2010), pp. 1 *et sqq*.; Dorothee Fischer-*Appelt, Agenturen der europäischen Gemeinschaft*, (Berlin: Duncker & Humblot, 1999), at p. 38.

14 Enjoying a certain degree of organizational and financial independence, Stefan Griller and Andreas Orator, 1 *ELRev* (2010), at pp. 8 *et sqq*.

15 See Giandomenico Majone, "The new European agencies, regulation by information", 4 *Journal of European Public Policy* (2001), pp. 262 *et sqq*.

16 See Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk-assessment and control of new psychoactive substances, OJ 2005 L 127/32.

17 See Council Decision 2010/759/EU of 2 December 2010 on submitting 4-methylmethcathinone (mephedrone) to control measures, OJ 2010 L 322/44; for further details see Barbara Kofler, "Tod den (oder durch?) Legal Highs – Hilfe durch europäische Netzwerke am Beispiel Mephedron", 3 *Journal für Strafrecht* (2011), pp. 91 *et sqq*.

18 Damien Géradin and Nicolas Petit, "The Development of Agencies at EU and National Levels: Conceptual Analysis and Proposals for Reform", 1 *Jean Monnet Working Paper* (2004), pp. 1 *et sqq*, at p. 50.

ing and which is a required criterion for a successful application as an expert for a scientific committee belonging to either the Commission´s administrative structure or the European policy agencies. However, it must be pointed out that this expertise may be linked to former employment as well as to consequent personal and/or financial interests.

As there is no way to find an expert completely free and independent of the above factors, every promise to do so raises unreasonable expectations. Therefore, guaranteeing impartiality and independence is a futile endeavor; however, this does not necessarily mean that it is impossible to make decisions based on objective information.

The requirement to disclose former employment and personal interests is the right way to diminish unwanted conflicts of interests. If all experts consulted have to fulfill the requirement of making this data public without being stigmatized, realistic expectations could be fulfilled and acceptance within society increased. If the aims pursued as well as the different interests represented are defined, it is possible to gain a balanced view of the issue. Transparency will not solve the problem itself – but it can lay down rules reducing the negative effects of information that is acquired from a biased source.

As a result the Commission launched an online register of expert groups in October 2005 that was completed in January 2009. From this date onward transparency has been enhanced resulting in increased access to valuable information on key elements. Not only are the mission, tasks and particular policy areas listed, but even the names and professional backgrounds of the experts participating are published to underline that they are supposed to act without any material or political interest. For this reason, all members must disclose conflicts of interest by signing a declaration of interest where, for example, their former employment will be listed. They have to sign a declaration of commitment and a declaration of confidentiality as well. If it is proven that the experts are not as independent as they profess to be, they will be removed from the expert group immediately and a new member will be appointed.

V. Conclusion

To summarize, there are both advantages and disadvantages when scientific experts become involved in the European risk assessment process: science-based regulatory policy may, on the one hand, be seen as a guarantor of rational decision making, increasing not only the quality of decisions but also their acceptance by all people affected. On the other hand, expert groups, scientific committees and agencies face the burden of unrealizable independence, a question that has already been raised, and lack not only transparency but also democratic control. In fact, there are widespread debates about how risk analysis should be used within the EU, and one of the main questions certainly is: how much influence do scientific experts actually have and how much influence should they have over European political decisions? Are they already the hidden[19] European lawmakers?

In its judgment concerning Pfizer Animal Health[20] the Court of First Instance stated that although scientific experts have scientific legitimization, this is not a sufficient basis for the exercise of public authority, which requires democratic credentials and political responsibilities. Nevertheless, the Commission, when disregarding a scientific opinion, "[...] must provide specific reasons for its findings by comparison with those made in the opinion and its statement of reasons must explain why it is disregarding the latter"[21].

The fact that many decisions in European legislation are taken behind closed doors by mostly unknown expert-groups, scientific committees or agencies is the crux of the matter. Therefore, enhanced transparency regarding the expert´s individual background is an essential start but no more than a drop in the ocean: another important matter of debate is the transparency concerning the decision making process itself. Article 15, paragraph 3 of TFEU provides the right of access to documents of the Union institutions' bodies, offices and agencies to any citizen of the Union[22]. Although it is true that it is the responsibility of the policy-makers to inform the

19 See Michaela Wittinger, "Europäische Satelliten: Anmerkungen zum Europäischen Agentur(un)wesen und zur Vereinbarkeit Europäischer Agenturen mit dem Gemeinschaftsrecht", 5 Europarecht (2008), pp. 609 et sqq., at pp. 620 et sqq.

20 Case T-13/99, *Pfizer Animal Health SA v. Council of the European Union* [2002] ECR II-03305, at para. 201.

21 Case T-13/99, *Pfizer Animal Health SA v. Council of the European Union* [2002] ECR II-03305, at para. 199.

22 For details see Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ 2001 L 145/43.

interested public and that the Commission indeed tries to give a current overview of the existing relationships between politics and administrations, it is just as true that European decision making processes are quite complicated due to a wide range of political and administrative instruments.

The problem is that the majority of the general public knows very little about European regulatory processes and even less concerning risk assessment procedures within the EU that may often have a great impact on individuals.

Therefore, the whole process of European risk regulation itself has to be made a lot more lucid and informative, especially the risk assessment procedures. The media plays an important role in this task; to support the policy-maker´s efforts, the focus should be even more on basic information, coherence and relationships between European institutions. Academia might help to develop communication skills and prepare the relevant contents so that even laymen can understand the reasons and importance of European (risk) regulatory actions. However, it would be a worthwhile and necessary attempt to increase European citizens´ acceptance and trust in European legislation.