Independent Scientific Advice: Comparing Policies on Conflicts of Interest in the EU and the US

*Simone Gabbi**

This article highlights the importance of unbiased scientific advice in the European Union's legal system. It then analyses and compares the policies in force throughout the European Food Safety Authority, European Medicines Agency and European Commission's Scientific Committees with the one implemented by the US Food and Drugs Administration. The author argues that at the present time the framework adopted and implemented by the European Food Safety Authority seems to be the most complete and stringent amongst those taken into account in the article and he advances some proposals for further improvement of the policies regulating conflict of interest.

I. Introduction and scope of the article

During the past few years, there has been significant public debate about the susceptibility of independent research to bias of various kinds[1]. The dialogue has extended to peer-reviewed literature, scientific conferences and, especially, to government and international advisory bodies[2]. In the Life Sciences domain, to name just one example, there has been serious debate regarding the independence – or alleged lack thereof – of the experts who provided the scientific arguments for the WHO communications and recommendations regarding the pandemic influenza that was supposed to have broken out in 2009[3]. In the last thirty years of the 20th century, legislators of several major legal systems (and a number of their respective judges) have turned to scientists to gain an objective analysis of a number of highly complex technical and scientific matters[4]. From a governance perspective, one of the main problems with scientific and technical bodies is that, by definition, they are not elected or accountable. Instead, they are formed in order to provide "pure" scientific advice and therefore their only source of legitimacy stems from the

* Ph.d., Legal officer at the European Food Safety Authority. The views and findings in this article are solely those of the author and do not necessarily reflect the views or position of the European Food Safety Authority or of any other Union Institution, agency or body.

1 Marcia Angell, "Science on Trial: The Clash of Medical Evidence and the Law in the Breast Implant Case" (W.W. Norton & Company 1997); Nicholas A. Ashford, "Implementing the Precautionary Principle: Incorporating Science, Technology, Fairness, and Accountability in Environmental, Health, and Safety Decisions", 5 *International Journal of Risk Assessment and Management* (2005), pp. 112 *et sqq*.

2 See Ronald Bailey, "Scrutinizing Industry-Funded Science: The Crusade Against Conflicts of Interest", American Council on Science and Health 2008, available on the Internet at <http://www.acsh.org/publications/pubID.1687/pub_detail.asp> (last accessed on 4 April 2011); Elizabeth Williamson, "Farming Critics Fault Industry's Influence", *Wall Street Journal,* 30 April 2008, available on the Internet at <http://online.wsj.com/article/SB120951584294254683.html> (last accessed on 4 April 2011); Center for Science in the Public Interest, "Integrity in Science Watch: Groups Decry Broken Peer Review Process at EPA", available on the Internet at <http://www.cspinet.org/integrity/watch/200709172.html#1> (last accessed on 4 April 2011); Donald G. McNeil Jr., "Gates Foundation's Influence Criticized", *New York Times,* 16 February 2008, available on the Internet at <http://www.nytimes.com/2008/02/16/science/16malaria.html> (last accessed on 4 April 2011). For an interesting analysis of media coverage on conflicts of interest see Katherine McComas, Leah M. Simone, "Media Coverage of Conflicts of Interests in Science", 24(4) *Science Communication* (2003), pp. 395 *et sqq*.

3 Deborah Cohen, Philip Carter, "Conflicts of Interest, WHO and the Pandemic Flu 'Conspiracies'", *BMJ* (2010), pp. 340 *et sqq*.; Fiona Godlee (*Editor in Chief*), "Conflicts of Interest and Pandemic Flu. WHO Must Act Now to Restore its Credibility, and Europe Should Legislate", *BMJ* (2010), p. 340; David Derbyshire, "Government Virus Expert Paid £ 116k by Swine Flu Vaccine Manufacturers", *Daily Mail Online*, 27 July 2009, available on the Internet at <http://www.dailymail.co.uk/news/article-1202389/Government-virus-expert-paid-116k-swine-flu-vaccine-manufacturers.html> (last accessed on 4 April 2011).

4 Robin Feldman, *The Role of Science in Law* (Oxford: Oxford University Press 2009), at pp. 19 *et sqq*.

quality and "objectivity" of their outputs. In other words, for any scientific body a severe reputational loss regarding its integrity and objectivity undermines its very *raison d'etre*.

Setting these practical considerations aside, in the European Union excellence, independence and transparency are the three essential requirements that any scientific advisory body to which risk assessment is delegated by the European legislator should comply with[5]. The prerequisite quality of independence, in particular, is already required as a by-product of the obligation for Union Institutions to analyse matters in a complete and objective way[6], and can now also be considered as a transposition of the general principle of sound and impartial administration as enshrined in Article 41(1) of the Charter of Fundamental Rights of the European Union, which has become legally binding for Union institutions, bodies and agencies with the entry into force of the Lisbon Treaty. However, there have been several important contributions that have highlighted an increased risk that regulatory agencies, specialised in a given domain, may become subject to the risk of "regulatory capture"[7]. According to those authors, professionals employed by a specialised regulatory agency may become extremely close to the same subjects whom they are supposed to regulate. This may happen for various reasons and via different processes, including the proven occurrence of the "revolving door" phenomenon, extremely common amongst senior officials and politicians on both sides of the Atlantic, whereby high-level officials, after leaving government service, accept positions in the very industries they used to regulate.[8] On a different level and more recently, in the legal system of the European Union the General Court of the European Union has delivered what I consider to be its first ruling in which the validity of a scientific output of a regulatory agency of the Union is scrutinised from the perspective of its compliance with the internal rules of the agency on the independence of its scientific experts. The Court adjudicated the case in the agency's favour, but this emphasizes the significance that this kind of internal rules have attained for regulatory agencies[9].

5 Clearly spelled out in the Commission Communication on Consumer Health and Food Safety, COM(97) 183 and more recently in the "Commission Communication on the collection and use of expertise by the Commission: Principles and Guidelines. Improving the Knowledge for Better Policies", COM (2002) 713. Of particular relevance also the seminal judgment Case T-13/99, *Pfizer Animal Health SA v. Council of the European Union*, [2002] ECR Page II-03305, at para. 172. Even more explicitly, Case T-70/99, *Alpharma Inc. v. Council of the European Union*, [ECR] 2002 II-03495, at para. 211, found that "expert scientific advice meeting the requirements of excellence, independence and transparency is of the utmost importance in risk assessment to ensure that the regulatory measures adopted by the Community institutions have a proper scientific basis and to ensure that the institutions were in a position to examine carefully and impartially all relevant evidence in a particular case".

6 According to Article 296 of the Treaty of the Functioning of the European Union "In carrying out their missions, the institutions, bodies, offices and agencies of the Union shall have the support of an open, efficient and *independent* European administration". From the perspective of the case law of the Court of Justice, see Case C-269/90, *Technische Universitaet Muenchen*, [ECR] 1991 I-5469, at para. 14 and Case C-326/05P, *Industrias Quìmicas del Vallés/Commission*, [ECR] 2007 I-6557, at para. 77.

7 See Cary Coglianese, Richard J. Zeckhauser, Edward Parson, "Seeking Truth for Power: Informational Strategy and Regulatory Policy Making", 89(2) *Minnesota Law Review* (December 2004), *available on the Internet at <http://www-personal.umich.edu/~parson/website/pdf/parson-minnesota-law-review-1104-seeking-truth-for-power.pdf> (*last accessed on 4 April 2011); Antoine Faure-Grimaud, David Martimort, "Regulatory Inertia*", in 34(3) RAND Journal of Economics*; Edward Glaeser, Andrei Shleifer, "The Rise of the Regulatory State", *41(2) Journal of Economic Literature* (2003), pp. 401 *et sqq.;* Dieter Helm, "Regulatory Reform, Capture and the Regulatory Burden", *22 Oxford Review of Economic Policy* (2006), pp. 169 *et sqq.*; Jean-Jacques Laffont, Jean Tirole, "The Politics of Government Decision-Making: A Theory of Regulatory Capture", *Quarterly Journal of Economics* (1991), pp. 106 *et sqq.*; Mary K. Olson, "Regulatory Agency Discretion Among Competing Industries: Inside the FDA", *Law Econ Organ.* (1995), pp. 379 *et sqq.*

8 The revolving door phenomenon is nothing else than one of the manners in which regulatees seek to influence their regulators, see Dieter Helm, Regulatory Reform, *supra* note 7, at p. 183. Just to name a concrete case, an "influenza" expert who formerly headed the World Health Organization's (WHO's) flu program and is now vice president of influenza strategy at Novartis Vaccines and Diagnostics in Cambridge, Robert Roos, "Proposal for Prepandemic Vaccination Sparks Discussion", available on the Internet at <http://www.cidrap.umn.edu/cidrap/content/influenza/panflu/news/may1310stohr-jw.html> (last accessed on 4 April 2011). Regarding the problematic relationship between Departments of Defense and the defense industries, see Anne Marie Squeo, J. Lynn Lunsford, "Ethics Scandals Show Pentagon-Industry Ties Are Still Problematic", *Wall St. J. Eur.,* 18 December 2003, at A1; Leslie Wayne, "Pentagon Brass and Military Contractors' Gold", *New York Times*, June 29, 2004, available on the Internet at <http://www.nytimes.com/2004/06/29/business/pentagon-brass-and-military-contractors-gold.html> (last accessed on 4 April 2011); Eric Lipton, "Former Antiterror Officials Find Industry pays better", Editorial, *New York Times,* 20 June 2006, available on the Internet at <http://www.nytimes.com/2006/06/18/washington/18lobby.html?_r=1> (last accessed on 4 April 2011); and Joseph Stiglitz, *The Roaring Nineties* (London: Penguin Books 2003), pp. 258 *et sqq*. Interestingly, Yeon-Koo Che, "Revolving Doors and the Optimal Tolerance for Agency Collusion" (1995), 26(3) *RAND Journal of Economics,* pp. 378 *et sqq.*, concludes that the presence of a revolving door between regulator and regulated undertakings can be beneficial to the public interest as regulator's efforts to enhance his industry qualifications may have a complementary effect on his regulatory performance and he may become more aggressive in regulating the market to signal his industry qualifications (thereby increasing his chance of achieving a profitable contract with the regulated entities).

9 Of particular significance is the fact that the complainant pleaded the invalidity of the output on the basis, *inter alia*, of the alleged breach of that agency's policy on declarations of interest with respect to a *single* expert of the competent Panel: Case T-74/08, *Now Pharm AG v. European Commission*, not yet published, at paras. 86–101.

This article analyses how some of the most important scientific bodies and agencies of the European Union strive to be, and to remain, independent from external interests. It then compares those policies with the one adopted by the Food and Drugs Administration, which can be considered the international benchmark against which Union agencies are frequently assessed. The article argues that, currently[10], the framework adopted and implemented by the European Food Safety Authority seems to be the most complete and stringent among those taken into consideration by the Author. However, the present work does not try to identify models or categories of conflicts of interest (CoI), for I believe that any attempt to do so may prove too rigid to reflect the systems applied in the real world by the institutions concerned, while not being of any real relevance to practitioners[11]. Similarly, I have deliberately chosen to focus on the objectivity of "independent" scientific advice to regulators, without touching upon the different, although linked, issues of objective scientific research[12] and obligations of civil servants working on scientific matters[13].

Before commencing the analysis of this topic, which is often discussed in scientific journals[14] but rather seldom in legal ones[15], it is appropriate to clarify the meaning of some basic concepts of fundamental importance for the discourse at issue in the present work. In the Union legal system it is not possible to find a definition of the concepts of "interest", "conflict of interests", "potential conflict of interests" or "bias"[16]. Nonetheless, I am convinced that by applying some common sense and by drawing on previous scientific publications on this topic, some reasonably sound definitions of those concepts can be identified[17]. By "interest" in this article I mean any activity or item carried out or held by a person[18] to whom the rules and policies on independence can be applied. Clearly, to be relevant, that activity or item has to be linked subject-wise to the activities of the appropriate scientific body or agency. What is meant by "Conflicts of Interest" is the situation in which one or more interests of a person concerned by these sets of rules either clash or substantially diverge (actually or potentially) from the institutional interest of the pertinent scientific body with which that person is co-

10 This work has been finalised in October 2010.

11 See C. Demmke, M. Bovens, T. Henökl *et al.*, "Regulating Conflicts of Interest for Holders of Public Office in the European Union. A Comparative Study of the Rules and Standards of Professional Ethics for the Holders of Public Office in the EU-27 and EU Institutions", European Institute of Public Administration in co-operation with the Utrecht School of Governance, the University of Helsinki and the University of Vaasa, available on the Internet at <http://ec.europa.eu/dgs/policy_advisers/publications/docs/hpo_professional_ethics_en.pdf> (last accessed on 4 April 2011), at p. 132 proposes three main categories of systems distinguishing between those countries and institutions who regulate, prohibit and restrict a number of issues, require a detailed number of reporting obligations and have independent control and monitoring mechanisms in place – Model 1: restrictive approach; who regulate, prohibit and restrict a number of issues but leave room for some exceptions and have less strict control mechanisms in place – Model 2: moderate approach; – who are mostly based on voluntary approaches and rely on different forms of self-regulation and self-enforcement – Model 3: soft approach. Nonetheless, it also admits that it is difficult to classify EU institutions in any of the models proposed, see *ibidem.*, at p. 135.

12 On this matter, see *ex multis* Adil E. Shamoo, David B. Resnik, *Responsible Conduct of Research* (Oxford-New York: Oxford University Press 2009).

13 For a complete and inspiring analysis of policies and rules adopted by international and national actors to guarantee the independence of their civil servants, see Bernardo Giorgio Mattarella, *Le regole dell'onestà. Etica politica, amministrazione* (Bologna: Il Mulino 2007), pp. 45–74 and 131–180.

14 See J.E. Bekelman, Y. Li, C.P. Gross, "Scope and Impact of Financial Conflicts of Interest in Biomedical Research: A Systematic Review", *JAMA* (2003), pp. 454 *et sqq.*; Laura M. Brockway, Leo T. Furcht, "Conflicts of Interest In Biomedical Research – The FASEB [Federation Of American Societies For Experimental Biology] Guidelines", *The FASEB Journal* (2006), pp. 243 *et sqq.*; Aruther Caplan, "Halfway There: The Struggle to Manage Conflicts of Interest", *Journal of Clinical Investigation* (2007), pp. 509 *et sqq.*; Sylvia Rowe, Nick Alexander, Fergus M Clydesdale *et al.* for the International Life Sciences Institute North America Working Group on Guiding Principles, "Funding Food Science and Nutrition Research: Financial Conflicts and Scientific Integrity", *Am J Clin Nutr* (2009), pp. 1 *et sqq*.

15 See Joey G. Conley, "Conflict of Interest and the EPA's Science Advisory Board", *Texas Law Review* (2007), pp. 165 *et sqq.*; E. Donald Elliott, "Strengthening Science's Voice at EPA", *Law and Contemporary Problems* (2003), pp. 45 *et sqq*.

16 With the notable exception of the internal rules adopted by several Institutions and agencies, such as the European Central Bank, that however are of internal relevance, see, e.g., Point 4.1 of the ECB Code of conduct for the members of the Governing Council, 2002/C 123/06, according to which conflicts of interests arise where "where the members of the Governing Council have private or personal interests, which may influence or appear to influence the impartial and objective performance of their duties. Private or personal interests of the members of the Governing Council mean any potential advantage for themselves, their families, their other relatives or their circle of friends and acquaintances."

17 There are of course several alternative definitions of the same concepts, although they do not differ substantially, see Paul J. Friedman, "The Troublesome Semantics of Conflict of Interests", *Ethics and Behaviour* (1992), p. 245 *et sqq.*; Katherine McComas, Leah M. Simone, "Media Coverage", *supra* note 2, at p. 397; Sylvia Rowe *et al.*, *supra* note 14, at p. 3, and The National Academies, "Policy on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports", 12 May 2003, available on the Internet at <http://www.nationalacademies.org/coi/bi-coi_form-0.pdf> (last accessed on 5 April 2011).

18 Or by a close relative or person belonging to the same household of that person.

operating, or create an unfair competitive advantage for any person or organisation affected by the advice of that body[19]. By way of contrast, by "bias" I mean any situation in which one of the persons providing scientific advice may find himself or herself because of subjective conditions which cannot be objectively assessed and which may result in potential conflict of interests mainly of an abstract or intellectual nature. These can be exemplified *inter alia* in religious, ethical or environmental beliefs as well as in personal prejudices and misconceptions, and also in previous publications on the same subject. Although of relevance in some specific cases, I believe these abstract interests cannot be objectively assessed by regulatory bodies without discriminatory consequences for the persons concerned and should therefore be excluded from the scope of the present article[20]. Indeed, in my view it is not possible to have completely unbiased scientific experts, in exactly the same way that it is not possible to have unbiased human beings[21]: in the words of the US EPA Science Advisory Board "although it is possible to avoid conflict of interest, avoidance of bias is probably not possible. All scientists carry bias due, for example, to discipline, affiliation and experience"[22]. Hence, I believe that policies ensuring the independence of experts should focus on preventing potential CoIs that can be proven by "objective" circumstances or facts.

II. The importance of independent scientific advice in the Union's institutional framework

Over the past fifteen years, scientific advice provided by advisory committees set up to assess a variety of risks, products and substances has become increasingly fundamental in the Union regulatory environment. Indeed, as the argument goes, it appears that the central administrative services represented by the Directorates General of the European Commission do not possess the right kind of expertise needed to look into extremely technical and sector specific matters that now underpin the Union regulatory decision-making process. In other words, the high level of complexity of modern science would not allow ordinary officials to regulate certain sectors in an efficient and reasonable manner. Finally, in certain sectors, such as those of life sciences and food safety, international agreements have required the attainment of a certain level of scientific excellence and independence insofar as scientific arguments supporting sanitary or phytosanitary measures are concerned[23].

It is therefore apparent that the independence of scientific experts providing technical advice, often as part of Union "regulatory"[24] agencies, has become of primary importance to the reputation of those scientific bodies that were set up in the first place to provide an objective and credible scientific advice to more political institutions. In the European Union, this is the case for instance for the European Chemicals Agency (ECHA), the European Food Safety Authority (EFSA)[25], the European Medicines Agency

19 The definition of CoI provided here is rather close to the one endorsed by The National Academies, "Policy on Committee Composition", *supra* note 17, at p. 4.

20 A similar conclusion has been reached by The National Academies, "Policy on Committee Composition", *supra* note 17, at p. 3.

21 The National Academies, "Policy on Committee Composition", *supra* note 17, at p. 3.

22 U.S. Environmental Protection Agency, Science Advisory Board Health Committee, Review of the draft report to Congress "Characterization of date uncertainty and variability in IRIS assessment, pre-pilot *vs* post-pilot", Washington DC (2000), available on the Internet at <www.epa.gov/sab/pdf/ehcl007.pdf> (last accessed on 5 April 2011).

23 For a comprehensive and comparative analysis of the EU/WTO framework see Alberto Alemanno, *Trade in Food: Regulatory Approaches in EU and WTO* (London: Cameron May Publishing 2007).

24 On the interesting subject of regulatory agencies of the European Union see Edoardo Chiti, "Decentralised Integration as a New Model of Joint Exercise of Community Functions: A Legal Analysis of European Agencies", 14(3) *ERLP/REDP* (2002), pp. 1267 *et sqq.*; Michelle Everson, Giandomenico Majone, Les Metcalfe *et al.*, *The Role of Specialised Agencies in Decentralising EU Governance*, Report Presented to the Commission, available on the Internet at <http://ec.europa.eu/governance/areas/group6/contribution_en.pdf> (last accessed on 5 April 2011); Damien Geradin, Nicolas Petit, "The Development of Agencies at EU and National Levels: Conceptual Analysis and Proposals for Reform", *Yearbook of 23 European Law* (2004), pp. 137 *et sqq.*; Giandomenico Majone, "Delegation of Regulatory Powers in a Mixed Polity", *ELJ* (2002), pp. 319 *et sqq.*; Giandomenico Majone, "The New European Agencies: Regulation by Information", *Journal of European Public Policy* (1997), pp. 262 *et sqq.*; Giandomenico Majone, *Regulating Europe* (London: 1996); Martin Shapiro, "Independent Agencies, US and EU", *EUI Working Papers*, RSC, n. 96/34; Mark Thatcher, "Analysing Independent Regulatory Agencies in Western Europe: Functional Pressures Mediated by Context, *Swiss Political Science Review* (2002), pp. 103 *et sqq.*; David Vogel, *The New Politics of Risk Regulation in Europe* (London: Centre for Analysis of Risk and Regulation at the London School of Economics and Political Science 2001), Paper; Xénophon A. Yataganas, "Delegation of Regulatory Authority in the European Union: The Relevance of the American Model of Independent Agencies", *Jean Monnet Working Paper* 3/01, 2001, available on the Internet at <http://centers.law.nyu.edu/jeanmonnet/papers/01/010301.html> (last accessed on 5 April 2011).

25 For a detailed analysis of the European Food Safety Authority, see Simone Gabbi, *L' Autorità europea per la sicurezza alimentare. Genesi, aspetti problematici e prospettive di riforma* (Milano: Giuffré 2009).

(EMA) and, albeit in a more limited fashion, for the Commission's internal scientific committees that advise on public health matters unrelated to food and feed safety[26].

However, what has now become apparent even to the casual onlooker[27] has not yet been recognised as particularly relevant by the Legislator. In effect, if a person paid attention to the discussions held in the competent committee of the European Parliament (EP)[28], he would soon realise that the independence of scientific experts (and staff) working for or cooperating with Union regulatory agencies has become a frequent subject of vigorous exchanges of views between Members of the EP and the representatives of the responsible bodies and Commission services. Nonetheless, that realisation has not yet found its way to the regulations establishing or governing those bodies and agencies. Indeed, thus far, the standard clauses inserted into the relevant founding regulations of those advisory agencies and bodies, with the aim of protecting their independence and therefore their reputation, foresee exclusively the obligation for the relevant expert to disclose potential conflict of interests[29].

III. The standard independence clause: Is disclosure an effective firewall against potential conflicts?

The theory of public financial disclosure is especially rooted in the concept of "Government in the Sunshine", which aims to increase public confidence through an enhanced policy of transparency[30]. According to the reasoning that has prevailed to date, the fact that experts divulge their potential conflict of interests prevents them from carrying out any wrongdoing as, by doing so, they would soon be exposed to the scrutiny of the general public and their professional circles alike. Therefore, the reasoning goes, their reputation would irremediably suffer, both inside and outside the scientific community if they adopted positions of dubious scientific validity. Furthermore, the founding regulation of the bodies examined in this article have to be put in the right perspective: when the original proposals of those text were put forward by the Commission, the European legislator and public opinion were most concerned with structural or institutional independence, that is, the independence of scientific agencies or bodies from the main political bodies represented by the Commission or by the Council.

However, according to Hood, "these policies [regarding disclosure] are often more preached than practised, more often invoked than defined, and indeed might ironically be said to be mystic in essence, at least to some extent.[31]" Indeed, it appears that in the current economic system, a financial gain of certain relevance in several instances may represent an incentive bigger than any (anyway merely hypothetical) reputational loss. This, combined with the claim that more and more regulatory decisions made at Union level are in effect close to rubber stamping of the risk assessments performed by certain scientific advisory bodies, has gradually reoriented the focus of NGOs, mass media and public opinion from institutional independence to the independence of the individual scientific experts who are competent to deliver the advice. In effect, the mere disclosure of a potential conflict of interests does not and cannot be considered sufficient to prevent the actual occurrence of those conflicts[32]. The interests at stake are, nowadays, too big to rely exclusively on the good will, professional integrity and coherence of the persons concerned by these matters.

As a consequence, the main concern of the legislators should also no longer be limited to the potential

26 Scientific Committee on Consumer Safety (SCCS), Scientific Committee on Health and Environmental Risks (SCHER), Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), Scientific Committee on Health and Environmental Risks (SCHER).

27 And to several journalists, see articles cited *supra* note 2 and Paul Benkimoun, "La grande truffa della 'suina'", *La Stampa*, 7/6/2010, available on the Internet at <http://www.lastampa.it/redazione/cmsSezioni/esteri/201006articoli/55702girata.asp> (last accessed on 5 April 2011).

28 The so called ENVI committee of the European Parliament (The Environment, Public Health and Food Safety Committee) is indeed competent for environmental, public health and food safety matters and therefore also for the policies falling under the remit of EFSA, and EMA, and of the Commission's scientific committees.

29 Article 63 of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ L 136/1, as last amended; Article 14 of the Commission Decision setting up Scientific Committees in the field of consumer safety, public health and the environment (2004/210/EC), OJ L 66/45, as last amended, and Article 37 of Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31/1, as last amended.

30 C. Demmke *et al.*, "Regulating Conflicts of Interest", *supra* note 11, at p. 115.

31 Christopher Hood, "Transparency in Historical Perspective", in Christopher Hood, David Heald (eds), *Transparency – The Key to Better Governance*? (Oxford: Oxford University Press 2006), at p. 3.

32 Sylvia Rowe *et al.*, "Funding Food Science and Nutrition Research", *supra* note 14, at p. 4.

political influence that the Commission or other political actors may exercise on the regulatory agencies of the European Union, but should acknowledge the potential of regulatory capture that may result from the adoption of unsound scientific outputs by experts, or other legal or natural persons, with conflict of interests[33].

The need for an improved system preventing the occurrence of conflict of interests becomes even more apparent if one merely considers the evolution over the past two to three decades of the funding of scientific research. It is indeed incontrovertible that while publicly funded research was still the rule or extremely common up until the first half of the 1980s, as of the second half of that decade it became more and more scarce. With the fall of the Communist ideology and the triumph of liberalism, and subsequently of market fundamentalism[34] that imposed a reduction in government intervention throughout all sectors of civil society, publicly funded research became even rarer. The ongoing financial and economic crises of Western economies that have forced cuts in public spending promise even more of that to come[35]. As a consequence, universities and researchers are pushed to focus on matters of immediate interest for private parties such as industry, thereby effectively becoming engines of economic development[36]. That implies that even "pure" academicians, entirely committed to "independent" research, are constantly in search of private and public funding or integrate their academic activities with private consultancies, offering their expertise to business operators and public institutions alike[37].

For this reason too, scientific experts nowadays are rarely considered as biased by their peers in the scientific community if they receive research funding from, or provide advice to, private parties such as industry. In turn, this runs the risk of jeopardising the supposed benefits that would derive from the disclosure of interests, *i.e.* the discredit deriving from close encounters with certain private interests.

The problems that might be encountered by a system based on the simple disclosure of relevant interests is also exemplified by the fact that, when reproached for having taken a particularly unsound position suspiciously favourable towards private interests, experts may even argue that by having declared those interests they complied with "disclosure" obligations and that, by not taking a remedial or preventive action, the relevant scientific bodies have implicitly accepted the *status quo* of their activities.

IV. Policies on conflicts of interest in the European Union: EFSA, EMA and the Commission's Scientific Committees

It is also for the reasons briefly explained above that EFSA, EMA[38] and the Commission Standing Committees have opted for an effective interpretation of the concepts of independence and disclosure that was initially foreseen in their respective founding regulations. I believe that the internal rules adopted to implement those concepts deserve closer attention from academics and practitioners alike, as they represent a firewall which may help preserve the objectivity and impartiality of the scientific outputs of those bodies. The latter may, in many instances, represent *de facto* the only basis for the regulatory decisions made by risk managers. In the ensuing paragraphs, I will provide a brief analysis of those rules or at least of their main characteristics, with the aim of comparing them and establishing a sort of benchmark against which scientific advisory bodies should measure themselves when devising policies on conflict of interests.

33 EFSA in particular was established with the objective of creating a scientific body independent from political influence. However, it is far from being the only scientific advisory body created with that primary objective; Dieter Helm, "Regulatory Reform", *supra* note 7, at p. 180.

34 See Paul Krugman, *The Return of Depression Economics and the Crisis of 2008* (New York/London: W.W. Norton Company 2009) and *George Soros, The Crisis of Global Capitalism: Open Society Endangered (New York: Public Affairs 1998)*.

35 Along the same lines also IOM (Institute of Medicine), *"Environmental Health Sciences Decision Making: Risk Management, Evidence And Ethics"*, Workshop Summary (Washington, DC: The National Academies Press 2009), at p. 42. This notwithstanding, some important economists argue in favour of the anticyclic function of an increase in public spending during a phase of recession: Paul Krugman, *The Return of Depression Economics*, *supra* note 34.

36 David Korn, "Conflicts of Interest in Biomedical Research", *JAMA* (2000), pp. 2234 *et sqq*.

37 From that stems a different problem, not linked to the subject of the present article, although probably even more important for ensuring an objective assessment of the scientific matters linked to food and feed safety (and to life sciences in general), that is how studies should be designed, by whom they should be financed, and under which conditions. On these problematic matters see Jason Juliano, "Killing Us Sweetly: How to Take Industry Out of the FDA", *Journal of Food Law and Policy*, forthcoming, available on the Internet at <www.ssrn.com> (last accessed on 5 April 2011) offers a few interesting proposals on how to best make the FDA completely independent.

38 On 13 October 2010, EMA adopted a new Policy on Declarations of Interest, which enters into force in the 2nd quarter 2011. It should be noted that the present article is based on the rules in force in 2010, which are, however, not amended by the new Policy.

Before embarking on the examination of the internal rules adopted by the aforementioned Institution and agencies in order to avoid the incidence of conflict of interests, it is appropriate to underline that those rules do not constitute the only defence those bodies may count on in order to prevent the adoption of biased or unsound scientific advice.

In this respect, I should indeed first recall the importance of the principle of collegiality that is common to those agencies and bodies. According to that principle, the drafting and adoption of scientific outputs is always the responsibility of at least the majority of the members of the relevant committee or panel and never that of a single scientist. It is irrefutable that the 'rapporteur' (usually a full member delegated by the chair or by the majority of the members of the committee or panel to provide a first rough assessment of the matter) has an important role to play in the risk assessment process. Nonetheless, that role should not be overemphasised. The initial draft position put forward by the rapporteur is indeed thoroughly discussed, amended and at times even rejected by a restricted working group even before it reaches the committee or panel competent for its final adoption. After being agreed at working group level, the draft assessment is then tabled before the competent committee or panel. There, once again, it is discussed from scratch with the committee or panel in a position to approve it as it is but also with authority to amend it or send it back to the working group in order to reinforce certain aspects of the draft. In other words, a correct implementation of the principle of collegiality ensures that the variegated composition of those scientific bodies ensures that different, and sometimes divergent, views are taken into account, and possibly balanced, when a scientific output is adopted by the college.

It follows that not even the rapporteur, let alone any other individual member of the relevant scientific committee, panel or working group, may exercise undue influence in the process of the adoption of a scientific output. In other words, one could rightly conclude that collegiality is a fundamental bulwark in the perspective of diminishing the possibility of unwarranted influence exercised by single expert(s).

Another fundamental aspect that helps scientific bodies avoid the occurrence of CoIs among its scientists is the possibility for the agencies concerned to set up a system of preventive screening of potential conflict of interests, and for this system to be embedded in the process for selecting those experts. Such a policy has been put in place by EFSA, which systematically requests scientists who apply for membership of its scientific panels and scientific committees to complete a declaration of interest in order to submit a valid application. This in turn allows the agency to perform the screening of the interests of the applicants at the first phase of the selection process, thereby avoiding the appointment of individuals who may have potential CoIs.

Having clarified that the relevant policies on CoIs do not constitute the sole defence of scientific bodies against the risk of adopting biased scientific advice, we can now turn to the analysis of those rules.

1. Fundamental principles common to the policies of EFSA, EMA and the Commission's Scientific Committees

One of the main fundamental principles that the sets of rules adopted by EFSA, EMA and the Commission's Scientific Committees have in common is that having an interest in the activity that expert is supposed to carry out in the context of his cooperation with the scientific body does not automatically imply a CoI. Indeed, it is easily understandable that in order to select scientists who can be considered as points of reference or experts in their sector of activity, the scientific advisory bodies must recognise that those people should also possess several interests in that sector. In other words, in order to be an expert, a person must have, or have had, a few activities carried out at a certain level in the relevant sector. It is therefore of paramount importance that the policies put in place by the institutions concerned lay down a regulatory system that is sufficiently detailed to allow their bodies to discern "ordinary" interests from potential CoIs.

An inherent problem of any system which aims to put in place a policy of CoIs is that the more stringent the policy, the more experts will be affected by the preventive or remedial actions foreseen therein. Put in different terms, the more an institution wants to be stringent in its CoI policy, the fewer experts it will have at its disposal, as many will to some extent fall prey to that very policy and fail to pass the "independence test". At first glance this may seem a matter of concern only for the people who are considered to be incompatible with the activity of scientific advisory bodies. In the long term, however, and when

taken to the extreme, this may also have a negative impact on the availability of high quality experts and therefore indirectly risk jeopardising the reputation of those bodies in the scientific community. This in turn would pre-empt them from fulfilling their mission, *i.e.* the provision of a sound scientific basis for risk management decisions. It is therefore necessary that any scientific advisory body implementing a CoI policy be aware of the repercussions that this policy may have on the quality of its advice; therefore it should strive to adopt a proportionate approach to these matters.

A second fundamental principle that we can find in the three sets of rules analysed in this section is that they all rely on the willingness of individuals to provide complete and truthful declarations. As a consequence, it is of particular importance that policies on CoIs adopted by those bodies should also provide for some kind of disciplinary mechanism for those experts who refuse to comply with the basic obligations contained therein, including the provision of complete and updated information. Once again, that is the case for EFSA's policy on declarations of interest: in cases of failure to submit a complete and updated DoI, it foresees *inter alia* the possibility for the Authority to dismiss the expert in question[39].

2. Selection and nomination of the members of Scientific Committees/Panels

There are significant differences in the way experts are selected for the agencies' Scientific Committees/Panels and for the non-food SCs.

In EFSA and the non-food SCs, public calls for expression of interest are published on the bodies' websites and for EFSA in pertinent scientific journals. Experts apply in their own capacity and undertake to commit themselves and to act in the public interest[40]. As mentioned above, both EFSA and the non-food SCs request candidates to complete and provide a thorough DoI which is identical to those demanded of actual members in the course of their three-year mandate. This DoI is part of their application form and its submission constitutes one of the eligibility criteria. This allows EFSA and the Commission to perform a preliminary screening of the declared interest in order to identify at an early stage any potential conflict of a nature that would be contrary to the nomination of those candidates to the position of members of the relevant scientific body. The other eligibility and selection criteria are specified in the call for expression of interest: members are selected on the basis of their expertise and experience in the primary scientific areas covered by each Committee/Panel, and, consistent with this, of as varied a geographical distribution as possible to reflect the diversity of scientific problems and approaches that can be found in the Union[41].

In addition, EFSA has put in place an external review of the evaluation of applications performed by its staff. External evaluators conduct the external review of the assessment in order to ensure that an objective and transparent assessment of candidates against the set criteria has been performed by EFSA staff[42]. Whenever unjustifiable discrepancies are found between the assessment of the external evaluators and that of EFSA staff, the application is reviewed in order to resolve possible inconsistencies. To achieve the same goals, the Commission for non-food SCs sets up a selection board chaired by an external evaluator.

With regard to the capacity of the selected experts to become members of the scientific panels and committees, for the non-food SCs members are nominated in their personal capacity. By way of contrast, in EMA the members of the Scientific Committees and their alternates are nominated by the Member States, *melius* by the National Authorities competent in each member state for the evaluation of medici-

39 Article 5 of the EFSA Decision concerning the establishment and operations of the Scientific Committee, Scientific Panels and of their Working Groups, MB 17 12 09 item 7 doc 5a – Rules of procedures of SC, Panels and WG – Adopted, available on the Internet at <http://www.efsa.europa.eu/en/keydocs/docs/paneloperation.pdf> (last accessed on 5 April 2011) and EFSA implementing act to the policy on declaration of interests guidance document on declarations of interest document, pp. 6 and 7, available on the Internet at <http://www.efsa.europa.eu/en/keydocs/docs/doiguidance.pdf> (last accessed on 5 April 2011).

40 Article 14 of the Commission Decision setting up Scientific Committees in the field of consumer safety, public health and the environment (2004/210/EC), OJ L 66/45, 4.3.2004, as last amended, and Article 2 of EFSA Decision concerning the establishment and operations of the Scientific Committee, Scientific Panels and of their Working Groups, *supra* note 29.

41 Article 1(2) of the EFSA Decision concerning the establishment and operations of the Scientific Committee, Scientific Panels and of their Working Groups, *supra* note 29.

42 Article 5 of the EFSA Decision concerning the selection of members of the scientific committee, scientific panels and external experts to assist EFSA with its scientific work, available on the Internet at <http://www.efsa.europa.eu/en/keydocs/docs/paneloperation.pdf> (last accessed on 5 April 2011).

nal products[43]. EFSA finds itself in an intermediate position as it has both experts nominated in their personal quality[44] and experts representing National Authorities[45]. Indeed, one could say that while EMA is built on the intergovernmental method, EFSA relies mostly, although not exclusively, on the supranational method.

It is therefore clear that substantial differences on the agencies' policies on CoIs derive also from the different processes regulating the selection and appointment of experts. In cases of Member States nominations, the EU scientific body will be in a difficult position regarding the implementation of a stringent policy on CoIs, as it will not be able to remove an expert unless the relevant National competent Authority also agrees to identify an alternate, or unless there is an explicit legal basis for imposing CoI-related requirements on experts selected by Member States[46]. I believe that, apart from this practical difficulty, the very fact that experts are appointed solely by Member States, with no input or influence from the advisory body's side implies a *de facto* political responsibility of the Member State to ensure the independence of the people it chooses and, conversely, the impossibility of considering the Union body liable for CoIs those experts may have[47].

3. Procedures for preventing potential conflicts of interest

The Founding Regulations of EFSA[48], EMA[49] and the Commission Decision setting up the non-food SCs[50] all stipulate that the members of the Scientific Committees/Panels must make a declaration of interests that may be considered prejudicial to their independence, to be renewed periodically[51].

All the three policies examined here initially provided a simple DoI form. On the basis of the experience gained, they were gradually strengthened over time. EFSA, for instance, adopted a first code of conduct[52], then a guidance on conflicts of interest[53] and finally a much improved set of rules in 2007[54], amended several times thereafter with minor adjustments.

Among the three examples chosen for this article, EFSA, in particular, has developed particularly stringent internal procedures for the management of potential CoIs. EFSA's policy provides a three-layered screening process in addition to the DoI screening performed at the time of the appointment of scientific experts.

In more detail, the first layer is represented by an Annual DoI (ADoI), which is a general declaration to be completed by scientific experts on any interests that may be conflicting with EFSA's mission. The second level is the Specific DoI (SDoI), to be completed before the beginning of each meeting in relation to the items on the agenda for each meeting. This allows EFSA's staff to screen SDoIs and to take any appropriate remedial actions before the meeting takes place, so that the occurrence of any conflict can be avoided. The third layer corresponds to the Oral DoI (ODoI), which is a verbal declaration made at the beginning

43 Differently from the food sector, the risk assessment of medicinal products is carried out in all Member States by bodies or agencies; Antoine Cuvillier, "The Role of the European Medicines Evaluation Agency in the Harmonisation of Pharmaceutical Legislation", in Richard Goldberg and Julian Lonbay (eds), *Pharmaceutical Medicine, Biotechnology and European Law (*Cambridge University Press 2001); John S. Gardener, "The European Agency for the Evaluation of Medicines and European Regulation of Pharmaceuticals*", ELJ* (1996), pp. 48 *et sqq.*; Thomas Gehring, Sebastian Krapohl, "Supranational Regulatory Agencies Between Independence and Control: The EMEA and the Authorization of Pharmaceuticals in the European Single Market*", Journal of European Public Policy* (2007), pp. 208 *et sqq.*; Charalambos Koutalakis, Frank Wendler and Susana Borrás, "European Agencies and Input Legitimacy: EFSA, EMEA and EPO in the Post-Delegation Phase", 29(5) *Journal of European Integration* (2007), pp. 583 *et sqq.*; Ellen Vos, *Institutional Frameworks of Community Health and Safety Legislation – Committees, Agencies and Private Bodies (Oxford/Portland:* Hart Publishing 1999).

44 Members of its scientific committee and of the scientific panels, Article 37 of Regulation (EC) No 178/2002, *supra* note 29.

45 Members of EFSA networks, Article 36 of Regulation (EC) No 178/2002, *supra* note 29.

46 As in the case of the European Medicines Agency, see Article 63(2) of Regulation (EC) No 726/2004, *supra* note 29.

47 To argue the opposite would be like saying that the European Commission is responsible for the independence of Member States representatives sitting in the comitology committees. On the comitology procedures see Christian Joerges, Ellen Vos (eds), *EU Committees: Social Regulation, Law and Politics* (Oxford/Portland: Hart Publishing 1999). One of the first analysis on the impact of the Lisbon Treaty on those procedures, with a particular focus on the food sector is provided by Luigi Costato, "Poteri delegati e poteri di esecuzione della Commissione U.E.: Dalla PAC al TFUE", *Rivista di diritto alimentare* (Gennaio-Marzo 2010), Anno IV, numero 1.

48 Article 37 of Regulation (EC) No 178/2002, *supra* note 29.

49 Articles 61 and 63 of Regulation (EC) No 726/2004, *supra* note 29.

50 Article 15 of Commission Decision 2004/210/EC, *supra* note 29.

51 Under those provisions, also subjects other than scientific experts are required to submit DoIs, see Article 37 of Regulation (EC) No 178/2002, *supra* note 29 and Article 63 of Regulation (EC) No 726/2004, *supra* note 29.

52 EFSA code of conduct on declarations of interests, MB 10.3.2004 – 5.

53 EFSA Guidance on declarations of interests, MB 16.12.2004.

54 EFSA Policy on declarations of interests, MB 11.9.07 –5.2., available on the Internet at <http://www.efsa.europa.eu/en/efsawho/doi.htm> (last accessed on 5 April 2011).

of each meeting and designed to capture any interest that may have been identified in the short time frame between the submission of the SDoI and the start of the meeting. The ODoIs and the decision made on the declaration, if any, are recorded in the minutes of the meeting. This system may be viewed by some critics as burdensome on the persons concerned and on EFSA's structure; but, with its continuing consultation of scientific experts and when performed through a dedicated IT software which ensures a complete traceability, accessibility and transparency of any information inserted therein, it does allow EFSA to be constantly aware of any potential CoIs of its experts and to react swiftly to prevent their occurrence. EMA and the non-food SC committees limit their policies to ADoIs and ODoIs.

The core of any CoI policy rests with the screening of the DoIs and with the preventive and remedial measures resulting from that screening. A scientific advisory body might have a very sophisticated system for guiding its experts in the declaration but that would be pointless without an adequate screening of declared interests and the clear provision of measures to prevent the occurrence of CoIs. As I have argued *supra*[55], I am indeed of the opinion that a system based on the mere disclosure of potential CoIs probably would not deliver tremendous results.

For screening the DoIs, both EFSA and EMA apply a system of three identified risk levels, to be assigned to each relevant interest declared by scientists. The three levels reflect an increasing intensity or seriousness of the potential conflict identified by the staff performing the screening. Depending on the results of the DoI assessment, and if a CoI is identified, the extent of the participation of each expert is evaluated by the head of the unit supporting the relevant panel or working group and subsequently by the relevant Director in EFSA, or in EMA by the DoI assessment group (DIAG). The two schemes are rather similar except that the one adopted by EMA foresees a fine tuning based on several factors, whereas the one followed by EFSA always utilises the same assessment, with the possibility of obtaining waivers only when an alternative scientist with the same degree of expertise in a given area cannot be identified. The main difference between the two systems is that the former considers the fine tuning criteria (such as the availability of the expert) as part of the screening aimed at assigning a level of potential conflict[56], whereas the latter considers the screening and the award of waivers as two separate processes: first the interests are assessed and then, where appropriate, a waiver may be granted if the corresponding requirements are met. Similarly, albeit in a simplified fashion, the Commission's non-food SCs' rules of procedure contain a dedicated chapter on independence[57], including descriptions of the practical implications resulting from the identification of potential CoIs.

EFSA, EMA and the non-food SCs have developed a DoI form along similar lines, covering a whole variety of interests, ranging from the holding of financial interests to intellectual property rights, advice activities and consultancies. The definitions provided in the three policies are not identical, although they appear to be compatible with each other. One major difference can be identified for financial interests, where EMA has identified a *de minimis* clause with a threshold of €50,000[58]. Below that value, EMA assumes that a financial interest held by one of its experts will not result in a potential conflict of interests. By way of contrast, both EFSA and the Commission's non-food SCs do not adopt such a threshold, thereby retaining a high degree of discretion on very low financial interests declared by their experts.

In EMA and in the non-food committees, any failure to submit a complete annual or specific DoI in accordance with the request received from the competent secretariat will make it impossible for that expert to attend the relevant meeting. In addition, EFSA's current measures include the possibility to propose to the Management Board the revocation of a Member's or expert's nomination in case of failure to meet any of the obligations stipulated in its internal rules.

If the DoI is submitted, experts may be barred from participation in the meeting(s) in which certain issues are discussed, from drafting certain outputs, and/or from voting on those outputs, depending on

55 See *supra* para. III.

56 EMA Procedure on the handling of conflicts of interests for EMEA scientific committees members and EMEA experts, EMEA/H/5475/04/Rev1 Final, London, July 2006, at p. 8, available on the Internet at <http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500005216.pdf> (last accessed on 5 April 2011).

57 See Article 14 of and Rules of Procedure of the Scientific Committees on Consumer Safety, Health and Environmental Risks and Emerging and Newly Identified Health Risks, available on the Internet at <http://ec.europa.eu/health/scientific_committees/docs/rules_procedure_en.pdf> (last accessed on 5 April 2011).

58 The US FDA applies the same threshold, albeit in US dollars; see U.S. Food and Drug Administration, August 2008, Guidance for the Public, FDA Advisory Committee Members, and FDA Staff on Procedures for Determining Conflict of Interest and Eligibility for Participation in FDA Advisory Committees, available on the Internet at <http://www/fda/gov/ohrms/dockets>, at p. 8 (last accessed on 5 April 2011).

the level of potential CoIs identified by the competent staff. Interestingly, both EFSA and EMA have laid down in their rules of procedure clear guidance regarding which preventive or remedial consequence should result from each interest declared by the expert.

However, that aspect is missing in the rules of the non-food SCs. In our opinion, the absence of this kind of provision risks undermining the efficacy of the system, allowing an excessive degree of discretion from the side of the competent services.

4. An effort to mitigate the negative consequences of the EFSA/EMA systems: The concept of hearings

We have seen that EFSA, EMA and the Commission apply rather stringent CoI policies and how these may have repercussions on the availability of scientific experts of adequate level[59]. In order to reconcile the requirements of strict independence with the business needs linked to the importance of gathering the most recent and qualified scientific expertise, EFSA's and EMA's policies allow for the possibility of having certain experts contributing their personal knowledge to the scientific committee and panels in the context of a hearing. Hearings are usually organised to enable the two Agencies to gather the views of people who are known to have conflicts of interest with the matters on the agenda. By setting up an *ad hoc* hearing, disclosing the conflict of interests and the fact that the expert in question is offering what is likely to be a biased view, EFSA and EMA aim to exploit all the knowledge available on the market while trying to preserve their intellectual freedom and independence by creating a virtual firewall that cannot be breached by experts at hearings. In effect, to avoid that such experts could be in a position to unduly influence the final output of the advisory bodies, both policies foresee that experts at hearings cannot draft the outputs, cannot take part in the process leading to the adoption of those outputs, cannot vote and in general cannot do anything else other than provide the information they were requested to submit.

In a world where companies hold patents for everything and seldom grant the authorisations needed by scientists to carry out independent studies without retaining powers of veto on the results of those studies, and where the interaction between scientific expertise and private interests is the norm and no longer the exception, the approach outlined above is in my view both pragmatic and realistic while not compromising the effectiveness of the CoI policies of the scientific bodies.

V. Some international flavour: The case of the US Food and Drug Administration's advisory committees

Having examined the policies on CoI put in place by several institutional actors in the European Union, we now turn to see if the North American counterpart to those agencies can serve as a benchmark with reference to the limited scope of the present work.

It is widely known that the FDA has adopted a system similar to the non-food scientific committees operated by the European Commission[60]. FDA's advisory committees provide independent expert advice to the agency on scientific, technical, and policy matters relating to the development and evaluation of FDA-regulated products. The decision-making process is very similar: although the advisory committees composed of scientific experts provide recommendations to FDA, it is only the FDA itself which takes the final regulatory decisions[61]. Regarding the food and feed sector, we can therefore conclude that the current governance of the FDA resembles the one in force in the Union prior to the "mad cow disease" crisis[62].

59 See *supra* para. III.

60 For a more detailed explanation of the differences and similarities of the two scientific bodies, and of their advisory committees, see Stephanie Tai, "Comparing Approaches Toward Governing Scientific Bodies on Food Safety in the United States and the European Union", 2 *Wisconsin Law Review* (2010), pp. 627–671.

61 See, e.g., Dov Fox, "Safety, Efficacy, and Authenticity: The Gap between Ethics and Law in FDA Decision Making", 4 *Michigan State Law Review (2005)*, pp. 1135 *et sqq.*; Joseph H. Golec, John A. Vernon, Randall Lutter and Clark Nardinelli, "FDA New Drug Approval Times, Prescription Drug User Fees, and R&D Spending", *AEI-Brookings Joint Center Working Paper* No. 06–21 (September 2006); Lewis A. Grossman, Richard A. Merrill, and Peter Barton Hutt, "FDA Jurisdiction: A Matter of Definitions", in Peter Barton Hutt, Richard A. Merrill, and Lewis A. Grossman (eds), *Food and Drug Law: Cases and Materials*, 3rd ed. (New York, NY: Foundation Press 2007).

62 European Parliament, "Report on alleged contraventions or maladministration in the implementation of Community law in relation to BSE, without prejudice to the jurisdiction of the Community and national courts", Rapporteur, Manuel Medina Ortega, 1997, available on the Internet at <http://www.europarl.europa.eu/conferences/19981130/bse/a4002097_en.htm> (last accessed on 5 April 2011); Patrick Van Zwanenberg, Erik Millstone, "BSE: A Paradigm of Policy Failure", 74 *Political Quarterly* (2003), p. 36; Keith Vincent, "Mad Cows' and Eurocrats – Community Responses to the BSE Crisis", 10(5) *European Law Journal (*September 2004), pp. 499 *et sqq.*; Ellen Vos, "EU Food Safety Regulation in the Aftermath of the BSE Crisis", *Journal of Consumer Policy* (2000), pp. 227 *et sqq*.

However, while the governance in place is similar to the one adopted by the Commission for its internal scientific committees, one cannot say the same about the FDA guidance on conflict of interests[63]. Reading this document, one cannot avoid the impression that the FDA attributes a great importance to the concept of waivers. This impression is reinforced by the fact that the former title for the guidance was "FDA Waiver Criteria 2000", which highlighted even more the centrality of the concept of waiver in the framework of the FDA policy on CoI and which consented to a more frequent use of waivers than its most recent version, adopted in 2008[64]. Even with the adoption of the amended guidance in 2008, however, waivers remain an important feature of the FDA CoI policy. They are granted to those experts for whom the occurrence of the conflict was not already excluded *ex lege* by a rather generous process[65]. Indeed, not only the FDA foresees a broader recourse to waivers but, in screening relevant interests, it also follows a decision tree that effectively excludes several, if not most, of those that would be considered as potential conflicts under the systems adopted by EFSA and EMA, and probably also by the European Commission.

At first glance, a difference between the EU and FDA policies on CoIs is that the latter's concept of relevant interest potentially leading to a conflict is limited to financial interests, while, as we have seen, the former considers a much broader set of activities could constitute a relevant interest. This is also due to the extremely specific legal basis under which the FDA operates[66]. Nonetheless, the implementation of those provisions by the FDA has almost annulled that dissimilarity, as the agency has interpreted the concept of financial interest in a broad manner, thereby including also employment, consultancy – advice, patents *et cetera*.

One major discrepancy between the US and the EU systems consists in the fact that, according to the North American guidance, a potential conflict of interests may arise exclusively in the context of meetings concerning particular matters, such as the assessment of substances and products[67] and where the meeting would have a direct and predictable effect on financial interests. For meetings in which more general matters are discussed or when it is not possible to identify a direct and predictable effect, no discretion is left and no conflict of interest is deemed to occur. By way of contrast, in the EU systems briefly analysed above, conflict of interests can also occur in meetings in which general horizontal matters are tabled. The nature of the matters to be discussed at the meeting will be taken in due account at the moment of deciding the intensity of a potential conflict, and therefore also of adopting the most appropriate preventive measure but will not result in the impossibility to identify a CoI.

Furthermore, when an interest passes the tests mentioned above and possesses all the characteristics considered to constitute a potential conflict of interest, a set of regulatory exemptions are applied by the FDA, with the consequence that those interests *a priori* are not labelled as conflicts. Regulatory exceptions are cases when financial interests have been determined by the Director of the Office of Government Ethics to be too remote or too inconsequential to affect the integrity of the services of the Government officers or employees[68].

Finally, as we have already seen, when an interest is considered as a conflict, a waiver may be granted when the expert in question is supposed to provide "essential expertise" to the relevant advisory committee. In order to pass the "essential expertise" test to obtain a waiver, it has to be demonstrated that this expertise cannot be obtained through alternative means. It is indeed clear that, even if some expert possesses some knowledge or expertise essential to the relevant advisory committee, there is no need for a waiver if the same expertise can be provided by another expert. That step is also a fundamental part of the DoI policies adopted by EFSA and EMA.

Although it cannot be denied that EMA and EFSA's policies also currently foresee the possibility of

63 See U.S. Food and Drug Administration, August 2008, Guidance for the Public, *supra* note 58.

64 See US Food and Drug Administration, August 2008, Guidance for the Public, *supra* note 58, at p. 7.

65 Indeed, also Stephanie Tai, "Comparing Approaches", *supra* note 60, at p. 40, finds that "exceptions to the conflict of interest provisions undercut any actual impact they might have on removing biased experts".

66 18 U.S.C. 208(b)(3) and section 712(c)(2) of the Federal Food, Drug, and Cosmetic Act. Section 712 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379d-1) was added by the Food and Drug Administration Amendments Act of 2007 (FDAAA), Pub. L. No. 110-85, sec. 701.

67 See U.S. Food and Drug Administration, August 2008, Guidance for the Public, *supra* note 58, at pp. 9–11.

68 Such as previous hospital employment and use/prescription of medical products for patients for advisory committee matters concerning medical products (5 CFR 2640.203(i)) and certain non-voting representative members of FDA standing technical advisory committees; see U.S. Food and Drug Administration, August 2008, Guidance for the Public, *supra* note 58, at p. 15.

granting a waiver under stringent conditions and requirements, the statistical relevance of these exceptions in the case of the Union agencies is on a completely different scale. While in the case of FDA the presence of an expert with a CoI and a waiver seems to represent the norm[69], this would be a real exception for Union agencies such as EFSA, as it is possible to infer from the scientific outputs and the meeting minutes disclosing CoIs and preventive measures taken by EFSA. This has been noticed and to some extent remedied by the US Congress, which enacted section 701 of the FDA Amendment Act (section 712 of the Act). That Act, in addition to establishing a new conflict of interest prohibition and standard for assessing waivers, encourages the FDA to focus its efforts on recruitment of advisory committee members with *fewer* potential conflicts of interest, and caps the numbers of waivers that the agency may grant in a given year. However, even that remedial action by the legislator will be enacted in a progressive manner, as it stipulates that by 2012, the FDA may issue waivers at a maximum rate of 75 % of the (considerable) rate issued in 2007[70].

In my opinion, the points examined in this paragraph identify the policies on conflicts of interest in EFSA and EMA as far more stringent than those currently implemented by the US FDA.

VI. Conclusions

In the preceding paragraphs, I have briefly analysed the current policies on CoI as currently implemented by EFSA, EMA, the non-food scientific committees and the FDA. We have seen how the policy currently implemented by EFSA seems to provide the most complete and stringent framework. We are now in a position to conclude that the main risk in designing a valid CoI Policy is the inherent difficulty in ensuring that it is correctly implemented with particular regard to the possibility of sanctioning breaches and omissions by concerned individuals. As far as the EU policies are concerned, there is no transparent procedure in place to sanction those who breach the rules, with the notable exception of EFSA.

We have seen how a starting point for all the policies consists in the impossibility to consider all interests declared by a concerned person as a CoI. As a matter of fact, in order to be considered experts on a certain subject, scientists should indeed have an important number of interests in that area. Therefore, the more stringent the independence requirements are, the fewer the experts who will qualify for membership of the relevant scientific bodies or the lower the level of expertise that those bodies should be prepared to accept. It follows that more stringent rules, heavy procedures and invasive controls may lead to difficulties in finding the appropriate level of expertise or in de-motivating potential candidates or experts serving their mandate. Furthermore, when imposing independence requirements on regulatory or scientific bodies, the costs of those policies should be considered by the legislator, in both bureaucratic and budgetary terms. One cannot ignore the fact that these policies result in burdensome administrative procedures for the persons concerned and that a sizable investment of human and financial resources must be made by the relevant bodies in order to implement them. For instance, in the USA and in Canada almost every State and administration has access to special Ethics Committees and Monitoring Bodies. Menzel estimates that "nearly 15,000 full and part-time Ethics Officials can be found in the Federal Executive branch."[71] In other words, building up professional ethics cannot be done without the allocation of a considerable budget[72].

Hence, it is difficult to avoid a problematic question: is it reasonable to impose on scientific experts and staff members such a heavy burden aimed at the prevention of CoI when the same criteria are often

69 Peter Lurie, Cristina M. Almeida, Nicholas Stine *et al.*, "Financial Conflict of Interest Disclosure and Voting Patterns at Food and Drug Administration Drug Advisory Committee Meetings", 295(16) *JAMA* (2006), pp. 1922 *et sqq.*, who found that at least one conflict of interests was declared for at least one advisory committee member or voting consultant in 73 % of the meetings taken into account in that study; Katherine A. McComas, Linda A. Sherman, "Conflicts of Interest and FDA Advisory Committee Meetings: A Study of Public Attitudes and Opinions", available on the Internet at <http://www.fda.gov/oc/advisory/acstudy0904/JIFSANresearch.html> (last accessed on 5 April 2011); Robert Steinbrook, "Financial Conflicts of Interest and the Food and Drug Administration's Advisory Committees", 353 *New England Journal of Medicine* (2004), pp. 116–118; and Center for Science in the Public Interest, "Twisted Advice: Federal Advisory Committees Are Broken", 2009, available on the Internet at <http://www.cspinet.org/new/pdf/twisted_advice_final_report.pdf> (last accessed on 5 April 2011); for a stark criticism of the alleged lack of independence of the FDA's advisory committees see Jason Juliano, "Killing Us Sweetly", *supra* note 37.

70 See U.S. Food and Drug Administration, August 2008, Guidance for the Public, *supra* note 58, at p. 6 and Susan F. Wood, Kristen L. Perosino, "Increasing Transparency at the FDA: The Impact of the FDA Amendments Act of 2007", *Public Health Reports* (2008), pp. 527 *et sqq.*

71 Donald C. Menzel, *Ethics Management for Public Administrators* (New York/London: 2007), at p. 15.

72 See C. Demmke *et al.*, "Regulating Conflicts of Interest", *supra* note 11, at p. 115.

not applied to senior officials and politicians who are making the final, binding decisions[73]? Do these policies make still any sense when the phenomenon of revolving doors occurs almost everywhere in the regulatory panorama? I believe it does[74] and that is linked to the main reason behind the creation of scientific advisory bodies which, in my opinion, is still the only argument that justifies their existence: the provision of *objective,* and hence *independent,* scientific advice.

At stake is not only the credibility of a handful of scientific advisory bodies, but also the very authority of science in the regulatory arena. Indeed, the very public who after the Enlightenment has elevated scientific reasoning to the highest altar of reliability, if deluded by the objectivity of its "ministers" could suddenly decide that a different approach to regulatory measures might be equally rational, to the detriment of science based standards.

73 *Ibid.*, at p. 142.

74 Although some empirical research allegedly shows that the results of the discussions at advisory committees do not have an impact on the shares of affected companies, as regards horizontal matters, Joseph H. Golec, and John A. Vernon, "What's the 'Interest' in FDA Drug Advisory Committee Conflicts of Interest?" (April, 24 2009), *NBER Working Paper* No. w14932, available on the Internet at <www.ssrn.com> (last accessed on 5 April). In our opinion those findings do not come as a surprise, if one considers that undertakings are affected by the opinions issued by advisory committees on regulated products, not on general matters such as guidelines and other opinions not directly linked to products.