

Project:
The Landscape and Isobars of European Values in Relation to
Science and New Technology (Value Isobars)

Project number:
230557

Title of deliverable:
Sketch of value based governance tools for S&T

Work package: 4

Authors:
Maria Eduarda Gonçalves
Maria Inês Gameiro

Partner (institution):
DINÂMIA-CET – Center for Socioeconomic and Territorial
Studies
ISCTE-IUL

Deliverable 3

Date: 14 November

**Hard law, soft law and self-regulation:
Seeking better governance for science and technology in the EU***

Maria Eduarda Gonçalves

Maria Inês Gameiro

DINÂMIA-CET – Centre for Socioeconomic and Territorial Studies

ISCTE-University Institute of Lisbon

1. Introduction

In the past, science was one of those fields, which like art or friendship were regarded as alien to market mechanisms as well as immune to state law. Research freedom and the free circulation of scientific data were among the basic principles featuring the codes of the scientific community thought to be spontaneously generated and controlled within the order of science. Yet, the social context that underlay this model of the relationship between science and the law changed profoundly throughout the 20th century up to present-day. Many scientific disciplines now have profound impacts on the economy, work, the environment and health, and even personal life. Moreover, the modern correlation of science to progress lost in part its base as scientific research and technological development became more and more associated not only with economic growth and welfare but also with new kinds of individual and collective risk namely in areas like the biosciences and biotechnology or information technologies. Recognition of this trend entailed growing regulatory action by public authorities, either at the national or international, including the European level. Behind this effort has been the aim to safeguard fundamental human rights, as well as the public interest, in particular the quality of the environment, public health and public safety. The normative frame of science as well as of technology has been reshaped as a result. The old order of science receded as various dimensions of the scientific practices have fallen under legal jurisdiction. The question, however, comes up of what should be the appropriate scope and methods for science and technology regulation.

The dynamics of scientific research, requirements for autonomy and flexibility, ethical considerations brought about by highly sensitive domains, and above all the principle of the

* This document is a revised version of the 2nd deliverable addressing the analysis of soft law instruments.

freedom of research account for the weight assigned since early times to **self-regulation** by the researchers themselves as the logical regulatory principle. More recently, the notion also gained supporters that **soft law**, meaning non-binding norms emanated from law-making bodies, might serve better the needs and purposes of science than legislative modes of top-down, hierarchical-based authority of the state and other public actors (EC 2007, 52). Today, this idea became closely related to the belief that **governance** resting upon multiple authorities, that are not necessarily public and state-centred, and based upon a fluid system of power sharing may be facilitated by 'soft law' rather than by 'hard law' (Mörth 2004; 2005). 'In systems of government the law is hard whereas it is soft in systems of governance', Mörth (2004) argues. Alleged motivations for resorting to soft law to govern science and technology (S&T) include uncertainties in rapidly developing technological or scientific fields; social uncertainty and controversy in sensitive areas; and lack of agreement within or among governments.

There is indeed a rather wide belief, in political as well as in scientific circles that 'non-binding governance' or 'soft law' as well as codes of practice, guidance, and reporting measures provide more suitable regulatory tools for scientific research and the development and use of emerging technologies than 'hard law' in the form of legislation. At the same time, there is the assumption that soft law and self-regulation may respond more easily to increased pressures for opening up policy-making arising from mounting public unease with particular scientific and technological developments. At least, this seems to be the perspective coming out of official documents linking soft law, self and co-regulation to a more participative society in S&T regulation and governance.¹

In the European Union (EU), the latest adoption by the European Commission (EC) of the recommendation for a code of conduct for nanosciences and nanotechnologies appears to bolster this assumption. European Parliament's resolutions on cutting-edge research and technology such as human cloning, electromagnetic fields and related health concerns, human egg cells' trade or respect for fundamental rights in the Internet offer additional illustrations thereof. Counter examples, i.e. recourse to legislation are EU directives and regulations on GMO or the EU regulation on biometrics in passports and travel documents.

Hence some questions come up, both empirical and normative:

- Are EU institutions preferring soft law to hard law as for regulating scientific research and technological development and use or is soft law operating as a preparatory stage leading to hard law?

¹ On citizen participation in EU governance of new technologies, arguing that 'it is not truly informed by human rights', see Flear; Vakulenko, 2010.

- What are the motivations or the circumstances under which EU institutions are using soft law as a regulatory tool in this area? Is soft law being used chiefly to address ethically or socially sensitive and controversial topics in science and technology?

- What role is being assigned by the EU to self-regulation as a means for regulating science and technology?

- Have soft law instruments been working as guarantees for a more democratic, inclusive governance of science and technology governance or are they rather a manifestation of deregulatory trends entailing the private definition of applicable rules, in other words, a deliberate move by the EU policy-makers and legislator to reduce constraints on scientific research and technological development?

These issues need to be placed in the context of the wider EU agenda on regulation and governance, particularly the so-called ‘better regulation’ agenda and EU explicit concerns with opening up regulation to stakeholders and society at large.

Following an overview of the genesis and conceptual debate around soft law and soft law’s rapport with self-regulation, we will endeavour to examine recent trends in science and technology regulation in the EU with a view to make out the part played by both soft and hard law, as well as codes of conduct, and motivations underlying the option for each of these regulatory instruments, and draw some possible explanations for the trends identified. In view of the amplitude of current normative frameworks in the research and technological domain in the EU, a few case studies deemed illustrative were selected for the purpose of the analysis, namely: nanotechnologies, human cloning, biometrics, and genetically modified organisms (GMO).

2. The ambiguous frontiers of soft law, self-regulation and co-regulation

Despite its widespread use in the academic literature, soft law is a somewhat imprecise analytical category.² Most often, the term encompasses a variety of normative, non-binding, instruments emanating from law-making bodies, including resolutions, recommendations, guidelines, communications, notices, etc. But soft law has also been employed *lato sensu* to include not only public, ‘top-down’, instruments, but also self-regulation by private, non-governmental, organisations particularly in the form of codes of conduct (Mörth et al., 2004).

The lack of binding force is the main feature distinguishing ‘soft’ from ‘hard’ law instruments (Senden 2004, 112). Authors agree in defining soft law as rules of conduct with no

² Lawyers are sometimes ‘more inclined to treat soft law as an analytical concept whereas the social scientists tend to treat it as an empirical phenomenon’ (Mörth 2005, 6).

strict legally binding force, but which nevertheless may have or are even intended to have practical and even legal effects (Snyder 1993, 198; Senden 2004, 112; 2005, 23). Though issued by law-making authorities, soft law rules do not comply with constitutional and other formalities required for the rule to be legally binding (Gersen, Posner 2008, 6). Besides, they are neither enforceable nor sanctionable through the modes of responsibility and accountability inherent to hard law (Wellens, Borchardt 1989, 274). Still, they have at least a potentially enforceable nature, contrasting with a mere ethical or moral nature (Andorno 2007).

While references to soft law in the context of European law emerged timidly in the 1980s (Senden 2004, 109), the soft law approach visibly expanded subsequently across several fields of EU jurisdiction from financial management and taxation to social policy, from workers' rights to competition policy.³ Article 288 of the Treaty on the Functioning of the European Union (ex-Article 249 of the Treaty of the European Community) now includes recommendations and opinions among the 'legal acts of the Union', stating that they 'have no binding force'.

As pointed out above, the notion of 'soft law' has also been applied to a different kind of normative instruments, i.e. codes of conduct adopted mainly by private, non-governmental entities, more properly termed self-regulation, as will be detailed below. The EU 'Inter-institutional Agreement on Better Law Making' defined **self-regulation** as 'the possibility for economic operators, the social partners, non-governmental organisations or associations to adopt amongst themselves and for themselves common guidelines at European level' (Inter-institutional Agreement 2003, 3)⁴. Codes of conduct within the EU are spreading too. Apart from the customary codes of conduct set by multinationals and professional associations⁵, there has been an upsurge of codes in the areas of consumer and environmental protection (EESC 2005, 16, 17). Though admitting that self-regulation can be a tactics to avoid public regulation, the European Economic and Social Committee (EESC) welcomed it as a flexible and dynamic regulatory tool suitable for areas that are continuously shifting and evolving, and

³ An example of a code of conduct is the Code of Ethical Criteria adopted by the members of the Executive Board of the European Central Bank. On the growth of soft law instruments in competition law see Oana Andreea Stefan, 'European Competition Soft Law in European Courts: A Matter of Hard Principles?', *European Law Journal*, Vol. 14, No 6, November 2008, pp. 753-772.

⁴ See also the Information Report adopted by the EESC in February 2005 on the *Current state of co-regulation and self-regulation in the Single Market* CESE 1182/2004 fin of 10.02.2005, 11. A useful database with self and co-regulation initiatives can be found in the European Economic and Social Committee website: <http://www.eesc.europa.eu/?i=portal.en.self-and-co-regulation-enter-the-database>.

⁵ These codes of conduct typically include codes of ethics addressing fundamental social values or the commitment to comply with shared principles. They are often set according to the guiding principles drawn up by the OECD or the code of conduct for multinationals from the European Parliament (Howitt report, January 1999) (EESC 2005, 16, 17).

capable of encouraging ‘a sense of co-responsibility among economic and civil society stakeholders’ (EESC 2005, 22). More and more, self-regulation appears to involve inputs from both the public and the private spheres. Private interests’ organisation, the EESC underlined, ‘cannot be done in a way that might appear damaging to the public interest’ and must take place in an atmosphere where fundamental values are respected (EESC 2005, 19). A relatively novel development, European legislation now explicitly recommends the enactment of codes of conduct in a relevant move towards complementary of both hard and soft law with self-regulation.

The connection between hard law and self-regulation appears distinctively in the phenomenon of **co-regulation**. Emphasised by EU institutions alongside with self-regulatory instruments, co-regulation has been defined as ‘the mechanism whereby a Community legislative act entrusts the attainment of the objectives defined by the legislative authority to parties which are recognised in the field (such as economic operators, the social partners, non-governmental organisations, or associations)’ (Inter-institutional Agreement 2003, 3). Co-regulation implies the prior involvement of a legislative authority, its main feature consisting of the active participation of both public and private actors in regulation (Verbruggen 2009, 425, 426, 429). Co-regulation has also been perceived as enhancing the legitimacy of EU governance.

In contrast with soft law properly speaking, self-regulation is not *law* in a strict sense, ‘which is not to say ... that it can be seen as detached from the law’ (Senden 2005, 12). Indeed, theories of legal pluralism tend to broaden the concept of law so as to encompass more than law as ‘command and control’. Rules of law, according to Mireille Delmas-Marty, can be seen as landscapes composed by normative space, time and order. Nowadays, ‘in this confused landscape, rules of law seem to spring up everywhere, at any time and in every direction: a spatial, temporal and conceptual relativity scrambles all the usual reference points’ giving place to a ‘denationalised’ normative space, ‘destabilised’ time and a ‘delegalised’ order’ (Delmas-Marty 2002, 31). For legal pluralists rules of conduct adopted by infra-national (and supra-national) organisations constitute *law* too (Carbonnier 1979, 213 ff). Carbonnier’s well-known definition states that ‘law is a mere lining, covering the external surface of social relationships’ (Carbonnier 1965, p 279 ff). Also, in its ‘soft’ version, law approaches self-regulation to the extent that it lacks enforcement means or sanctions.

Actually, one should not overlook the ambiguities at the frontiers of the concepts of soft law, self-regulation and law properly speaking: while self-regulation may in practice be sensed by its instigators or addressees as compulsory (e.g. professional codes of conduct), ‘hard law’ is sometimes mainly ‘hortatory’, for example when it proclaims very general and abstract

principles, its effectiveness being conditional upon implementation (Gersen and Posner, 2008, 21; Fauré, 2011). Besides, the notion of 'soft law' covers a diverse set of normative instruments with various degrees of authority and influence. The same type of instrument, a communication or a recommendation, emanating from the same institution, the EC, for instance, may be considered 'soft law' or a mere political declaration depending on their stronger or weaker language and the context of their adoption or implementation. A case-by-case basis analysis is therefore required, considering the purpose and objective of the specific instrument, namely whether it performs a pre-legislative function (preparatory or informative, such as green and white papers), a strategic guidance (e.g. action plans) or if it has a true normative even if not binding character, stating principles, norms or setting some interpretative framework. Some instruments may play more than one function: that is the case of the EC's communications, which sometimes provide guidance to the application of existing EU law but can also serve to prepare upcoming EU law (Senden 2005, 23-24).

Let's recall that the notion of 'soft law' first emerged in the field of international law where non-binding instruments appeared as a natural consequence of the characteristics of an international society composed of sovereign entities (Di Robilant 2006). In 1950, Hersch Lauterpacht regretted, states had only agreed to the terms of the Universal Declaration of Human Rights because they would not be bound by them (von Bernstorff 2008, 905). International relations continue to offer a fecund ground for debates concerning soft law as well as the legal nature of international conventions, non-binding treaties and other agreements. From the late 1990s and the early 2000s, attention to soft law came to reflect 'the increasing awareness of globalisation and the importance of non-state actors, but also how globalisation makes traditional law making more problematic when states are embedded in various formal and informal organisations.' (Mörth 2005, 4). Mörth recognises, the concept of soft law 'fits nicely with the analysis of the EU as a system of multilevel governance' (2005, 4).

To be true, EU law departs from public international law because of its direct effect not only on states, but also on individuals. Notwithstanding, the part played by soft law in the EU legal system appears to be growing, as already noted. How may this apparent paradox between EU law as a supranational legal framework and the growing role of soft law be accounted for?

Soft law can no doubt offer ways to tackle uncertainty and controversy in ethically and socially sensitive areas, including for public authorities to test the reaction of public opinion to a specific matters (Gersen, Posner 2008, 41). Soft law can also facilitate stakeholders and public involvement in consultative processes leading to EC green or white papers as

preparatory stages for EU decision-making and in this way enhance EU legitimacy (Senden 2004, 224). This attribute has been underlined in several opinions from the EESC and is consistent with the wished-for proximity between institutions and citizens that has increased in the last decades. Lack of agreement between Member States and lack of formal EU jurisdiction can also be more easily bypassed through soft law originating from European institutions. In all these circumstances, soft law will mostly operate as a preparatory stage for legislation. To the extent that soft law features pre-regulatory or bottom-up regulatory action, it may also be regarded as a favourable and flexible vehicle to translate ethical, values-related concerns linked to the impacts of science and technology.

However, pros and cons of soft law have been debated. The European Parliament has cautioned against the dangers of too strong reliance on soft law, especially when the authority of the design of particular soft law is delegated to bodies lacking democratic control. Soft law may, it has been alerted, also 'become a tool in the hands of a few powerful or privileged players that sidestep constraints of the legal process and that view it as a powerful alternative to lobbying elected representatives'. The European Parliament also admitted that soft law does not 'provide full judicial protection' (EP 2007, paragraph D), brings 'confusion and insecurity' (EP 2007, paragraph N) and generating a 'public perception of "superbureaucracy" with no democratic legitimacy' (EP 2007, paragraph Y).

A setback of soft law instruments certainly is its 'loose' character for lack of binding force. However, soft law has a persuasive characteristic too, namely the threat that if it does not meet the objectives set by the European institutions, these can resort to hard law. This notion comes out clearly from the White Paper on Governance: soft law does not preclude the adoption of hard law if the former does not reveal itself effective (EC 2001, 21). An additional difficulty may be the lack of transparency, since elaborating and publicising soft law does not always take place through a mandatory process. This should be balanced against the trend to publish soft law acts through the Internet and growing awareness of the need for consultation and dialogue (Senden 2004, 496).

Indeed, in the European legal and institutional system the role of soft law is far from consensual. Though the EC has favoured soft law as one policy tool among others, the European Parliament voiced a severe critique against soft law. Considering the distinction between *dura lex/mollis lex* to be conceptually aberrant, therefore, to be discarded, the European Parliament argued that extensive recourse to soft law instruments would signify a shift from the unique Community model to that of a traditional international organisation. 'So-called soft law instruments, such as recommendations, green and white papers or Council conclusions, do not have any legal value or binding force', the European Parliament pointed

out (EP 2007, paragraphs B and C). These instruments, ‘which can be used as interpretative or preparatory tools for binding legislative acts, should neither be treated as legislation nor be given any norm-setting effectiveness’ (EP 2007, paragraph M). ‘Only where the Treaty expressly provides for them, soft law instruments are legitimate, *provided that they are not used as a surrogate for legislation*’, the Parliament concluded. For the Parliament, the EU Commission ‘better legislation agenda’ should not be subverted in order to allow the EU executive to legislate by means of soft law instruments, thereby potentially undermining the European legal order, avoiding the involvement of the democratically elected Parliament and legal review by the Court of Justice and depriving citizens of legal remedies.

Both the Commission and the European Court of Justice (ECJ) admitted that soft law may produce legal effects. Soft law (e.g. notices and guidelines in the field of competition policy) have been considered by the ECJ as entailing legal effects to be taken into account in deciding cases submitted for their judgment, when this serves the enforcement of certain superior principles of law (Stefan 2008, 753 ff). In *Commission v Germany*, Advocate General Mazak acknowledged the legal effects of soft law⁶.

Resort to soft law in the EU can be related to the objectives announced in the EC’s White Paper on European Governance, published in 2001. The White Paper and additional documents addressing a ‘better regulation agenda’ point toward greater use of different policy tools, namely regulations, framework directives, guidelines, recommendations, co-regulatory mechanisms, and even self-regulation to be selected on a case-by-case basis. In this connection, the EC has shown its concern ‘to react more rapidly to changing market conditions and new problems by reducing the long delays associated with the adoption and implementation of Community rules’ (EC 2001, 20). Improving efficiency converges with a concern with public involvement and participation in the wider context of governance set up in the White Paper meaning ‘rules, processes and behavior that affect the way in which powers are exercised at European level, particularly as regards openness, participation, accountability, effectiveness and coherence’ (EC 2001, 8). According to the Commission, ‘investment in good consultation “upstream” may produce better legislation which is adopted more rapidly and easier to apply and enforce’ (EC 2001, 20). However, the White Paper attracted criticism around Europe, from those who regarded the use of ‘new tools’ such as co-regulation and the open-method of coordination as step-backs in the integration process.

⁶ Opinion of Advocate General Mazak delivered on 12 November 2009, Case C-518/07, *Commission v Germany* [2010] ECR P-I01885, § 11, <http://eur-law.eu/EN/Opinion-Mr-Advocate-General-Mazak-delivered-12-November,395943,d>.

Strikingly, self-regulation has not raised similar controversy in the EU. While condemning soft law, the Parliament acknowledged that codes of conduct constitute ‘important elements of self-regulation’ (EP 2007, paragraph 12). Doing so it distinguished soft law from self-regulation, as did the White Paper whilst stressing the need to ‘combine formal rules with other non-binding tools such as recommendations, guidelines or even self-regulation’ as means towards a ‘less top-down approach’ in EU law making (EC 2001, 4, 20, 22; Senden, 2005).

Codes of conduct and codes of practice are common at the initiative of scientists and scientific associations, and sometimes of technology developers too⁷. European law explicitly recommends the enactment of codes of conduct in a move towards complementarity of hard and soft law with self-regulation. The European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers was the object of an EC Recommendation in 2005⁸. Decision 2011/12/EU states that the European Scientific Council shall adopt ‘a code of conduct on confidentiality, potential conflict of interest, and processing of personal data’ (EC 2011, Article 1, no 5). Directive 95/46/EC, the Data Protection Directive, also encourages the adoption of codes of conduct by Member States and the Commission ‘intended to contribute to the proper implementation of the national provisions adopted by the Member States pursuant to this Directive, taking account of the specific features of the various sectors’ (Article 27). Still another example is the EC Recommendation on a code of conduct for responsible nanosciences and nanotechnologies research (EC 2008), to be addressed below⁹. Codes of conduct adopted by scientific researchers typically regulate matters like scientific fraud, misuse or misconduct. Yet, as the social relevance of scientific activities grew, professional and

⁷ Examples of codes of conduct in science and technology include the ‘Code of Conduct regarding Genetic Modification’ (<http://www.rabobank.com>), the Ethical Guidelines for the use of human embryonic or foetal tissue for experimental and clinical neurotransplantation and research’ of the Network of European CNS Transplantation and Restoration (NECTAR) (<http://www.nesu.mphy.lu.se/nectar/eth.1.html>), the ‘Memorandum on Scientific Integrity’ from the All European Academies (ALLEA) (<http://www.allea.org>). At the national level examples are the Deutsche Forschungsgemeinschaft (DFG) ‘Proposals for Safeguarding Good Scientific Practice’ (http://www.dfg.de/aktuelles_presse/reden_stellungnahmen/download/self-regulation_98.pdf), in Germany, and the Uppsala Code of Ethics for Scientists (<http://user.it.uu.se/~pugwash/Etik/uppsalakodex.html>), in Sweden.

⁸ http://ec.europa.eu/eracareers/pdf/am509774CEE_EN_E4.pdf. According to the European Charter for Researchers, ‘Researchers should adhere to the recognised ethical practices and fundamental ethical principles appropriate to their discipline(s) as well as to ethical standards as documented in the different national, sectoral or institutional Codes of Ethics’ (EC 2005, 11).

⁹ European Parliament resolution of 24 April 2009 on regulatory aspects of nanomaterials, (2010/C 184 E/18), P6_TA (2009) 0328 (10).

ethical misconduct by scientists came to the core of the relationship between society and science, calling for more than just self-regulation (EESC 2001, paragraphs 4.9, 4.9.1)¹⁰.

As a matter of fact, EU institutions greet self-regulation as a tool towards a more citizen-oriented governance. In a number of documents, namely, 'Current state of co-regulation and self-regulation in the Single Market', the 'Opinion on better law-making' and the 'Opinion on making European citizenship visible and effective', the EESC favoured 'socio-professional self-regulation and co-regulation in all areas of direct relevance to civil society' whereby the 'socio-professional actors themselves are not only consulted but are actually involved in defining economic or social rules which concern them directly' (EESC 2006b, 163, 168). The other side of the coin may, though, be that self-regulation is 'representing groups one-sidedly' (Héritier 2001, 6). Despite its generally favourable attitude towards self-regulation, the need to prevent self-regulation to bypass EU law in areas 'that very directly affect health and safety, and more broadly in the case of services of general interest' has been recognised (EESC 2005, 23). In the end, notwithstanding the specific roles recognised to both soft law and self-regulation, these tend to be regarded against the backdrop of European law properly speaking; in other words, their scope and their practical effects as regulatory tools appear to draw ultimately their legitimacy and influence from EU 'hard law'.

Against this somewhat fuzzy background, what trends may one perceive in EU regulation of nanotechnologies, biometrics, human cloning and genetically modified organisms? In the following section, we will seek to review and compare the current EU normative frameworks in these domains with a view to make out the part played by hard law and soft law, as well as self-regulation and co-regulation, and discuss the extent to which they enable more or less open and participative governance.

3. Comparing EU regulatory tools for several technologies

The nanosciences and technologies are among novel scientific and technological developments that appear difficult to frame by formal legislation: to start with, the scope of the field is still unclear, including their potential applications which range from chemicals to electronics, food or cosmetics, rendering it problematic to adopt a 'single regulatory framework' (European Parliament 2010, paragraph R; paragraph 10).

¹⁰ The OECD addressed scientific misconduct (fabrication, falsification and plagiarism) as a problem that 'damages the scientific enterprise' and 'undermines the trust of citizens in science and government', recommending the adoption of codes of conduct covering 'traditional ethics issues (e.g., rights of human subjects, handling of experimental animals, philosophical/moral aspects of research in human reproductive biology, defence-related research)'. See OECD, 'Best Practices for Ensuring Scientific Integrity and Preventing Misconduct', generally points to a science-based regulation, p. 1 and 13.

The EU chose to regulate scientific research and technological development in this area by the means of a soft law instrument, a recommendation from the EC, proposing a self-regulatory one, a code of conduct. The code of conduct for responsible nanosciences and nanotechnologies research is addressed to all stakeholders involved in nanotechnologies, i.e. 'Member States, employers, research funders, researchers and more generally all individuals and civil society organisations' (EC 2008, 5)¹¹. The EC Recommendation also emphasises the need for Member States to 'encourage the voluntary adoption of the Code of Conduct by relevant authorities, employers, research funding bodies, researchers, and any individual or civil society organization'. The code was presented as 'an appeal and a driving force for Member States and the research community to provide a tangible contribution to the good governance of technology' (EC 2007c, 2).

The public consultation carried out under the EC's auspices before the adoption of the Recommendation evidenced a wide consensus on the code of conduct as the appropriate regulatory tool in the circumstances. The major concern was to subject research and development in this field to a set of ethical principles.¹² In its Opinion on the 'Communication from the Commission: Towards a European strategy for nanotechnologies', the EESC also related openness and public dialogue to the need to clarify the ethical principles applicable:

'There must be an on-going and scientifically well-founded dialogue with the public. ... History has taught us that, very often, fear and concern regarding new products are born more out of ignorance than reality. This is one of the reasons why the EESC hopes that there will be an unceasing and direct connection between research results and universally recognised ethical principles' (EESC 2005b, paragraphs 8.12 and 8.12.1, original emphasis).

Stakeholders who adhere to the code should ensure that 'N&N research is undertaken in the Community in a safe, ethical and effective framework' (EC 2008, 5). Industry also

¹¹ See also Council Meeting No. 2832, 22-23 November 2007, p. <http://www.consilium.europa.eu/App/TransparencyCouncil/default.aspx?lang=en&cmsid=1119&pagenu m=25>. http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/intm/97225.pdf.

¹² The Council's conclusions of 25-26 September 2008 stressed that principles of responsible research warranted special attention in this area (Council Conclusions 2008, 34). Six major principles are proclaimed by the Recommendation: sustainability, precaution, inclusiveness, excellence, innovation and accountability. Initially, the Consultation Paper emphasised precaution, inclusiveness and integrity (p. 3 and 4). There were numerous proposals on principles. Examples include 'transparency' (proposed by civil society organizations) and 'Sustainable Development, Transparency, Openness, Security, Safety, Quality of Science, Responsibility, Anticipation and the Precautionary Principle in line with Progress' (proposed by industry) (p. 3, 4). In fact, if 100% of the policy-makers consulted agreed with the principles, 0% of the civil society agreed with them (Detailed analysis of results, p. 2). In the remaining categories, 79% of the Researchers and 54% of Industry agreed with the proposed principles (Detailed analysis of results, p. 2).

acknowledged ethical concerns ‘conscious of the importance of societal support to Nanotechnologies in order to gain trust and avoid GMO block’ (EC 2007d, 3). The European Parliament recently sent out an appeal to manufacturers of nanomaterial to adhere to the code of conduct¹³ (EP 2010, paragraph Z), considering that ‘the likely convergence of nanotechnology with biotechnology, biology, cognitive sciences and information technology raises serious questions relating to ethics, safety, security and respect for fundamental rights’ (EP 2010, paragraph Y). The Parliament also called for a new opinion by the European Group on Ethics in Science and New Technologies as well as for pursuing a ‘EU-wide public debate on nanotechnologies and nanomaterials and on the regulatory aspects of nanomaterials’ (EP 2010, paragraph 23)¹⁴.

Though emphasising the voluntary nature of the code, the EC determined that the EU should not fund nanoresearch whenever it ‘could involve the violation of fundamental rights or fundamental ethical principles’ (EC 2008, 9). Accordingly, the nanotechnologies action plan, launched in 2009, subjected research and development proposals submitted for funding under FP7 to a thorough ethical review. They should be funded only ‘if they address ethical issues adequately and meet the necessary Community and national requirements – including the EU Charter of Fundamental Rights’ (EC 2009, 6).

Novelty and uncertainties involved in this area, either with respect to their scope or to their potential ethical and legal as well as physical impacts surface as primary motivations for the EC option to combine soft law with self-regulation (EC 2007d, 4-5). By the same token, drawing lessons from the highly contested regulatory history of GMO, the EU used this opportunity to open up and involve all stakeholders in the debate on the appropriate regulatory principles for nano S&T.

Yet, noticeably, the European Parliament has just started consideration of proposals for specific regulations on the use of nanotechnologies in two fields, cosmetics and novel food.

Soft law has also provided a key regulatory tool in respect of human cloning. The European Parliament’s resolution on human cloning, of 2000, reflected the Parliament’s recognition of the need to address a new technology at an initial stage of development, raising highly sensitive ethical dilemma.

¹³ ‘Calls for the application of a duty of care for manufacturers that wish to place nanomaterials onto the market; and calls on them to adhere to the European code of conduct for responsible nanosciences and nanotechnologies research’ (10), European Parliament resolution of 24 April 2009 on regulatory aspects of nanomaterials, (2010/C 184 E/18), P6_TA (2009) 0328.

¹⁴ On the EGE and the blurring of normative ethical and legal orders cf. Plomer 2008 845, 846: ‘the EGE’s Opinions have historically drawn on a mixture of ethical principles and fundamental (legal) principles contained in a variety of sources. (...) The danger lies in the blurring of normative ethical and legal orders in areas which are already potentially highly charged’ as happens with S&T and on the EGE as a ‘grey governance’ institution cf. Flear; Vakulenko 2010, 684.

Cloning, a technology at an experimental phase is indeed one of the most controversial issues in the bioethics debate nowadays; a debate that is far from being closed. 'Cloning is the process of producing 'genetically identical' organisms. It may involve division of a single embryo, by prompting a fertilised egg to split in two, in which case both the nuclear genes and the small number of mitochondrial genes would be 'identical', or it may involve nuclear transfer, in which case only the nuclear genes would be 'identical' (GAEIB 1997, p. 2).¹⁵ The GAEIB¹⁶ accepted that research on nuclear transfer could have important therapeutic applications for the development of appropriate stem cell cultures for the repair of human organs, and could also provide insights into how to induce the regeneration of damaged human tissues.¹⁷ The GAEIB also admitted non-therapeutic research on human embryos involving nuclear substitution as long as it is conducted under strict licence and only with 'the objective either to throw light on the cause of human disease or to contribute to the alleviation of suffering.'¹⁸ Instead, for the European Parliament, reproductive and therapeutic cloning should equally be banned since any relaxation 'will lead to pressure for further developments in embryo production and usage.'¹⁹ Cloning involving the creation of human embryos for research purposes poses a 'profound ethical dilemma' and 'irreversibly crosses a boundary in research norms', the Parliament believed.²⁰ While recognising that 'the undoubted need for medical research resulting from advances in knowledge of human

¹⁵ This distinction is relevant in considering the implications of cloning (GAEIB 1997, p. 4). The first method is the simpler way to create a clone. This is a technique already employed for stock breeding that constitutes with somatic cell nuclear transfer the main techniques of reproductive cloning, or simply put, the use of technology to create a living copy of an existing human. The second method, cloning by nuclear replacement, or therapeutic cloning, is a technology whereby embryonic stem cells can be harvested for curing diseases and eventually to replace organs and tissues.

¹⁶ The Group of Advisers on the Ethical Implications of Biotechnology to the European Union preceded the European Group on Ethics.

¹⁷ GAEIB, Ethical Aspects of Cloning Techniques, 5.

¹⁸ GAEIB, Ethical Aspects of Cloning Techniques, 6. In the same vein, Dir 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions prohibits the granting of patents on processes for cloning human beings and uses of human embryos for industrial or commercial purpose (paragraphs 41 and 42) as contrary to the purposes of public order and morality (Art 5, No 1 and 6). However, such exclusion did not affect 'inventions for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it' (paragraph 42 and Art 6, No 2).

¹⁹ European Parliament Resolution on Human Cloning, paragraph H.

²⁰ European Parliament Resolution on Human Cloning, paragraph 2 and paragraph E. This was in line with trends in EU research and development policy. cf Dec 1982/2006/EC, of 18 December 2006, 7th framework programme, Art 6 ('Ethical principles'), paragraph 2: 'The following fields of research shall not be financed under this Framework Programme: research activity aiming at human cloning for reproductive purposes'; Dec 1513/2002/EC, of 27 June 2002, 6th Framework Programme, underlining that fundamental ethical principles shall be respected, including the principles highlighted in the Charter of Fundamental Rights and in the Council of Europe Convention on Human Rights and Biomedicine (Oviedo, 1997) and the Additional Protocol on the Prohibition of Cloning Human Beings (Paris, 1998) (Annex I); and Council Dec 2002/834/EC, of 30 September 2002, 'The following fields of research shall not be financed under this programme: research activity aiming at human cloning for reproductive purposes' (Annex I).

genetics must be balanced against strict ethical and social constraints²¹, the European Parliament resolution on human cloning proclaimed that 'there should be a universal and specific ban at the level of the United Nations on the cloning of human beings at all stages of formation and development'²². To justify this ban, the European Parliament's resolution emphasised the value of 'human dignity and the consequent value of each human being'²³. Article 3 of the EU Charter of Fundamental Rights eventually prohibited the reproductive cloning of human beings, leaving out therapeutic cloning (Article 3, paragraph 2, d). Hard law was therefore employed to the extent that a social and political consensus existed in Europe, indeed an early and rather broad one, on the rejection of human cloning for reproductive purposes. Accordingly, the 7th framework programme on research and development forbade research involving reproductive cloning²⁴.

Divergences among EU institutions in this regard reflect the imprecision of the right to human integrity and of the principle of human dignity and the consequent passing on of their practical definition to EU institutions, which show different degrees of sensitivity to the ethical values at stake.²⁵

In contrast to both the nanosciences and the technologies and human cloning, biometrics, an information technology, which rose to the centre of techno-juridical and techno-political debates following the '9/11', has been regulated predominantly through hard law instruments, namely Regulation (EC) No. 2252/2004, of 13 December 2004, on standards for security features and biometrics in passports and travel documents issued by Member States, and Directive 95/46/EC, of 24 October 1995, on the protection of individuals with regard to the processing of personal data and on the free movement of such data. Biometrics relies on human characteristics such as face features, fingerprints, hand impressions, iris recognition or DNA to verify the identity of an individual. Biometrics is nowadays one of the central pieces of national and international security and immigration policies in Europe and became also increasingly important economically as it is more and more employed to control access of workers, students, and other categories of people in various organisations (IPTS 2005, 80-87).

²¹ European Parliament Resolution on Human Cloning, paragraph B.

²² European Parliament Resolution on Human Cloning, paragraph 10.

²³ European Parliament Resolution on Human Cloning, paragraph A.

²⁴ Decision 1982/2006/EC, of 18 December 2006, 7th framework programme, Article 6; Decision 1513/2002/EC, of 27 June 2002, 6th Framework Programme, Annex I; and Decision 2002/834/EC, of 30 September 2002, Annex I

²⁵ Recent news about the discussion in the EU of novel food (meat and milk) produced through animal cloning confirms the opposing views of the Parliament and the Council: whereas the Parliament rejected their commercialisation, the Council of Ministers of Agriculture favoured the assignment of the statute of novel food to such products. cf 'Des aliments issues du clonage dans l'assiette anglaise', *Le Monde*, 7 August 2010, 4.

Although not absolutely secure as an identification technique according to the experts, biometrics has not raised uncertainties or social unrest equivalent to those surrounding other new technologies entailing risks for man and the environment such as biotechnologies or even nanotechnologies. In fact, biometrics technologies allow the collection of data on intimate features of individuals, yet this does not seem to have been perceived widely as a peril for individual liberty. In the EU context, biometrics was furthered primarily for security purposes following US government's pressure on the EU to adopt the biometrical passport for EU citizens travelling to the USA. Both the urgency of the implementation and the security policy background made biometrics prone to be framed by a hard law instrument.

However, in some way biometrical data protection also illuminates how hard law may call upon self-regulation as a complementary regulatory tool. The Data Protection Directive, rendered applicable to biometrical data to be processed in the context of passports and travel documents by Regulation No. 2252/2004 (Article 4), remits, in Article 27, 1, to self-regulation. Codes of conduct should be encouraged by Member States as a means to contribute to the proper implementation of the Directive. Examples of such codes of conduct are the Irish Biometrics Organisation's Code of Ethics and the International Biometrics & Identification Association (IBIA)'s Ethics Statement²⁶.

The privilege assigned to hard law rather than soft law and self-regulation as regulatory tools for biometrics may account for the insufficiency of the procedural arrangements practiced from the point of view of public or citizens' involvement. 'The dialogue to date has been heavily influenced by commercial interest and political aspirations', and 'there has been remarkably little genuine consultation with citizens on a matter which will have a significant impact upon society', a report prepared for the EC admitted (Ashbourn 2005, p. 21).

A somewhat similar path has been followed previously with respect to genetically modified organisms (GMO). GMO regulation developed in the EU in the last two decades mainly by way of EU legislation, i.e. directives and regulations. As a technology already employed in field experimentation and starting to be used for agro-industrial production, hard law and formal institutional procedures under the EU and Member States offered the appropriate means to control GMO research and applications in agriculture and food production. Starting with Directives 90/220/EEC and 90/219/EEC, the EU regulatory framework for GMO now includes Directive 2001/18/CE on the deliberate release into the environment of GMO, Regulation 1829/2003 on genetically modified food and feed and Regulation 1830/2003

²⁶ Both codes have been adopted by not-for-profit trade associations, and proclaim the principles of safeguarding the public, respect competitive technologies, accountability in marketing, legitimacy and free trade. See www.ibo.ie/code_of_ethics.php; www.ibia.org/association/ethics-statement/.

concerning the traceability and labeling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms.

But this technology also offers an illustration of the role that self-regulation and soft law can play in anticipating hard law, either because the topics are sensitive or tend to be addressed first in a flexible non-binding manner, or due to the novelty of the subject matter.²⁷ A well-known anticipatory move of this kind was the pioneering Asilomar Conference held in 1975 when scientists drew up a self-regulatory instrument²⁸ admitting uncertainties involved in genetic research and the need to have it regulated. In the European space, prior to Directive 90/220/EEC, genetic research and engineering was the subject of a number of written questions to the European Parliament. Two relevant resolutions were adopted, the 'Resolution on the effects of the use of biotechnology on the European farming industry' (1987)²⁹ and the 'Resolution on the ethical and legal problems of genetic engineering' (1989)³⁰.

In sum, soft law and self-regulation were resorted to at earliest stages paving the way to legislation once research and technological applications and their impacts on the economy and society became perceivable.

Yet, remarkably, soft law has been the main option for regulating the coexistence of genetically modified crops with conventional and organic crops. The Commission Recommendation of 13 July 2010 on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops (2010/C 200/01), replacing Recommendation of 23 July 2003 (2003/556/EC), recognized that 'Member States need sufficient flexibility to take into account their regional and national specificities and the particular local needs' (EC 2010, paragraph 7). In this instance, European soft law paved the way for national rather than European legislation, leaving to Member States the choice of regulatory tools (Directive 2001/18/CE, Article 26 a). Recommendation 2003/556/EC stated that 'Member States may prefer to explore the use of different policy instruments, e.g., voluntary agreements, soft-law approaches and legislation' (Recommendation 2003/556/EC, p. 10).³¹

²⁷ New developments in food law have seen the expansion of codes of conduct. The aquaculture industry constitutes another example of this self-regulatory trend: http://www.piscestt.com/consumer/codes/feapintro_en.asp.

²⁸ Summary Statement of the Asilomar Conference on Recombinant DNA Molecules, 20 May 1975, http://profiles.nlm.nih.gov/QQ/B/C/G/D/_/qqbcgd.pdf.

²⁹ Official Journal C 076, 23/03/1987, p. 0022.

³⁰ Official Journal C 096, 17/04/1989, p. 0165.

³¹ At the national level, voluntary codes or non-binding codes of good practice have been chosen by a minority of countries as policy instruments to address coexistence. Spain and Netherlands are among these countries. Cf. Commission Staff Working Document, Annex to the Commission Report on the implementation of national measures on the coexistence of genetically modified crops with conventional and organic farming (SEC (2006)313), p. 17 and Commission Report on the implementation of national

The Commission's reports on the implementation of coexistence measures help clarifying the *ratio* behind the recommendations³². Lack of knowledge on the impact of coexistence and of coexistence measures and the 'need to conclude the process of implementing national coexistence measures' were presented as justifications for not developing a 'dedicated harmonized legislative approach' (EC 2006, 4 and 10). In this instance, soft law has been employed by the EC as a coordinating method of national measures. Despite the use of recommendations as regulatory tools, hard law keeps providing not only the underlying basis (particularly, Directive 2001/18/EC), but also their follow-up. The EC underlined the compulsory character of the proposed measures, and even raised doubts about compliance of Member States with the Commission's 'advice' (EC 2006, 6). 'National coexistence measures cannot introduce requirements to protect the environment which go beyond the provisions laid down in Community legislation' (EC 2006, 5).

This shows how these recommendations as "soft law"³³ have in fact been invested with some degree of binding force.³⁴

4. Conclusion

As pointed out in the introduction, there is a pretty wide belief that soft law together with voluntary self-regulation provide suitable regulatory tools for S&T, possibly better tools than 'hard law', to cope with the need for both flexibility and adjustment to novelty and prevailing uncertainties. There are indeed some plausible reasons for embracing soft law and for encouraging self-regulation in S&T. In the EU, the need for harmonization of rules among Member States combined with the necessary elasticity to deal with technologies progressing at a fast rhythm, and involved in uncertainties with respect to their economic and social, as well as environmental, impacts triggers the recourse to soft law, namely recommendations, resolutions, guidelines and similar normative instruments by EU institutions.

What tendencies may one draw from the above comparative overview of the EU regulatory response to various emerging technologies?

measures on the coexistence of genetically modified crops with conventional and organic farming (COM(2006)104 final), p. 7.

³² The Commission will report in 2012 on Recommendation of 13 July 2010 (Report of 2 April 2009 on the coexistence of genetically modified crops with conventional and organic farming, COM (2009)153 final, p. 11).

³³ Commission Recommendation of 13 July 2010 underlines that 'the present guidelines take the form of non-binding recommendations' (paragraph 1.4). Commission Recommendation 2003/556/EC of 23 July 2003 has the same phrasing (paragraph 1.5).

³⁴ The legal effect of recommendations was addressed by the ECJ in the *Grimaldi* case regarding national courts: 'national courts are bound to take recommendations into consideration in order to decide disputes submitted to them'. See Case C-322/88, *Grimaldi* [1989] ECR I-4407, para 18. Cf. Ştefan 2008, p. 767.

The EC recommendation on a code of conduct for Nanos S&T provides a paradigmatic illustration of soft law as a means to promote self-regulation in an emerging scientific and technological area where doubts and uncertainties persist with respect to the scope itself of the area, potential applications, and ethical and social implications generally. The recommendation and the code of conduct represented, for the EU institutions that launched it, a conscious, deliberate “effort to integrate the societal dimension into R&D” and “to involve all stakeholders”.

In contrast, the prohibition of reproductive human cloning in the EU Charter of Fundamental Rights may be understood in light of the wide social and political consensus already existing in that regard. Yet, this consensus was confined to human cloning for reproductive purposes. Uncertainties remaining with respect to possible therapeutical applications of human cloning, soft law in the form of a European Parliament resolution was the regulatory tool used to address it.

EU regulation of biometrics consists mainly of hard law instruments. Biometrics being a security technology widely employed for social control by the police and security services, accounts for the preference for hard law, but maybe also the alleged lack of transparency of and public involvement in the decision making process that led to the adoption of the biometrical passport legislation.

Then the question comes back: are soft law and self-regulation being preferred by EU institutions as regulatory tools in the field of new sciences and technologies or are they operating mostly as a preparatory stage or as a complementary tool of hard law? Is soft law being used chiefly to address ethically or socially sensitive or controversial topics in science and technology? And is soft law working as guarantee for a more democratic governance of science and technology?

We draw from our overview of recent EU regulation that soft law is being used primarily a preparatory or opening phase for hard law. In turn, self-regulation is being promoted by EU institutions as a complementary means to further implementation of legislation: in other words, they both work as preliminary or complementary stages of hard law; besides, they are either grounded or dependent upon EU legislation, the latter yielding them their authoritative force.

While soft law indeed seems to provide a reply to the rhythm of change and the need to accommodate the societal and ethical dimensions at stake in emerging sciences and technologies, doubts subsist concerning its effectiveness as a regulatory means. Moreover, a paradox seems to follow the growing use of soft law approaches, self-regulation and co-regulation as new governance instruments: although they are often designed to enhance more

active participation and dialogue with civil society, and ultimately to increase the legitimacy of the EU, they are perceived as lacking transparency and accountability too³⁵. In the European regulation of S&T a difficult balance comes out between governance and citizen effective participation, on the one hand, and the dangers of a deregulatory and undemocratic movement that can accompany this phenomenon, on the other hand³⁶. Reaching the right equilibrium between soft and hard law instruments, governance and citizen participation, and hard law democratic enactment, namely in view of protecting human rights, is one of the main challenges that European S&T policy has to defy³⁷. Currently hard law instruments seem to prevail but the institutional European discourse points to a preference for alternative forms of regulation. The certainty required in contentious fields, combined with concerns for the lack of transparency surrounding some soft law instruments and the suspicion regarding powerful economic stakeholders' influence may be among the explanations for the prevalence of hard law instruments in S&T regulation.

³⁵ Cf. Verbruggen 2009, 431 and Scott and Trubek, 2002.

³⁶ The 'two-way negotiation' entails the idea of dialogue, already expressed in Article 11(2) of the TEU stating that institutions shall dialogue with civil society (Flear; Vakulenko, 2010, p. 670).

³⁷ E.g. the Horizon 2020 strategy, http://ec.europa.eu/research/horizon2020/index_en.cfm?pg=home.

5. References

Andorno, Roberto (2007), 'The Invaluable Role of Soft Law in the Development of Universal Norms in Bioethics', <http://www.unesco.de/1507.html>.

Ashbourn, J. (2005), 'The Social Implications of the Wide Scale Implementation of Biometric and Related Technologies', Background paper for the Institute of Prospective Technological Studies, DG Joint Research Centre, European Commission.

Carbonnier, Jean (1965), 'Le grandi ipotesi della sociologia teorica del diritto', *Quaderni di Sociologia*, Torino, XIV, n° 3, pp. 279 ss.

Carbonnier, Jean (1979), *Sociologia Jurídica*, Coimbra: Livraria Almedina.

Delmas-Marty, Mireille (2002), *Towards a Truly Common Law: Europe as a Laboratory for Legal Pluralism*, Cambridge: Cambridge University Press.

Di Robilant, Anna (2006), 'Genealogies of Soft Law', *The American Journal of Comparative Law*, 54, pp. 499-554.

Fauré, Christine (2011), *Ce que Déclarer des Droits Veut Dire*, Paris: Les Belles Lettres.

Flear, Mark L.; Vakulenko, Anastasia (2010), 'A Human Rights Perspective on Citizen Participation in the EU's Governance of New Technologies', *Human Rights Law Review*, 10(4), pp. 661-688.

GAEIB, Ethical Aspects of Cloning Techniques, 28 May 1997, 2, http://ec.europa.eu/european_group_ethics/docs/opinion9_en.pdf

Gersen, Jacob E., Posner, Eric A. (2008), 'Soft Law', Public Law and Legal Theory Working Paper No. 213, The Law School, The University of Chicago, <http://www.law.uchicago.edu/academics/publiclaw/index.html>.

Héritier, Adrienne (2001), 'The White Paper on European Governance: A Response to Shifting Weights in Inter-institutional Decision-Making', Jean Monnet Working Paper No. 6/01, Symposium: Mountain or Molehill? A Critical Appraisal of the Commission White Paper on Governance, <http://centers.law.nyu.edu/jeanmonnet/papers/01/011301.html>.

Institute for Prospective Technological Studies (IPTS), 'Biometrics at the Frontiers: Assessing the Impact on Society', (2005) Joint Research Centre, European Commission, 80-87 http://ec.europa.eu/justice_home/doc_centre/freetravel/doc/biometrics_eur21585_en.pdf

Mörth, Ulrike (2005), 'Soft Law and New Modes of EU Governance – A Democratic Problem?', http://www.mzes.uni-mannheim.de/projekte/typo3/site/fileadmin/research%20groups/6/Papers_Soft%20Mode/Moerth.pdf

Palmer, Aurora (2008), 'The European Group on Ethics: Law, Politics and the Limits of Moral Integration in Europe', *European Law Journal*, Vol. 14, Issue 6, November, pp. 839-859.

Scott and Trubek (2002), 'Mind the Gap: Law and New Approaches to Governance in the European Union', *European Law Journal*, Vol 8, No. 1, pp

Senden, Linda (2004), *Soft Law in European Community Law*, Portland, Oregon: Hart Publishing.

Senden, Linda (2005), 'Soft law, Self-regulation and Co-regulation in European Law: Where Do They Meet?', *Electronic Journal of Comparative Law*, vol. 9, <http://www.ejcl.org>.

Snyder, Francis (1994), 'Soft Law and Institutional Practice in the European Community', in Stephen Martin (ed.), *The Construction of Europe: Essays in honour of Emile Noël*, Dordrecht: Kluwer Academic Publishers, p. 197-225.

Ștefan, Oana Andreea (2008), 'European Competition Law in European Courts': A Matter of Hard Principles?, *European Law Journal*, Vol. 14, No.6, November, pp. 753-772.

Verbruggen, Paul (2009), 'Does Co-Regulation Strengthen EU Legitimacy?', *European Law Journal*, Vol. 15, No. 4, July 2009, pp. 425-441.

Von Bernstorff, Jochen (2008), 'The Changing Fortunes of the Universal Declaration of Human Rights: Genesis and Symbolic Dimensions of the Turn to Rights in International Law', *The European Journal of International Law*, Vol. 19, no. 5, 903-924.

Wellens, Karel. C., Borchardt, G. M. (1989), 'Soft Law in European Community Law', *European Law Review*, 14, pp. 267-321.

8. EU legislation and policy documents

Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013).

Directive 95/46/EC of the European Parliament and of the Council of 24th October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

European Commission (2000), Working Document 'Science, society and the citizen in Europe', SEC (2000) 1973.

European Commission (2001), 'White Paper on Governance', COM(2001) 428 final.

European Commission (2002), 'European Governance: Better lawmaking', COM(2002) 275 final.

European Commission (2003), Recommendation on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming (2003/556/EC).

European Commission (2005), Recommendation on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers, (2005/251/EC), http://ec.europa.eu/eracareers/pdf/am509774CEE_EN_E4.pdf.

European Commission (2006), Communication from the Commission to the Council and the European Parliament - Report of the implementation of the national measures on the coexistence of genetically modified crops with conventional and organic farming (COM(2006) 104 final).

European Commission (2007), 'Taking European Knowledge Society Seriously', Report of the Expert Group on Science and Governance to the Science, Economy and Society Directorate, Directorate-General for Research.

European Commission (2007b), Decision of 2 February 2007 establishing the European Research Council (2007/134/EC).

European Commission (2007c), Consultation paper "Towards a Code for Responsible Nanosciences and Nanotechnologies Research", <https://europa.eu/sinapse/sinapse/index.cfm?&fuseaction=cmtypubdiscdetail.detail&highlightsource=>.

European Commission (2007d), Detailed Analysis of Results from the Consultation on a 'Code of Conduct for Responsible Nanosciences and Nanotechnologies Research', http://ec.europa.eu/research/science-society/document_library/pdf_06/consultation-nano-sinapse-feedback_en.pdf.

European Commission (2008), Commission Recommendation on a code of conduct for responsible nanosciences and nanotechnologies research, COM (2008) 424 final.

European Commission (2009), Communication 'Nanosciences and Nanotechnologies: An action plan for Europe 2005-2009. Second Implementation Report 2007-2009', COM(2009)607 final.

European Commission (2010), Recommendation on 'guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops' (2010/C 200/01).

European Commission (2011), Decision of 12 January 2011 amending Decision 2007/134/EC establishing the European Research Council (2011/12/EU).

European Economic and Social Committee (2001), Opinion on 'the Commission Staff Working Paper, SEC(2000) 1973 "Science, society and the citizen in Europe"' (2001/C 221/25).

European Economic and Social Committee (2005), Information Report 'Current state of co-regulation and self-regulation in the Single Market', CESE 1182/2004, 10.02.2005.

European Economic and Social Committee (2005b), Opinion on the 'Communication from the Commission: Towards a European strategy for nanotechnologies' (2005/C 157/03).

European Economic and Social Committee (2006), Opinion on 'Better lawmaking' (2006/C 24/12).

European Economic and Social Committee (2006b), Opinion on 'Making European citizenship visible and effective' (2006/C 318/28).

European Economic and Social Committee (2009), Opinion on 'Fair trade food products: self-regulation or legislation?' (2009/C 318/06)

European Parliament (2000), Resolution on human cloning (7 September 2000).

European Parliament (2007), Resolution on institutional and legal implications of the use of "soft law" instruments (4 September 2007).

European Parliament (2009b), Resolution on regulatory aspects of nanomaterials, (24 April 2009).

Inter-institutional Agreement on Better Law Making (2003/C 321/1).