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Governing by Values. EU Ethics: Soft Tool, Hard Effects

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Abstract The institutionalization of ethics and the direct influence of politics on how ethics bodies frame their opinions have been widely recognized and explored in the last few years. Less attention has been paid to what kind of normative instrument "ethics" as an institutional phenomenon has become in the State under the rule of law, and which institutional powers it has depended on. This paper analyzes the rise of ethics in the European Union context, where ethics, constructed as an isolated set of values, has been exploited for its symbolic capacity to evoke citizenship, has become quite formalized as to certain features, and has acquired the potential to redefine the traditional divisions of powers in the State under the rule of law.

Keywords EU ethics · Technology assessment · Soft normativity · Subsidiarity · State under the rule of the law

A Soft Regulatory Tool Called "Ethics"

The vision of the ethics undertaking as "the determination, so far as that is possible, of what is right and wrong, good and bad, about the scientific developments and technological deployments of biomedicine" (Callahan 1999, p. 276) has accompanied and justified the rise and role of ethics as a means to improve the rationality and the rationale of public decisions in the domain of life sciences and technology. In this narrative, ethics has been regarded as a "neutral" normative tool, endowed with the potential to speak for rationality. The institutionalization of ethics through

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ethics commissions and committees, namely appointed bodies with consultative and administrative functions, has been seen as the beginning of the blurring of boundaries between a supposedly rational programme and a practice to implement political will (Galloux et al. 2002, p. 136). In fact, the creation of ethics committees and commissions as a method for decision-making produced a radical transformation of the fundamental needs for a public ethical discourse in modern democracies, namely a more intense and open dialogue between science and society (OTA 1986; Jecker et al. 1997; Stevens 2000).

This change, taking place in the U.S. in the 1970s and in Europe in the late 1980s, has been seen by several critics as problematic (Galloux et al. 2002; Eckenwiler and Cohn 2007): seemingly, it stopped an initial public debate, crystallizing the framing of relevant issues, and heavily reducing ethical inquiries and discussions to an expression of the intellectual establishment.

Though ethicists have been often in denial about this bureaucratic drift—and have at times dismissed more democratic proposals of decision-making about public values (Levitt 2003; Jasanoff 2005; Wynne et al. 2007) as belonging more to politics than to ethics (Ashcroft 2003, p. 12)—the increasing politicizing of ethics (Powers 2005; Brown 2009) has been widely discussed in recent years both in the U.S. and the European contexts as it has become apparent that so-called "ethical" positions adopted by governments represented the direct expression of their political views. Whilst this phenomenon has been interpreted by some ethicists as a degeneration of ethics and bioethics endeavour (Pellegrino 2006), according to other opinions, "bioethics has always been a biopolitics and the political dimension is only now coming into relief for bioethicists" (Bishop and Jotterand 2006, p. 205). In this perspective, ethics is "implicitly designed" (Evans 2006, p. 214) for renewed forms of technocracy (Bauer and Gaskell 2002; Jasanoff 2005; Evans 2006; Dodds and Thomson 2006; Elliott 2007) and clearly framed for policy goals, but its methodological reference is to moral expertise and to academic philosophical norms.

However, if the criticism of bureaucratized ethics as a governmental instrument—more of government than of governance—is now widely recognized, still under-examined are the questions about what kind of "normative tool" "ethics" has become, namely what is its statute within the formal sources of normativity in the State under the rule of law.

The evolution of regulatory needs in the so-called knowledge society has given rise to new forms of normativity besides the traditional features of the law, and "ethics" is one of these (Wynne et al. 2007), but its statute is unclear.

In what follows, "ethics" in quotes is characterized as something different from ethics (no quotes). This is precisely the idea that, in moving from academic to institutional settings, moral thought has been radically reinvented and reframed. Though still displaying a theoretical and objective aura, "ethics" has acquired a quite established soft regulatory status consisting in the production of "valid ethical knowledge" that legitimately enters in the legislative process as a datum no further exposed to debate. Thus, in talking about "ethics" I will not refer to specific theoretical approaches to ethics. Instead, I will analyze the characteristics that "ethics" as a "soft regulatory tool" has acquired over time in the EU and its relationship to the process of European integration (Christiansen et al. 1999;

Trubek et al. 2005, p. 14), by looking at how institutional facts and norms generated each other (Jasanoff 2005).

A distinction has to be made between the committees dealing with research ethics and clinical trials and ethical commissions and committees, mostly at national or supranational levels, appointed to provide political and policy inputs on ethical matters (Dodds and Thomson 2006). Research ethics committees have been also widely discussed in critical terms, and some concerns about them equally apply to ethics commissions—e.g. as appointed expert bodies and as regulatory more than advisory bodies (McGuinness 2008). However, their main role, at local or regional level, is that of examining protocols involving human beings and of standardizing already defined good clinical practice.

Here I will analyze ethics primarily as expressed by national and supranational bodies—thus as a formalized procedure to define public values for policy purposes—focusing on the specific political role that ethics has played in the construction of Europe. In this respect, the case of European Union (EU) ethics is quite unique. In fact, though the rise of ethics as a normative source has also been examined in the U.S. context (Kelly 2003; Leinhos 2005; Eckenwiler and Cohn 2007), ethics has been assigned peculiar normative meanings and functions, as historically its rise in the European Communities context has been strongly connected to the shift from the primarily economically and commercially based Rome Treaties to the construction of a more integrated political society.

The term "soft law", originally created in the 1930s by Lord McNair to refer to "non-treaty law" in the domain of international law, has since been increasingly applied to "rules of conduct which, in principle, have no legally binding force but which nevertheless may have practical effects" (Snyder 1993, p. 2), such as guidelines, standards, recommendations.

The term has thus been extended to a large number of new practices existing in the penumbra of law, whose common thread "is that while all have normative content they are not formally binding" (Trubek et al. 2005). Both in the international and European contexts, lawmaking has become a complex and hybrid activity, with descriptions and prescriptions merging together in several ways. The phenomenon is so extensive that, according to some commentators, the EU is experiencing an "era of soft law" (Flynn 1997, p. 2).

"Ethics" is not mentioned in the extended literature dealing with the EU "soft law turn" (Cini 2001; Peters and Pagotto 2006). Ethics opinions are formally classified as expert advice, namely as documents aimed at providing knowledge and information to EU institutions. From the normative point of view, ethics, as the domain of values that legislation may touch on, is a prerogative of Member States. However, in both these dimensions, the characteristics that ethics reveals and the functions that have been attached to it make it comparable to a soft normative tool. Also, if the crucial criteria to define soft law are "the effects of the activities in the spheres of law and politics rather than the source of the activities" (Mörth 2005, p. 9), ethics can be properly understood as soft normativity.

The European Parliament has become quite critical of these "informal" normativities—ethics included (EP 1997)—and in 2007 has adopted a resolution to stop the proliferation of soft law documents (EP 2007). In its Resolution the

Parliament, while observing that "'soft law' does not provide full judicial protection" and that "there is currently a dispute as to how to make the regulatory function of the European Union more efficient with regard to both 'soft law' and 'hard law'", recalls that "the European legal order is based on democracy and the rule of law" and that "this means that the EU institutions may only act in accordance with the principle of legality". The wide application of soft normative instruments represents a challenge to the law as a defined and transparent process involving citizens' representatives, and the soft legal tools used by the executive power—often through appointed committees of experts—lack these warrants.

As to "ethics" and its problematic nature, two issues merge together: the issue of its normative status and the issue of the institutional power making use of it.

My reflections on this double issue will proceed as follows. I will firstly consider the broad process of construction of "ethics" as an isolated item in the assessment of the social aspects of innovation, referring to the shift from technology assessment to ethical implications of new technologies. Secondly, I will look at the rise of "ethics" in the European Communities in the context of biotechnology and at the beginning of the process of European political integration. I will then analyze the structural characters that EU "ethics" has acquired through its institutional consolidation. I will specifically explore the main feature of "ethics", namely subsidiarity (the power of national governments to determine their own values) through the approval of a recent regulation on therapeutics products based on human tissues and cells (Regulation 1394/2007)—considered as a major EU act of biopolitics (Flear 2009). This case shows how "ethics" has been given a "quasi-legal content" allocated to Member States and, to some extent, to the Commission (on which the European Group for ethics depends), but totally alienated from the Parliament, representing citizens and the legislative power. Here, "ethics" has been played to implicitly redefine the boundaries of the State under the rule of law—with more powers for the executive branch and less for the legislative.

As most of my analysis focused on the historical rise and consolidation of ethics—although the case for the approval of Regulation 1394/2007 is quite recent—in my conclusions I will consider, though briefly, the most recent "ethical" developments in emerging technologies (as nanotechnology), where important efforts of democratization and inclusiveness have been deployed.

"What Makes an Issue an 'Ethical Issue'?": Ethics vs. Technology Assessment

A relatively unexplored issue in the analysis of the beginnings of "ethics" as a soft regulatory tool is the comparison with the concept and practice of technology assessment (TA) (Paula 2008), especially as defined in the early 1970s by the U.S. Congress Office of Technology Assessment (OTA) (Kunkle 1995; Bimber 1996).

Technology assessment and "ethics" are historically characterized and connected by the rise and fall of the former and the rise and ongoing expansion of the latter. They also represent two different strategies to make public sense of the multiple fact-based and value-based dimensions of technological innovation.

The need to foresee and assess the potential impacts of new technologies in the regulation and governance of biosciences had led, initially in the U.S., to experimenting in the early 70s with a variety of consultative/deliberative committees (OTA 1986). Though during the 1970s the U.S. government set up three different commissions to deal with biomedical research issues, the first broad attempt to explore the social, legal and political environment for technology was related to the (controversial) establishment, by the U.S. Congress in 1972, of the OTA[1] which served the Congress until 1995, when—after a tormented existence always challenged by accusation of being too politicized—it was discontinued by a Republican-sponsored funding cut (Kunkle 1995; Bimber 1996).

The relevance of OTA history here concerns what kind of "instrument" technology assessment was and the role it played. The need for such an office was justified by a variety of reasons. The increasing necessity to legislate in scientific and technological domains, the potential risk connected to environment pollution, and the new experiments with genetic engineering had left Congress with the desire to have information not coming directly from the government and allowing the legislative branch to counterbalance the executive power. In other words, the need for an independent agency serving the Congress was intimately related to the attempt to balance the different branches of the State by strengthening the legislative branch and by offering it a source of knowledge to widen the discussion on policy options.

It is remarkable how technology assessment was defined in the OTA Act. "(Congress has to) equip itself with new and effective means for securing competent, unbiased information concerning the *physical*, *biological*, *economic*, *social*, *and political effects* of such applications" (TA Act 1972, SEC 2 (d)) (emphasis added). The list of what should be included in the assessment ranged from physical and biological effects to economic, social, and political aspects. Ethics per se was not listed as an issue clearly identified and isolated from the other general evaluative domains. Technology assessment was thus portrayed as an integrated methodology connecting all scientific and social potential outcomes.

Only in the 1990s did ethics attract major institutional attention as a separate requirement. In 1993 and in 1995, respectively, OTA and the Institute of Medicine (IOM) were asked to give their opinions about the opportunity to set up a permanent ethical body (OTA 1993; IOM 1995). The answers provided by the reports are enlightening for what happened later. In analyzing the issue and in exploring the policy options, OTA expressed some perplexities about the U.S. federal institutions appointing a permanent ethics commission. "Does the United States need a government sanctioned body, or bodies, dedicated to deliberating about the ethical issues raised by biomedical research, medical innovation, and health care?" (OTA 1993, p. 38). Why OTA was rhetorically asking this question was made clear through the analysis of the history of past ethical activities, and of the critical elements for success or failure of ethical bodies. "Absent from the list," OTA

[1] *Office of Technology Assessment Act, Public Law 92–484*, 92d Congress, H.R. 10243, October 13, 1972.

warned, "is politics, since creating a new body is inherently political, and the system will affect each factor" (OTA 1993, p. 38).

The same kind of criticism OTA had been exposed to during its own existence, that of being too politicized, was here reversed as a matter of concern toward a potential ethical body.

Two years later IOM, an independent arm of the National Academy of Sciences (NAS) associated with the government since 1863 as an advisory body on matters of science, was required to address the same problem. After having systematically assessed the various social processes through which ethical and social issues in medicine and biotechnology had been debated, IOM answered by identifying and isolating "those characteristics that make an issue an *ethical* issue and the circumstances under which it is determined that an ethical issue should be publicly deliberated" (IOM 1995, p. 1, italics originally in the text). Though recognizing that ethical judgments are all "judgments grounded in values", and that "these issues arise during the deliberation and resolution of nearly every public issue" (IOM 1995, p. 1), IOM helped purifying ethical issues from other kinds of social problems, thus framing the very concept of what an *ethical* issue is and which requirements an ethics body should satisfy.

In September of 1995, OTA was discontinued, and in October of 1995 the National Bioethics Advisory Committee (NBAC), the first permanent U.S. governmental ethics body, was established by the U.S. President.

Though very limited, these few elements may provide some hints about the passage from a complex form of assessment of the potential implications of technological changes to a more simplified vision of the potential outcomes, reductively constructed in terms of ethical implications. A passage accompanied by the shift from advising a parliament to shaping opinions aimed at legitimizing governmental decisions.

Clearly a policy tool, TA seemed to represent a more complex and integrated approach to social aspects of new technology, and much less controllable in its approaches and contents. Because its competence over both the framing of science and social issues had not been previously limited and defined—what instead happened later with ethics—its domain of analysis remained wide and open. During the OTA experience TA was described as "whatever OTA is doing at the moment" (Bimber 1996, p. 94), an undefined policy tool perceived as holding an unauthorized political power. This is why throughout its life OTA made the constant attempt to perform a politics of neutrality (Bimber 1996).

Also, since its very historical and theoretical beginnings TA—that, wherever it has been institutionalized, has also been associated with Parliaments—has raised the necessity of opening up to forms of public participation (Coates 1975), and has constantly evolved in this direction.

As to OTA, its capacity to provide information to complement the more narrowly defined objectives of the executive branch lost the battle when confronted with a different kind of advice: ethics. Though directly pointing at values underlining policy-making, ethical advice was constructed as a more expert and neutral "ethical knowledge" and advertised as a "depoliticized" way to make politics.

The Office was never restored in the U.S.,[2] but it represented an influential example for several European countries[3] and also for the European Communities, launching "a 'technology assessment' movement" between the 1970s and the 1990s (Bimber 1996, p. 47). In 1978, the European Commission approved its first Forecasting and Assessing for Science and Technology (FAST) (1978–1983)[4] with the objective of contributing to the development of a coherent long-term policy on science and technology, and later the Scientific Technology Options Assessment (STOA).[5] But in the meanwhile the EU was already starting its ethical experience with the inbuilt potential for a political concept of Europe. Since then, TA as an institutional instrument used by Parliaments has regretfully become a residual tool with a marginal position in the explorations of policy options (Smits et al. 1995).

The history and contemporary evolutions of the different bodies in charge of TAs would require a deeper and dedicated analysis, also with regard to their theoretical and practical relationships with ethics bodies. My limited intention here is to show how the transition from TA to "ethics" as different ways of making sense of technoscientific innovation had major political meanings and implications. These are: the framing of a well defined and more controllable decision-making instrument, the passage from an explorative perspective of value-laden options to the normative identification of "the" ethical aspects, and the shift from a parliamentary advisory system to a governmental one.

The Political Construction of "Ethics" in the EU

Ethics as an institutionalized phenomenon was started in the European context in the field of biotechnology and in connection with biotechnological development. Ethics as a bureaucratized concept has followed, similarly as in the U.S., the identification of "what makes an issue an ethical issue". In April of 1991, a few months before the first European ethics advisory body was appointed, the European Commission addressed the issue of ethics in a Communication to the Parliament and the Council. The title itself, *Promoting the Competitive Environment for the Industrial Activities Based on Biotechnology within the Community* (CEC 1991), made very clear why and where ethics was needed. In discussing the key elements for a successful implementation of biotechnology in Europe, the Commission discarded the proposals supporting a broad social assessment of new biotechnology, adding the concern for social benefits to the established criteria of safety, quality and efficacy (the so-called fourth hurdle) (Wynne et al. 2007, p. 84). The main

[2] The demise of OTA was perceived in Europe as a sign of concern and a warning against the risk of TA becoming obsolete. Where it survived, Parliamentary TA evolved towards more democratic ways of decisions.

[3] See the European Parliament Technology Assessment, http://www.eptanetwork.org/EPTA/what.php. Accessed August, 2009.

[4] See http://cordis.europa.eu/search/index.cfm?fuseaction=prog.document&PG_RCN=176328. Accessed August, 2009.

[5] *Scientific Technology Options Assessment* (*STOA*) *Rules*, adopted by the Bureau of the European Parliament on 19 April 2004, PE 343.325/BUR.

reason against a wide public discussion of biotechnology was envisaged by the Commission in the "imperative" to "avoid a situation creating uncertainty (which) could result in a diversion of investment and could act as a disincentive for innovation and technological development by industry" (CEC 1991, p. 8).

The preamble that "decisions have to be based upon objective assessments using clearly identified criteria" aimed at introducing a new dedicated ethics body. More importantly, the Commission directly associated "ethics" with the importance of avoiding an uncertain and confused public debate: "This is important for industry as such confusion can adversely influence the whole climate for industrial development of biotechnology" (CEC 1991, p. 11).

The announcement of the creation of a European ethics body merged with a first definition of the categories of values that would have entered European ethics. "The questions arising in public debate belong to distinct categories and debate will continue to be ill-defined (and for public policy purposes, ineffectual) so long as a clear differentiation is not made between these issues" (CEC 1991, p. 11). The issues waiting for differentiation were therefore framed and classified as ethical considerations relating to human life and as "other values", namely animal welfare, environmental issues, health and safety related issues, transparency, and socio-economic impacts (the last one already allocated to FAST programmes).

The Communication of 1991 was straightforward in spelling out the direct connections between the uncertainties surrounding biotechnology, industrial development, and ethics. But after the first European ethics body was created, the language of the Commission suddenly changed radically, shifting from the need for market normalization and legitimation to an *ad hoc* narrative about ethics as a way to "represent" citizens' values, to bring society closer to European institutions and to establish the European identity.

In November of 1991, with the establishment of the Group of Advisers on the Ethical Implications of Biotechnology (GAEIB) "ethics" as a bureaucratic component was incorporated in the decision-making process—originally in relation to biotechnology, and later for all areas of application of science and technology.[6]

The integration of ethics in the EU procedures is officially presented as a broad political factor in the shift from the ECSC Treaty of 1953 and the Single Market of 1991 to the Treaty of Maastricht in 1993, when "a new phase of the European integration began: to build an ever-closer European Union".[7] According to the Commission, despite ethics and cultural values are predominantly regulated on the national level and follow the principle of subsidiarity, European legislation necessarily touches on the issue of ethics.

"That is the role of the Group of advisers on the ethical implications of biotechnology. In setting it up the European Commission has highlighted its desire to integrate Europe's science and technology in a manner that serves the interests of European society and respects the fundamental rights of every European citizen.

[6] *Commission Decision on the renewal of the mandate of the European Group on Ethics in Science and New Technologies*, 11 May 2005, (2005/383/EC).

[7] This page, as others listed below, exists now only in the Internet Archive Wayback Machine: http://web.archive.org/web/20030418165425/http://europa.eu.int/comm/research/science-society/ethics/research-e-legislation_en.html. Accessed August, 2009.

(…) European integration must mean more than establishing a single market; progress in science and technology must be given a human, social and ethical dimension, otherwise European citizenship cannot be established".[8]

Ethics has thus become essential to frame the idea of European citizenship. The roles of "ethics" included "to identify and define the ethical issues raised by biotechnology; to assess, from the ethical viewpoint, the impact of the community's activities in the field of biotechnology; to advise the commission, in the exercise of its powers, on the ethical aspects of biotechnology and to ensure that the general public is kept properly informed".[9]

The willingness to use ethics as a symbolic form of public involvement in decision-making seemed to emphasize the role of civil society in building the broader political community. But ethics has never been implemented accordingly. The identification of "the ethical values of all Europeans" has remained confined to the judgments of appointed expert committees.

In 1997, a few months before GAEIB's mandate ended, the European Parliament—that had initially supported the establishment of the ethics body—passed a Resolution partly critical of it, observing that GAEIB had paid too much attention "to the interests of research and not enough to the possible effects on society". Also the Parliament complained about not having been adequately involved in the discussion of ethical questions and in the appointment of GAEIB's members (EP 1997).

The new group replacing GAEIB, the European Group on Ethics in Science and New Technologies (EGE), was appointed in 1997 and its mandate was renewed in 2001 and 2005. EGE was given the broader mandate "to cover all areas of the application of science and technology" (CEC 2005a), but its role—to provide the Commission with high quality and independent advice on ethical aspects of science and new technologies in connection with the preparation and implementation of Community legislation or policies—would increasingly become that of an expert committee.

EU "Ethics": The Established Framework

Since its institutional start, EU "ethics" has been characterized by distinct features that have consolidated over time, composing a recognizable framework (Table 1). Some of these features can be similarly found in most existing "ethics" regulatory tools, others are more specific to the EU, revealing some structural elements of EU institutions.

Also, starting with its Action Plan on science and society of 2002 (CEC 2002) and White Paper on European Governance (CEC 2001), the European Commission—after the political and regulatory problems primarily caused by the disagreements existing in Member States about biotechnology, and by the so-called "public

[8] http://ec.europa.eu/european_group_ethics/archive/1991_1997/bilan_en.htm. Accessed August, 2009.

[9] http://ec.europa.eu/european_group_ethics/archive/1991_1997/organisation_en.htm. Accessed August, 2009.

Table 1 Characteristics of EU "ethics"

(a) Expertized and technocratic
Constructing ethics as expert knowledge in analogy with scientific expertise
De-legitimating citizens' ethical competence
(b) (E)Universality
Evoking European citizenship by establishing EU values
(c) Subsidiarized "ethics"
Strengthening national sovereignties
Legitimizing State-based ethics
(d) Verticality
Top–down ethics and top–down governance of ethics
(e) Outsourcing of values
Commissioning of values, pre-framing relevant questions, extracting values from the law
(f) "Ethics" as a criterion of demarcation
Using ethics to isolate the polity from the market
(g) "Ethics" as a procedural requirement
Ethics as a procedural step to legitimate legislation and access to research funding (Directives, FP7)
(h) "Ethics" as a mechanism to speed-up the law
Ethics as a way to make the legislative process faster

unease" with scientific innovation—launched a seemingly more open vision of the relation between science and society (reflected in the Framework Programmes), attempting to find ways to bring society closer to research through more participatory procedures. This "participatory turn" has produced some effects on the more recent emerging technologies searching for legitimation. I will comment on this shift in the final section. What I am going to describe in this section is instead what can be called, from an historical point of view, the "established framework" of ethics. Under this expression I wish to refer to the main distinctive characters that have shaped the European ethical identity, as an expression of the needs emerging at its beginnings and at the beginning of the political Europe, of the biotechnological context, and of the initial attempts to formally design ethics as a form of normativity different from the legislative and the regulatory ones—a sort of "advisory normativity".

Notwithstanding, as I will try to argue in the remaining part of this paper, there is more evidence that the features and role of ethics have not substantially moved away from this framework, and that ethics still represents more a way to avoid the legislative process on certain issues than a form of democratic involvement.

Expertized and Technocratic

Science and technology play a crucial role in the evolving normative landscape. They do not simply represent one among other tasks for policy and regulation but, within the concept of knowledge-based society as endorsed by the EU, they

represent a founding political principle providing both ends and means (Wynne et al. 2007).

The idea of science endorsed by the EU has not gone too far from the traditional image of the scientific community (Polanyi 1962; Merton 1968). In the domain of "ethics", the use of science as a methodological and regulatory model has lead to the adoption of committee procedures, in analogy with expert scientific committees, as supposedly producing the best informed and valid knowledge outcomes. The transfer of decision-making procedures from the scientific community to ethics has been part of the willingness to endow the public ethical discourse with more objectivity (Daston and Galison 2007) that should imply acceptability. Scientific expertise procedures have become the template for comitology procedures,[10] and ethics is one of these. In expert comitology procedures, both theoretical validation and bureaucratic legitimation seem to converge (Salter and Jones 2005; Larsson 2003). In the DG Research site presenting research on ethics, the European Commission referred to ethics as "the science of ethics",[11] i.e. "the scientific discipline dealing with the systematic reflection on ethical questions" (Paula 2008, pp. 12–13). Focusing on the solely "ethical" dimension of scientific and technological issues as opposed to the broad socio-political and economic ones represented a way to emphasize and rely on "the presuppositions of rationality upon which the debate is conducted" (Galloux et al. 2002, pp. 135–136).

This "ethics" construct, however, is anything but unproblematic. Firstly, although having loaded "ethics" with sophisticated scientific expertise as part of making it more "scientific", this transformation may be seen as contradicting the very nature of moral reasoning and its foundational connections with the State under the rule of law.

It may be questioned that morality may require, at least in its seminal meaning and goal, any specialized knowledge; and this would conflict with the basic need of theoretically providing all citizens with freedom and equality.

The most prominent modern moral traditions, still largely informing the European institutional ethical debates and documents, are the Kantian, the Benthamite, and the Habermasian philosophies—as the wide presence of the principles of autonomy and utility and, to some extent also the idea of discoursive rationality, show (Galloux et al. 2002; Paula 2008). In all these traditions the individual's capacity to perform moral reasoning represents a precondition in the construction of the "rational subject" legitimately participating in the social contract—an individual agent autonomously capable either of universalizing the maxim on which an action should be based or of calculating the consequences of one's action, or of sharing a rational discourse with others.

Being a "rational moral agent", i.e. to be endowed with the common rational capacity to perform moral reasoning, provides the explanatory and foundational background for all citizens to accountably participate in the social contract. In other

[10] Council Decision 1999/468/EC Council Decision of 17 July 2006 amending Decision 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission (2006/512/EC).

[11] http://ec.europa.eu/european_group_ethics/archive/1991_1997/bilan_en.htm. Accessed August, 2009.

words, ethical reasoning, where conceived of as a fundamental endowment for individuals' acting and making choices in societal life, constitutes an unavoidable basis and a precondition for equality, freedom, and participation in liberal-democratic societies. In this respect, the construction of ethical expertise has threatened "individual sovereignty" (Elliott 2007, p. 46) by removing from non-expert citizens their fundamental entitlement to perform moral judgments. Thus, institutionalizing expert "ethics" not only disempowers citizens but also delegitimizes them by discarding fundamental assumptions about individuals in the State under the rule of the law.

Legitimacy has been defined as "the capacity of the system to engender and maintain (citizens') belief that the existing political institutions are the most appropriate ones for the society" (Lipset 1959, p. 77). Expert ethics radically challenges this citizens' competence by reducing what can be socially legitimized to the limited notion of experts' legitimation.

According to Evans (2006), the ethical disempowerment of citizens may also explain why "ethics" has been largely a failure from the public point of view. The fact that the legitimation of bioethics has been primarily constructed with reference to academic philosophical norms and not to the norms of the public sphere partly explains why it has never gained the degree of public legitimacy that other forms of technocracies have gained.

(E)Universality

EU "ethics" has been evoked as a bridge towards building Europe as a polity (Jasanoff 2005) for its symbolic capacity to refer to citizens' values in a quite universal way. In fact, though "ethical aspects" are actually deferred to expert committees, the mainstream implicit philosophical traditions endorsed at the EU level are supposed to embody some rational, and thus universal, form of reasoning (Galloux et al. 2002, pp. 132–133). Therefore, committees themselves (the individuals in their personal expert capacity and the group as a whole) are expected—thanks to a sort principle of transitivity—to perform "rationally", at least according to a "European" idea of rationality.

From this perspective, ethics has thus become another form of "contextualized universality" created in the EU, like the single market and the harmonized legislation connected to it, as a "single European ethics" capable of defining and providing with non-commercial contents the Union.

These passages explain the establishment of an overall European "ethical identity" aiming to universally represent all European citizens. This identity encompasses both an ethical and an epistemic vision, as it is shown in the precautionary principle (Tallacchini 2002), and defines European citizens by describing, and prescribing their moral identity: namely, which values are legitimately endorsed in the EU.

It is worth noting that no definition of "which and whose" ethics is being taken into account, and this vagueness is reflected in the institutional language used to justify the relationships between values and laws. The formal expressions created

for this purpose have changed over time from referring to "legislation on ethics" and "ethical legislations"[12] to grounding ethical choices in the European Charter of Fundamental Rights.

What kind of entity an ethical issue is has been increasingly codified through the catalogue of "ethical issues" in the EU research area, the so-called "ethics checklist".[13] However, the specific ethical choices that each Member State may adopt within their national borders can be quite different. The ultimate principle on which ethics relies is not the European Charter and citizens' rights, but the principle of subsidiarity, the single most characteristic element of the EU ethics.

Subsidiarized "Ethics"

This third feature, subsidiarity, together with expert ethics as rationality and European universality, constitute what can be defined as the EU "ethical method", i.e. what makes it possible that the values accepted at the Community level and in Member States may differ, and still may coexist notwithstanding their discrepancies.

Member States made the juridification of subsidiarity a matter of principle that resulted in the incorporation of the "principle of subsidiarity" into Article 3(b)2—now Article 5(2) of the ECT.[14] Subsidiarity is defined as a way "to ensure that decisions are taken as closely as possible to the citizens of the Union" (CEC 1992). More specifically, subsidiarity is the principle whereby the Union does not take action (except in the areas which fall within its exclusive competence) unless it is more effective than action taken at national, regional or local level. This means that this principle allows Member States to make their national choices in a certain field without challenging the legal harmonization in the EU. As an admission of insuperable divisions among Member States, subsidiarity has been considered detrimental to the continuation of the process of European integration. As it has been pointed out, "the Member States' fundamental objective when they decided to incorporate subsidiarity into the ECT was precisely to place another obstacle in the path of the transfer of sovereignty from Member Sates to the EC" (Estella 2002, p. 2). In this respect, subsidiarity is criticized "not only for technical, or functional, reasons—it does not work as a legal tool—but also for normative ones—it runs counter to the process of 'integration', and so is counter-productive". (Estella 2002, p. 2).

Ethics is a matter of subsidiarity. "Ethics and cultural values", the Commission stated in establishing the GAEIB, "by nature, are predominantly regulated on the national level. They follow the principle of subsidiarity. However, while seeking for harmonized market conditions, European directives necessarily touch on the issue of ethics".[15]

[12] http://web.archive.org/web/20030614221600/http://europa.eu.int/comm/research/science-society/ethics/research-e-legislation_en.html. Accessed August, 2009.

[13] See: http://cordis.europa.eu/fp7/ethics_en.html. Accessed August, 2009.

[14] Protocol (No 30) on the application of the principle of subsidiarity and proportionality, (Amsterdam, 2 October, 1997).

[15] http://web.archive.org/web/20030418165425/http://europa.eu.int/comm/research/science-society/ethics/research-e-legislation_en.html. Accessed August, 2009.

Ethics' belonging to Member States means that harmonization cannot be reached in this field and that a multiplicity of moral visions have to coexist, as both the GAEIB and the EGE had to recognize on several occasions. Subsidiarity allows different ethical choices to coexist and be compatible within EU legislation, preventing the EU from being fragmented by ethical dilemma in the coordination of different State-based ethics.

However, in its application to ethics, subsidiarity appears profoundly altered regarding its declared meaning and goal, namely ensuring that decisions are taken as closely as possible to the citizens of the Union. The subsidiarized construction of values in the EU may respect Member States' will in their relationships within the EU, but it certainly deprives citizens of the ability to express their own views, whenever their visions are not subsumed by Member States' sovereign morality. From the citizens' point of view, this way of framing ethical deliberation, though making the sovereign power of "national ethics" stronger, does not represent them but only States' ethics—literally, the ethics-of-the-States.

Citizens are thus disempowered twice: because ethics is conceived of as an expert knowledge and because it belongs to the governments of Member States. And in both cases, the alleged justification is that these mechanisms better represent European citizens.

But subsidiarity about values is also a challenge to European legislation and the European Parliament as the main institution directly representing European citizens. As committees and Member States are entitled to making ethical decisions, the legislative content (the values) is separated from the legislative process, and lawmaking is relocated to different powers: the legislative branch keeps the control of the process, but the executive power provides the substantive content of decisions.

The rejection of the idea of "natural law" as an independent domain informing positive law is a major legacy of modern legal positivism (Bobbio 1993). Law exists as far as it has gone through a valid process of approval and enactment that encompasses its content. As subsidiarity allows ethical contents to be removed from the European legislative power and be given to Member States' governments, it represents an indirect reintroduction of the concept of natural law—here coinciding with Member States' will.

Ethics and subsidiarity have been intimately connected from the very beginning of the European integration process. In his 1989 Discours de Bruges, Jacques Delors has described subsidiarity as the practical way to make possible "l'émergence de l'Europe unie et la fidélité à notre nation" (the emergence of the united Europe and the faithfulness to our nation) (Delors 1989); and he also saw the role of "ethics" as providing the symbolic dimension to reconcile the State and individuals: "Au-delà d'un nationalisme triomphant et d'un individualisme exacerbé, l'éthique revient en force" (beyond a triumphant nationalism and an extreme individualism, ethics has to be strengthened again) (Delors 1989). Subsidiarity and community ethics are thus strongly connected terms, as the former concept "stems from a traditional society organized in communities to which each person 'naturally' belonged"; where "naturally" means that the individual was feeling this belonging as a part of himself, as a fundamental element of his humanity (Soudan 1998, p. 180). However,

in today's context, one may challenge both the assumption that States-ethics can actually convey citizens' values as a community at the EU level, and that this mechanism may constitute a better way to represent citizens than through their own rights and parliamentary procedures.

Verticality

A fourth feature of European "ethics" is its verticality, the top–down relationship characterizing interactions, within the EU, between sovereign Member States and their citizens. A consequence of the characteristics already described—expert nature, intrinsic rationality, presumed universality within the European context—EU "ethics", belonging primarily to Member States, de facto brings to the EU level only the ethical visions of States and does not allow European citizens to express their own values independently of "State ethics", or "State-sponsored ethics" (Levidow and Carr 1997). Therefore, citizens enter this ethical domain more as intended objects than as subjects and actors of ethical decisions, notwithstanding the assumption that "ethics" represents citizens.

Outsourcing of Values

The problem of comitology has been widely explored in terms of technocracy, conflict with democratic representation, criteria of appointment (Bell 1969; STOA 1998). Far from being resolved, these issues bear a heavy weight on the ethical committees' representation capacity (Dodds and Thomson 2006), while their numerical presence and contexts for involvement have constantly grown.

As already seen, committee procedures are multitask entities, capable of hosting and legitimating a variety of different ends and goals. Committees are part of the rhetoric of expert knowledge; they may refer to plurality and multidisciplinarity as to their composition; they may be played to perform objectivity and neutrality, as their procedures tend to create generally agreed and de-personalized opinions.

Furthermore, "ethics" as a committee affair is a strategy to outsource values, i.e. to construct "ethical issues" as isolated and purified dimensions allowing the extraction of values from a legal issue and the legislative context to allocate them externally to a third expert party, thus confirming that values legitimately exist only as objectified expert knowledge.

The outsourcing of values contributes to the institutional framing of moral and social choices as a matter of neutral expertise and technical knowledge. Values are not perceived as an integral part of European legislation but are supplied through specialized knowledge; this is analogous to other fields of expertise. In this way, the substantive content of directives and regulations touching on values does not really involve any value judgment. Instead, it consists of incorporating "ethical knowledge" into laws as an external expertise, sometimes consisting of the awareness that no general agreements can be reached on the subject.

Inherently political decisions may thus be neutralized and depoliticized through the deference to expert opinions, although the ad personam experts' appointment

procedure shows, on the contrary, that ethics performed by committees may be considered as "commissioned ethics" and a "commissioning of ethics"; i.e. it is ethics on demand. Whereas this does not necessarily imply a direct choice of the relevant values, the extraction of the ethical dimensions from an issue to be regulated always involves a pre-framing of the issue itself and of what is important, and the inevitable reduction of value-laden issues to their mere "ethical implications".

"Ethics" as a Criterion of Demarcation

It was noted above that the construction of a contextualized universality of values within Europe has been applied to build the official concept of citizenship and to fill the gap between the economic and the political EU.

However, European citizens' identity still appears in most EU policies to be shifting between two different dimensions: the citizen and the consumer (Lehning 2001). Though the existence of this double identity is not unique to the EU, the non-communicative nature of this double identity is a significant sign of the EU structure.

Ethics has played a major boundary role in separating the political society from the market: seemingly, to introduce ethical control of the market, especially in the biotechnology field, but also to allow the market to perform better and faster by removing all potential barriers.

A triangular affair among ethics, science, and the market emerges from the analysis of the European politics of ethics. Ethics should be the normative environment for the market in the field of biotechnology. According to a GAEIB opinion, "…the affirmation of the citizen's rights in the European Union implies that the economic advantages derived from biotechnological developments should in no way affect the respect of ethical requirements" (GAEIB 1996, § 2.7). Notwithstanding these declarations of intent, the way ethics has entered the normative framework of biotechnology has revealed how ethical values have been used primarily to draw boundaries between citizens and the market. Thus, citizens are always evoked as the intended beneficiaries of innovation policies, and sometimes they are also required to agree with these; but they are steadily excluded from decisions about the relevance and the directions of innovation, which they can not access as citizens but only as consumers.

The two identities of the citizen and the consumer are thus simultaneously connected and non-communicating. As it has been observed, "a free European market, if this is all that is to be, does not 'require' a 'Europe of the citizen'; in fact, citizenship makes the market less 'free'" (Streeck 1995, p. 413).

"Ethics" as a Procedural Requirement

Though "ethics" opinions as formulated by the GAEIB–EGE possess the formal status of non-binding advisory documents, not only have they been invoked by different institutions at the EU and national levels as informal sources of normative

directions, but they have become part of the EU deliberative process, as a procedural step officially belonging to it. Whenever Directives touch upon values, the Whereas provisions explicitly mention that "the opinion of the European Group on Ethics in Science and New Technologies has been taken into account", thereby providing a broad sense both of institutional and scientific legitimacy.

"Ethics" to Speed-up the Law

"Ethics" has also a procedural relevance as it allows decision-making to proceed at a faster pace than the law. A strong reason to apply committee procedures to a variety of domains consists in their agility compared to the legislative process.

The mandate of European ethical bodies has increasingly focused on "speed", as the capacity to provide timely advice. Since its beginnings, a significant advantage of the GAEIB was envisaged in its "dynamism": "Its openness and dynamism are the best response to the accelerating pace of development in the relationship between science, technology and the key values of society".[16] The 2005 EGE mandate explicitly insisted on the "timely manner" ethics advice has to respond to "more rapid science and technology developments" and on the necessity to set time limits for opinions to be released.

The European Commission has made clear, in its White Paper on European Governance, that legal rules need to be complemented by a broad variety of policy tools and non-legislative instruments. The legislative process needs to be fixed to address its rigidity, well established forms, limited capacity to organize broader participation, and its slow pace. "The Union", it is said, "must renew the Community method by following a less top–down approach and…when legislating, the Union needs to find ways of speeding up the legislative process" (CEC 2001, p. 5).

The so-called law-lag is frequently evoked in EU documents as the chronic delay affecting the pace of the law compared to the pace of technoscience, and the informal features of ethics combined with the logic of experts' decisions represent an efficient way to speed-up legislation.

Reframing the Separation of Powers Through "Ethics"

In the previous sections I described some elements of the rising process of ethics and the elements involved in what I called the "established framework".

The case described below concerns the ethical/legal fight on embryos (and embryonic tissues and cells), which has taken place at the end of 2007 during the final approval of the EU legal framework on human biological materials and the products hence derived. This is more than an illustration of the role of "ethics" in the EU—with special reference to subsidiarity—it suggests how "ethics" has become a crucial tool in redefining the powers of European institutions.

Starting in 1998, the creation of a harmonized European regulatory environment for the use of human cells and tissues had been urged by the EGE as a "moral

[16] http://ec.europa.eu/european_group_ethics/archive/1991_1997/bilan_en.htm. Accessed August, 2009.

imperative" (EGE 1998). Although the legal framework finalized through Directive 2004/23 and Regulation 1394/07 aimed at ensuring safety and health for European citizens, at strengthening the idea of solidarity amongst European citizenship, and also at overcoming the illegal trading of human biological materials, it has de facto also created and legitimated a European market for cells and tissues.

While Directive 2004/23/EC[17] has set standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells; Regulation 1394/07[18] has established a central authorization for products based on these cells and tissues—so-called advanced therapies medicinal products (ATMP), namely gene therapy, somatic cell therapy, and human tissue engineering.

The combination of the two documents is paradigmatic regarding the splitting of the economic vs. the political EU identity. In fact, while Directive 23/2004 looked at the European public as the "ethical and safe citizens" who are required to endorse the "philosophy" of freely supplying the EU market with their cells and tissues, Regulation 1394/2007 envisaged them as potential patients/consumers, willing to buy their own engineered tissues from the industry health sector.[19]

What is relevant to focus on here is the approval process for Regulation 1394/2007. This process shows how, in the controversy about placing in the market embryonic cells-based products, "ethics" has become a way to redefine the relationships between the Parliament, the Council, and the Commission.

Two committees, the Committee on Environment, Public Health and Food Safety (ENVI)—with Miroslav Mikolášik as Rapporteur to the Parliament (ENVI 2006)—and the Committee on Legal Affairs (JURI) had been in charge of the proposal—with the final report drafted by Hiltrud Breyer. Due to some controversial points, the destiny of the Regulation had remained quite uncertain for a long time. The main controversy concerned the so-called 'ethical amendments' introduced by JURI as the body responsible for ethical questions related to new technologies. According to the "ethical amendments", the regulation should not apply to products containing or derived from human embryonic or foetal cells, primordial germ cells or cells obtained from those cells (ENVI/JURI 2007), whilst the Council and the Commission wanted them to be equally regulated and placed in market.

After the negotiation process was closed, three members of the parliament (MEPs) and their political groups—socialists, liberals and European United left/nordic green left group—separately agreed with the Council on a "compromise package" rejecting the ethical amendments in order to speed up the legislative process. Despite the strongly negative reactions of the Rapporteur and the involved committees, and a tough battle during the final vote, the parliament eventually approved Regulation 1394/2007, modified to appear "ethically neutral", i.e.

[17] *Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells*, L 102/48 Official Journal of the European Union, 7 April 2004.

[18] *Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC*.

[19] I discussed the concept of the "safe-and-ethical" citizen in Tallacchini 2008.

entrusting the decision about embryonic cells' commercialization to Member States and to the principle of subsidiarity.[20]

JURI's members defended their "ethical amendments" as a legal matter belonging to their exclusive competence, warning that the concept of "legal safety" was at stake in the modified proposal. According to JURI, a regulation may legally take place as a measure to harmonize the single market (Article 95 Treaty of European Communities) only when dealing with products not 'ethically sensitive': otherwise the market cannot be harmonized. Products based on embryonic and fetal tissues, being 'ethically sensitive', could not legitimately enter a Regulation, as different legal rules are going to be enforced by Member States. Therefore, for the Regulation to be "legally safe", embryos should be excluded from it. A different decision, in JURI's opinion, would have been challenged in the Court of Justice.

Furthermore, the exclusion of embryos was also needed to harmonize Regulation 1394/2007 with the existing EU legislation: products which intervene in the human germ line are already excluded from clinical trials by Directive 2001/20/EC, and they are also non-patentable according to Directive 98/44/EC (ENVI/JURI 2007).

Although disagreements among the MEPs clearly depended on their different ethical visions, the discussion took place primarily at the legal level (through the concept of legal safety), touching on Parliament's power, on the principle of subsidiarity, and on the "subjective" or "objective" nature of ethical values.

Hiltrud Breyer, as draftsperson of JURI's opinion, strongly defended the formal role of the JURI committee in treating legal questions, including ethical contents, as a matter of legal certainty and clarity.

"The Rules of Procedure give the committee a most prominent role in the treatment of ethical issues, and I trust that everyone here accepts that—not just the Council and the Commission, but also many Members of this House, none of whom, I hope, are seeking to deny the members of the Committee on Legal Affairs their authority in matters of law. The committee calls for the reference to embryonic stem cells to be deleted, but why? As you know, the Court of Justice's interpretation of Article 95 is that a fully harmonized measure must not allow derogations for Member States, so, it is a matter of doubt as to whether the article would stand up to the Court's scrutiny".[21]

On the opposite side, Dagmar Roth-Behrendt, one of the MEPs agreeing with the Commission, challenged the legal basis for the Parliament to deal with ethics, which belongs—she contended—exclusively to Member States.

"As regards the so-called 'ethical' amendments, yes, Member States who want to ban the use of fetal stem cells should be allowed to do so, and, Mrs Breyer, everybody who says that the Court of Justice would deny that and would put it under Article 95 is either not knowledgeable—which you are not—and then giving the wrong impression, I am afraid. If you read Article 30 of the Treaty, you are exactly

[20] http://www.europarl.europa.eu/news/expert/infopress_page/066-5722-113-04-17-911-20070420IPR05538-23-04-2007-2007-false/default_en.htm. Accessed August, 2009.

[21] See: http://www.europarl.europa.eu/oeil/FindByProcnum.do?lang=2&procnum=COD/2005/0227. Accessed August, 2009.

sure that it says that public morality is always a reason to make sure that a Member State can ban something".[22]

The correct implementation of the principle of subsidiarity was also disputed. According to MEPs supporting the inclusion of embryonic-cell-based products within the Regulation, subsidiarity implied that "ethical matters are reserved to the Member States, and we, in the European Union, cannot end up in a situation in which one of them can impose its ethical convictions on another"[23]; and "it is not Europe's role to legislate on ethics".[24] On the contrary, for MEPs arguing for exclusion, the principle of subsidiarity is reinforced "…by keeping these products outside of the regulation's scope", otherwise Member States' authority would be challenged "…by a Committee sitting at EMEA in London".[25]

Throughout the discussion the boundaries among ethics, law, and the market were highlighted by the majority of MEPs in a way implying that the Parliament had no power to represent European citizens. MEPs' opinions—the majority argued—are "subjective", i.e. they express personal subjective views; and thus cannot "objectively" represent "public morality", which only Member States are entitled to embody.

There is "no room in the text for personal ethical views", one MEP declared. "The purpose of this proposal is not to harmonize questions of ethics or morals. The personal, moral and ethical views of each of us must not conflict with this approach, especially as each Member State will be responsible for deciding which type of products it will allow to be".[26]

"Any self-styled ethical objections are completely overthrown by the fact that the independence of the Member States guarantees them the power to impose restrictions on research", another MEP commented.[27]

All these statements quite uniformly indicated "ethics" not as a matter of value, but only as a matter of power; implying that the power to make the final decisions about values in Europe does not belong to the representatives of European citizens—MEPs—but to national governments.

The role of the market was also called in to complement ethics in defining the institutional boundaries. The relationships between ethics and the market were quite differently framed by the Commission and the Council, and by ENVI and JURI. 'Ethically non-neutral products' should not be placed in the market—ENVI and JURI claimed—as they constitute an obstacle to harmonizing European legislations. Vice versa, according to the Council and the Commission, the market is per se capable of neutralizing all products placed in it, and harmonization is going to be achieved through subsidiarity. (In Fig. 1, the divergent views on ethics, law and the

[22] *Ib.*

[23] Günter Verheugen, the German Vice-President of the Commission.

[24] Frédérique Ries, on behalf of the ALDE Group.

[25] Johannes Blokland, on behalf of the IND/DEM Group—(NL). For all these citations, see http://www.europarl.europa.eu/oeil/FindByProcnum.do?lang=2&procnum=COD/2005/0227. Accessed August, 2009.

[26] Adamos Adamou, on behalf of the GUE/NGL Group.

[27] Marco Cappato (ALDE), in writing, Italy.

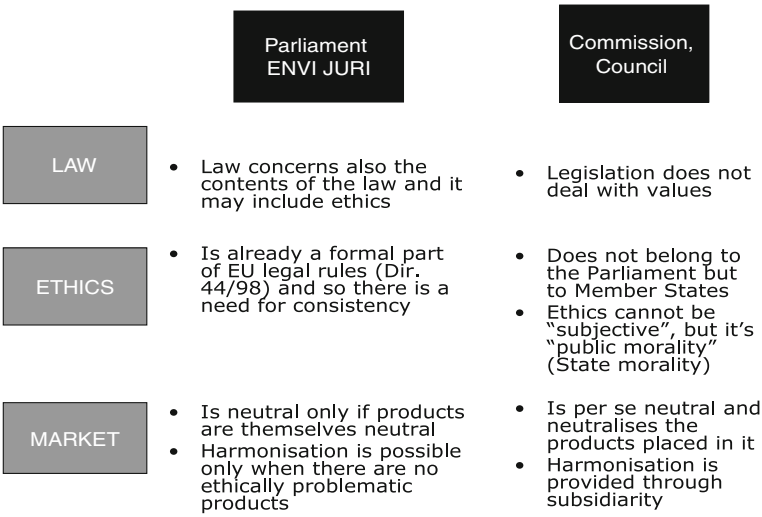

Fig. 1 Law, ethics and the market

market by the Council, the Commission, and by the Parliaments' committees are presented and compared).

Eventually, the majority voted in favor of placing all tissue-based products in the market (embryonic cells included). However, the Parliament found itself caught in a double bind between either claiming its full legislative role and accepting ENVI and JURI's "ethical amendments", or accepting its limited competence on ethical matters and having its majority position passed.

Ironically, in order to 'win', the Parliament's majority had to argue in favor of its own lack of competence and power to legislate, whenever law touched on values; had to accept that values are not an integral part of the law; and had to agree that deliberation on the contents of law does not constitute a right of citizens' representatives, but, instead, a prerogative of Member States' governments.

A More Democratic Way Forward?

In this paper I have looked at what characterizes EU "ethics" as an institutionalized entity and have suggested that it appears as a soft legal tool, capable of producing hard normative effects. Framed as an isolated regulatory dimension, exploited for its symbolic capacity to evoke citizenship, quite formalized as to certain features, with the potential to redefine the traditional division of powers in the State under the rule of law, "ethics" is a complex and stratified entity, certainly still in flux.

As an effect of the extended criticism that bureaucratized "ethics" has encountered, of the prolonged fights in the EU and Member States about biotechnology (both the Directive on GMOs and on the patentability of biotechnological inventions), and not least of some forms of institutional reflexivity, the most recent developments in new technological areas—starting with nanotechnology and

converging technologies (Nordmann 2004)—have profited from major improvements in the way ethics is envisaged.

De-expertizing of ethics and consideration for lay-ethics, citizens forums and other forms of public participation, new understandings of interdisciplinarity—to mention only a few elements—have become part of what seems to be a different approach in dealing with innovation's scientific and social quandaries.[28]

But, though promising, what is happening in these fields still belongs to the research level, and has not yet proved to have the capacity to change the established "ethics" characters and procedures. What is funded as research within the Framework programmes has not yet got rid of the past bureaucratic framework. Also, together with these innovative ethical practices, the European Commission's research activities on ethics still make reference to concepts and expressions such as "the science of ethics",[29] contradicting the idea of de-expertized ethics.

Though all these new experimental practices sound promising, the regulatory reality of emerging technologies appears quite traditional.

Within the context of the Action Plan on nanotechnologies launched by the European Commission in 2005 (CEC 2005b), the current regulatory outcome does not appear convincingly innovative. Several committees have provided their opinions, such as the Scientific Committee on Emerging and Newly Identified Health Risks (SCENHIR 2009) and the EGE (2007) on risks and ethics. The Commission *Recommendation on a Code of conduct for responsible nanosciences and nanotechnologies research* has addressed Member States by calling for "the voluntary adoption of the Code of Conduct by relevant national and regional authorities, employers and research funding bodies, researchers, and any individual or civil society organization and of its principles" (CEC 2008)—principles already listed as: meaning, sustainability, precaution, inclusiveness, excellence, innovation, accountability. The Council has agreed with the Commission in its conclusions on responsible nanosciences (EUR 23906 2009), and both institutions are supporting the voluntary and inclusive adoption of ethical conducts by a responsible market. This means that "good governance of N&N research should take into account the need and desire of all stakeholders to be aware of the specific challenges and opportunities raised by N&N" (EC 2008, at 4.1)—with the terms 'need', 'desire' and 'awareness' gravitating in an unspecified way around the descriptive/prescriptive concept of governance; and that inclusiveness should "allow all stakeholders to *enrich* the *preliminary* discussions" (italics added) (CEC 2008, at 4.1.8).

The Parliament, in its Resolution on regulatory aspects of nanomaterials of 2009 (EP 2009), has strongly disagreed with both the Commission and the Council. While seeing the current discussion about nanomaterials as characterized by a "significant lack of knowledge and information, with disagreement starting … at the level of definitions", and considering the Commission's regulatory work on nanomaterials

[28] For an integrated understanding of the ethical challenges posed by emerging nanotechnologies, see, for instance, the DEEPEN project.
http://www.geography.dur.ac.uk/projects/deepen/Home/tabid/1871/Default.aspx. Accessed August, 2009.

[29] http://ec.europa.eu/research/science-society/index.cfm?fuseaction=public.topic&id=74. Accessed August, 2009.

as "rather limited" and not adequate to the legislative and policy challenges posed by nanomaterials, the Parliament has explicitly rejected the Commission and Council's soft approach "in the absence of any nano-specific provisions" covering the risks related to nanomaterials, and providing protection of health, safety and the environment.

This narrative is anything but new, and "ethics", though reframed to be more inclusive, still helps strengthen governments and make parliaments—and citizens—weaker.

Though some research in the field of 'nano' and other emerging technologies are inspired by a genuine spirit of reform, the regulatory path followed by the European Commission still seems to operate in the old framework, and willing to adopt fast non legislative measures as long as these can favour the market.

Also in this more open and inclusive version, "ethics" does not seem to offer the guarantees provided by the legislative process and is, on the contrary, still managed more as a tool to exert power in a self-legitimatizing way than as an exercise of democracy.

It has been remarked (Eriksen 2005) that in the EU integration process citizens have achieved rights, but have not been able to give them to themselves. The lack of a European collective identity and the absence of a unifying public sphere for identity-formation of the European citizens is the most apparent reason for the democratic deficit in the EU. Hopefully new "ethical" practices may lead to the construction of widely shared public spheres; for the time being, the EU remains a "process of unfinished democratization" (Eriksen 2005, p. 13).

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