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Converging by procedures: Assisted reproductive technology regulation within the European Union

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Abstract

This article is structured in three sections. In the first section, the theoretical framework of the analysis will be laid out, grounded on the need for a paradigm shift when classifying national regulations on assisted reproductive technologies (ARTs). Instead of focusing directly on the specific content of each national regulation, it is more appropriate to move towards a focus on the characteristics of the decision-making process which drive political choices. In the second section, a comparative analysis will be provided of legal systems belonging to different legal families (civil law and common law families), such as Spain and the UK, France and Italy. The analysis will be conducted using a set of classificatory indexes covering both the decision-making process and the theory of law which is developed within specific but different regulatory regimes. According to these criteria, the legal systems analysed have been classified according to a threefold distinction: the 'procedure-oriented' model (UK and Spain); the 'hybrid' model (France); and the 'value-oriented' model (Italy). Comparison seems to show the need for new actors, sites and procedures of law-making in the field of ART. Accordingly, it seems advisable to devise new regulatory systems, in order to achieve, on the ground of comparative analysis, original mechanisms of law-making, starting from the assumption that sharing common deliberative methods proves to be more effective in view of a convergence of national policies. In the last section, a new regulatory mechanism will be proposed. It has been defined as 'integration by specialisation' of regulatory tools. This proposal stems from the assumption that, rather than harmonisation by imposing common regulatory content, harmonisation between national regulations (which is crucial in the light of both

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a uniform health care system and a common 'market' of biotechnological research in the European Union framework) can be effectively achieved by enforcing common regulatory mechanisms. These mechanisms can be based on the plurality of regulatory tools, each characterised by a specific (autonomous) normative function.[1]

Keywords
Bio-law, assisted reproductive technologies, law-making process, comparative law

From legislative content to legislative method: new routes for classifying ART regulation

A preliminary issue to deal with in this comparative examination of assisted reproductive technology (ART) regulation is the question of why harmonisation should be considered necessary within the European legal framework.[2] It is possible to isolate three classes of reasons:

The desirability of a uniform health care system

The freedom of movement of patients within the European Union (EU) inevitably facilitates a 'cherry-picking' process when accessing national health care systems. Patients move, when they are financially able to do so, towards Member States that provide an ART, which is prohibited in their own country (i.e. the case of gametes donation or preimplantation genetic diagnosis (PGD)).[3]

The need for a common European space for biomedical research

A fragmented and differentiated regulatory framework inevitably clashes with the aim of facilitating the circulation of both researchers and research projects within EU, as the same research (i.e. human embryonic stem cell (hESC) research) is regulated in often opposite ways within Member States. This leads to legal uncertainty (researchers do not understand what is allowed and what is not, such as in the case of imported embryonic stem cell lines in Italy). It also tends to limit the freedom of research;

1. Regarding the concept of 'regulatory tool', refer to R. Brownsword, *Rights, Regulation, and the Technological Revolution* (New York: Oxford University Press, 2008).
2. The call for harmonisation within EU is neither new nor original: see, among others, C.M. Romeo Casabona, 'Embryonic Stem Cell Research and Therapy: The Need for a Common European Legal Framework', *Bioethics* 16(6) (2002), pp. 557–567.
3. The so-called 'reproductive tourism' phenomenon, on which see G. Penning, 'Reproductive Tourism as Moral Pluralism in Motion', *Journal of Medical Ethics* 28(6)(2002), pp. 337–341; R.F. Storrow, 'The Pluralism Problem in Cross-Border Reproductive Care', *Human Reproduction*, 25(12)(2010), pp. 2939–2943.

Supporting the shift from an 'ethics-focused' approach towards a 'rights-centred' perspective

Ethical concerns develop a 'block-function' when regulating ARTs and biomedical research, which would be better regulated by sharing a perspective in which fundamental rights protection is the focal goal. In democratic pluralistic societies, an 'ethics-centred' approach inevitably leads to a clash of opposite ideological perspectives which can be resolved exclusively by imposing a hierarchy among values. A 'rights-centred' perspective may, however, allow for a regulatory regime aimed at accommodating and balancing different rights and principles, by renouncing a predefined hierarchy of values.[4]

Regulating science: ethical, economic and social concerns arising from ARTs

The issues and concerns currently raised by the regulation of new medical treatments or new scientific and technological discoveries affect many aspects of society: cultural, economic, ethical and social. Therefore, the regulation of science has become a key issue. Recent cases have also shown the relevance of science regulation at both the supranational and international levels.[5] A good example is provided by the recent case of *Greenpeace v. Brüstle*,[6] in which the European Court of Justice (ECJ) stated that both commercial invention based on, and technical processes using, embryonic stem cells cannot be patentable, as they infringe upon morality and human dignity.[7] According to the ECJ, as the aim is to exclude any possibility of patentability, where respect for human dignity could thereby be affected, the concept of 'human embryo' within the meaning of the Directive must be understood in a wide sense (para 34). The ECJ goes on to articulate a definition of 'human embryo' that extends not only to any fertilised human ovum but also any non-fertilised human ovum. Therefore, the cell nucleus transfer from a mature human cell and a non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis also fit within the definition (para 36). This is quite an innovative and controversial development. If we look to ECJ case law, when facing the concept of 'human dignity' in the *Omega* case,[8] the Court refuses to propose – at the EU level – a comprehensive definition,

4. C.R. Sunstein, *Designing Democracy: What Constitutions Do* (Oxford University Press, 2001), refers to 'incompletely theorised agreements' within the constitutions, which play a central role in the constitution of a democratic social order (p. 52).
5. On the role played by the European Court of Justice in developing a European health policy, see E. Brooks, 'Crossing Borders: A Critical Review of the Role of the European Court of Justice in EU Health Policy', *Health Policy* 105(1) (2012), pp. 33–37.
6. European Court of Justice (October, 2011, C-34/10).
7. On patentability of embryonic stem cells, S.R. Donnelly, 'The Patentability of Human Embryonic Stem Cells: Is the Inconsistent Application of the European Union Biotechnology Directive's Moral Exclusion Clause Undermining Investor Confidence in Europe, Providing a Competitive Advantage to the United States?', *Dalhousie Journal of Legal Studies* 20 (2011), pp. 106–128.
8. 'Judgment of the European Court of Justice (First Chamber) of 14 October 2004 – C-36/02 – Omega'.

binding each Member State. On the contrary, it leaves it to States to come up with their own definition, on the grounds of their concrete constitutional, cultural and social backgrounds. In the case of 'human embryo', leaving aside the traditional reluctance of European jurisdictions when they are called to define when life begins and what has to be intended with the human embryo,[9] the ECJ decided to accept the risk of introducing a very wide definition of 'human embryo'. It tried to act with caution, by specifying that the definition binds Member States exclusively for the purposes of the Directive (patentability). As stressed in paragraph 40 of the decision, the Court points out that 'the purpose of the Directive is not to regulate the use of human embryos in the context of scientific research'.[10]

However, the ECJ also stated that the use of human embryos for the purposes of research which constitutes the subject matter of a patent application cannot be separated from the patent itself and the rights attaching to it. Accordingly, the use of human embryos for purposes of scientific research, which is the subject matter of a patent application, cannot be distinguished from its industrial and commercial use: thus, the exclusion from patentability cannot be avoided (para 44). In order to protect human dignity and morality, research on embryonic stem cell is not prohibited in itself, as the decision refers exclusively to patentability and commercial exploitation of inventions, but the use of embryos for research purposes cannot be patentable.[11] This outcome, linked with both the very wide definition of 'human embryo' and the absolute lack of discretion for Member States, may produce at least an indirect effect on research with embryonic stem cells: private enterprises rarely invest funds on research from which they cannot derive economic benefits.[12] Therefore, the route of public funding will be the (almost exclusive) resource for financing this research and this – as outlined by some Italian scholars commenting on the ECJ decision[13] – may increase low-profit research, in which the exclusive goal will be public health instead of commercial exploitation of research results.[14]

9. Both the ECJ and the European Court of Human Rights (ECtHR) – see the cases *Vo v. France* ('Application no. 53924/00, decision of 8 July 2004 – European Court of Human Rights-Grand Chamber') and *Evans v. UK* ('Application no. 6339/05, Grand Chamber, decision 10 April 2007').
10. The consequences for researchers working on commercialising cell therapies based on hESC still remain unclear (see N. Moran, 'European Court Bans Embryonic Stem Cell Patents', *Nature Biotechnology* 29 (2011), pp. 1057–1059.)
11. On the threats deriving from the concept of commodification, also referring to the *Brüstle* case, see T. Caufield and U. Ogbogu, 'Stem Cell Research, Freedom of Research and the Commodification Concern', *EMBO Reports*, 13(2012), pp. 1–5.
12. See A. Abbott, 'Stem Cells: The Cell Division', *Nature*, 480(7377) (2011), pp. 310-312 saying that 'if academic scientists using human ES cells want to found a biotechnology start-up company, they'll now find it hard.' See also R. Isasi and B.M. Knoppers, 'From Banking to International Governance: Fostering Innovation in Stem Cell Research', *Stem Cells International* 11 (2011), p. 5.
13. See M. Tallachini, in *L'Avvenire*, October, 19th, 2011.
14. It still remain unclear how this approach may work in legal systems in which hESC research is excluded from public founding, such as it happens in Italy.

At the international level, the case *S.H. and Others v. Austria*[15] seems to raise all of the issues related to the beginning of life, particularly when ART comes into view.[16] We will return to this case at the end of the article, as it is relevant to assessing the way in which national legislatures, even when equipped with a wide margin of appreciation, must exercise their own discretionary power in science-related fields. For now, it is important to stress that the European Court of Human Rights (ECtHR) in this case recognised the compatibility of the ban of gametes donation for in vitro fertilisation purposes with article 8 of the ECHR (right to respect private and family life). This decision seems to show that, within the biomedical context we are moving from a normative particularism to an interconnected, multilevel and multilayered regulatory system, in which States must also consider legal perspectives that come from outside their own legal framework. In fact, the constitutionality of an absolute ban of gametes donation provided by the Italian Law on ART has been challenged before the Italian Constitutional Court[17] on the grounds of a previous decision of the First Section of the ECtHR, asserting the incompatibility of this kind of prohibition with article 8 of the ECHR. The *S.H.* case is also relevant for another reason. If we consider the whole '*S.H.* saga' (both the abovementioned decision by the Grand Chamber and the one by the First Section (April 2010)), it may have possibly established at the international level a set of procedural requirements with which national legislatures must comply when regulating science-related issues, in order to guarantee the scientific and social soundness of political discretionary intervention. We will come back to this point in the last section of this article.

A Hamletian dilemma: to legislate or not to legislate?

What do these cases show? They seem to demonstrate the need to achieve a common understanding of the relationship between law and science within the European legal framework and a common approach when legislating at a national level, in order to guarantee a reasonable level of harmonisation. From this perspective, ART is a crucial issue, due to increasing social demand for access to these techniques. The more social demand increases, the more scientific, ethical and economical concerns arise. Particularly relevant are issues such as:

- the legitimate purposes for having access to ART (should it be authorised exclusively for overcoming infertility problems or also for avoiding the risk of transmission of some or all genetic diseases?);
- limitations on the application of ART (must the determination of the number of producible and transferable embryos be reserved for physicians or can the legislature introduce legislative limits, as happens in different ways in Italy, Germany, Austria and Spain?);

15. ECtHR, November 2011.
16. K.D. Brudy, 'Recent Developments: *S.H. v. Austria*: European Court of Human Rights Holds That the Right to Family Life and Sexism Trump Governmental Limitations on Artificial Procreation', *Tulane Journal of International and Comparative Law*, 19 (2011), p 691.
17. Article 7, no. 40/2004.

- the admissibility of preimplantation genetic diagnosis (a vast range of regulatory solutions is evident, from prohibition to admissibility in so called 'saviour sibling' cases, such as in Spain and the UK);
- the utilisation of non-transferred ('spare') embryos (whether they should be available for donation for reproductive purposes; cryopreservation; donation for research purposes or destruction); and finally,
- the effects of accessibility on freedom of movement within the EU (so-called 'reproductive tourism').[18]

Within the welfare-state model, decision-making institutions must respond to social demand and provide answers to these questions. In so doing, decision-making bodies are faced with a legal version of Hamlet's dilemma when they come to regulate science: to legislate or not to legislate?[19] The question relates to the adequacy of statutory law in guaranteeing sufficiently adaptable regulation in a field inevitably characterised by fluidity of scientific knowledge and medical and experimental applications.[20] Regulation can also be guaranteed by different (concurring) regulatory sources, inside traditional legal means (such as statutory law, case law, secondary regulation) or outside them (utilising professional codes of ethics, guidelines published by professional organisations, international boards or scientific societies and self-regulation).[21] The issue is to understand which kind of relationship the law of Parliament is to have with these supplementary regulatory tools. Accordingly, the Hamletian dilemma, to legislate or not to legislate, raises further questions: how to legislate and how much to legislate?

If our goal is to be the achievement of a common decision-making process within the European legal framework, it can be more easily achieved, in my understanding, if there is a paradigm shift in analysing ART regulations. We must integrate the perspective based on the analysis of statutory content with that based on the method of the decision-making process enforced at the national level.

Different classifications can be proposed, according to the perspective that is applied (content-based or procedure-based). Focusing on the *content* of national regulations, the reaction of different national legislatures has been traditionally classified in order to derive different regulatory approaches. If we consider hESC research

18. R.F. Storrow, 'The Pluralism Problem in Cross-Border Reproductive Care', *Human Reproduction* 25(12) 2010, pp. 2939–2943.
19. R. Deech, 'Playing God: Who Should Regulate Embryo Research?', *Brooklyn Journal of International Law* 32(2) (2007), pp. 335–339, proposes five reasons for justifying legislative regulation.
20. See recently S. Devaney, 'Regulate To Innovate: Principle-Based Regulation of Stem Cell Research', *Medical Law International* 11 (2011), pp. 53–68, that refers to 'principle-based regulation' which 'has the capacity to maintain its credibility in the face of the dynamism of the SC world' (p. 64).
21. See M.H. Johnson, 'Regulating the Science and Therapeutic Application of Human Embryo Research: Managing the Tension between Biomedical Creativity and Public Concern', in J. R. Spencer and A. Du Bois-Pedain, eds. *Freedom and Responsibility in Reproductive Choice* (Portland: Hart Publishing, 2006), pp. 98.

regulation, according to the spectrum of permitted research and the limits introduced by law in terms of both research aims and means, we may face different models: closed or open; liberal or restrictive;[22] imposing or permissive. Accordingly, the same perspective has been taken on ART regulation. Classification based on the content of the law is useful in a descriptive way: it is possible to understand what approach (open or closed; liberal or restrictive) is prevailing in a specific legal framework and therefore it allows us, for instance within the ECHR context, to understand whether or not a consensus among States exists and the margin of appreciation to be recognised in each State. But this kind of classification tells us little about the reasons a specific approach is implemented by a national legal system (e.g. why PGD or gamete donation are commonly allowed but surrogate motherhood is forbidden). The *content* perspective seems to fail in explaining theoretical reasons for a specific approach and the reasons why legal orders that differ in terms of legal tradition, cultural and social background and theory of law assume similar approaches when regulating ART (such as Spain and the UK). It also fails to shed light on why States belonging to the same legal family differ profoundly when it comes to regulating socially and ethically sensitive issues (for instance, Spain and Italy).

As stressed before, the aim of the article is to verify whether there exists a common regulatory understanding of the connection between law and science. If it does exist, it may drive what can be defined as a process of 'harmonisation by procedures' among national legal systems.[23] This goal is not achievable exclusively by delegating it to international and supranational institutions. They have to be integrated with the role played by national legislatures. But today national regulations vary greatly from one to the other, due not only to different cultural and social backgrounds, but also to distinct understanding of the relationship between science and law, the role and function of legislature in regulating science and the characteristics and function of the decision-making process.

Conversely, the process of 'harmonisation by procedures' must be grounded on common understanding of these three issues: the relationship between law and science; the role and function of statutory power and the characteristics of the decision-making process. By applying the comparative method in the second section of my article, I will try to verify whether these preliminary conditions exist. Ultimately, it must be questioned whether traditional procedures, sites and actors of decision-making are suited for regulating science in a consistent, effective and feasible way, or whether we need to build new methods and contexts for decision-making in science-related fields.

In the process of verifying whether a common approach to decision-making is detectable and its impact on the content of the law, the following three preliminary steps must be taken:

a. To identify and describe a set of indexes that will drive this comparative analysis, starting from the hypothesis of a shift from the content of national legislations to

22. R.M. Isasi and B.M. Knoppers, 'Beyond the Permissibility of Embryonic and Stem Cell Research: Substantive Requirements and Procedural Safeguards', *Human Reproduction*, 21 (2006), pp. 2474–2481.

23. Also this approach is not free from concerns: see R. Brownsword, *Rights, Regulation, and the Technological Revolution*, pp. 126.

the decision-making process activated in each national system.[24] Those indexes have to be coherent with this methodological and theoretical proposal: to derive new methods of law-making that are able to achieve a constitutionally consistent, scientifically feasible and socially acceptable (and then effectively enforceable) legislative product. Accordingly, the focus will be on the characteristics of decision-making (expertise involvement, extra-parliamentary sites of deliberations, etc.), but it will be also verified whether the law provides for procedural requirements to be enforced in cases of new statutory interventions;[25]

b. To provide a classification of the analysed national legal systems, by applying the described indexes. The hypothesis is that, even if it is not possible to completely overcome ethical and social concerns raised by ART regulation, by enforcing the indexes provided, States may approach them in a more effective, feasible and adequate way in order to manage and regulate them. The goal of a welfare-oriented and constitutional system is not to eliminate both social and ethical pluralism, but to manage and include it within a democratic and deliberative context. Institutional mechanisms such as decision-making participation and transparency, and regulatory flexibility, may effectively facilitate the inclusion of social conflict, which is the expression of a vital and pluralistic society, within the constitutional framework. This might be demonstrated by comparing different national approaches, as will be clarified in the last section of the article. Now it can be anticipated that social and scientific reaction to ART regulation is more positive within national systems that have implemented many of the provided indexes, such as the UK and Spain. Conversely, national systems developing a non-participatory and rigid approach, such as Italy, are characterised by a high level of both social and judicial conflicts, as will become apparent later on.

c. To analyse what the specific characteristics of each model are, such as the pros and cons, and whether it is possible to identify a model that is prevailing within the European framework, in order to understand whether a convergence towards a common deliberative process is detectable.

The classification indexes: procedural and substantive

The indexes identified in this article have been identified by focusing on both the characteristics of decision-making and the theory of law applied when regulating science. These indexes can be termed ‘procedural’ and ‘substantive’.

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24. M.H. Johnson and K. Petersen, ‘Public Interest or Public Meddling? Towards an Objective Framework for the Regulation of Assisted Reproduction Technologies’, *Human Reproduction* 23(3) (2008), p. 723, proposes a ‘five-step model’ regulation, in order to ‘shift the focus of regulation from simply enforcing regulatory objectives towards questioning and testing those objectives and the methods being used to implement them’.

25. See the case of the new French Law on Bioethics, 2011.

Procedural indexes

Expertise participation. First, it is appropriate to distinguish between different kinds of participation, according to the subjects involved. The object of the article is expertise participation, to be distinguished from lay involvement. The analysis is focused on the former, in terms of both legitimisation and information of political decisions. Lay involvement requires different principles, such as participative and deliberative democracy. Expertise participation can be provided *ex ante* (within the decision-making process) and/or *ex post* (within the implementation process). In general terms, expertise involvement may be defined as a structural precondition, in order to classify a specific legal system, as it becomes a foundational principle for the regulatory model.[26] This index develops a threefold function:

- an informational one, as participation guarantees a higher level of scientific adequacy within the *ex ante* phase and effectiveness of regulatory intervention *ex post;*[27]
- a legitimisation one, as it increases legitimisation of decision makers by integrating traditional democratic and constitutional sources with the scientific one[28] and
- finally, a legitimacy one, as it guarantees at least a presumption of legitimacy in favour of political decisions when checked in the light of a constitutional framework.

As stressed above, expertise participation can occur both *ex ante* and *ex post*. With regard to the former, it may occur in an institutionalised or occasional way. Institutionalisation may occur by praxis or by law: in the first case (Spain and UK), any regulatory reform at the legislative level is integrated by autonomous technical bodies, which are afforded consultative and propositional functions. In the second case, the same law provides for a general rule according to which every reform must be preceded by a consultative/deliberative process, incorporating both expert and lay involvement (France). The binding nature of participation is linked with the way – institutionalised by praxis or by law – in which the latter is established. Participation is mandatory only when the law provides for it, even if not binding: it is a duty to activate consultative mechanisms provided by the law. Interestingly, even when the law does not provide for either institutionalised or occasional participatory means, a duty to involve expertise within the

26. According to K. Syrett, 'Deconstructing Deliberation in the Appraisal of Medical Technologies: NICEly Does it?', *The Modern Law Review* 69(6) (2006), p. 863, 'in a state of ethical pluralism such as this where consensus upon substantive principles is likely to remain elusive, the adoption of proceduralist strategies that are designed to develop deliberation and enable participation might appear to be the solution to a regulatory problem'.
27. See T. Prosser, *The Regulatory Enterprise* (New York: Oxford University Press, 2010), pp. 22; analysing the background to and function of the UK Human Fertilisation and Embryology Authority.
28. On threats related to the undemocratic nature of technical bodies, see S. D. Pattinson, *Medical Law and Ethics* (London: Sweet & Maxwell, 3rd edition, 2011), p. 282.

decision-making process arises from the adjudicatory and judicial context. This is the case in Italy, where the Constitutional Court has stressed the 'essential role played by scientific bodies in the medical-scientific context'. The Court has established a procedural duty, binding Legislature, according to which Parliament must verify the level of scientific-medical development by consulting national technical bodies, when it legislates; it cannot base its evaluation merely on its own discretionary power.

With regard to *ex post* involvement, different options are abstractly available. They may differ for subjects, functions and powers provided by the law. Subjects that participate in the law-enforcement process can be an institution (ad hoc bodies) or the physician involved in the specific case. When the law provides for institutionalised means of participation, an ad hoc body can be vested with different functions: informative; consultative/proposal; deliberative and monitoring/evaluative. When the law does not provide for it, participation in the law-enforcement process occurs indirectly. Physicians, even if not entitled by law, perform a substantial regulatory function by means of their own decision-making autonomy, in order to guarantee a reasonable and adequate enforcement of statutory content. Again, Italy represents a case in point. According to the Italian Constitutional Court, the Legislature must guarantee physicians the power to evaluate every concrete case to be treated, according to the most advanced and feasible scientific knowledge. Accordingly, the Court states that the scientific and experimental knowledge represents a boundary for Legislature's discretionary power.[29]

Extra-parliamentary sites for deliberation/consultation. This represents a means for concreting expertise participation, linked with society and stakeholder involvement. In this case, the law-making process is preceded by institutionalised mechanisms of consultation, as happened in France in 2010. They cannot substitute the traditional parliamentary process, but they must be understood in an integrative and complementary way: they increase both scientific feasibility and legitimisation of political options.[30] Consultative mechanisms may be formalised/institutionalised, when they have a periodic and mandatory nature (linked with statutory reform, such as in France); or conversely, they may have an episodic nature, when a consultative body is activated case-by-case at the time of legislative reforms (e.g. as in Spain and the UK).

Decision-making procedural criteria. Mandatory procedural requirements are established by law, in the case of statutory reform, based on both substantial and procedural criteria to be fulfilled in order to guarantee the legitimacy of the decision-making process. These

29. Decision no. 151/2009.

30. On threats raised by society involvement, see J. Black, 'Regulation as Facilitation: Negotiating the Genetic Revolution', *Modern Law Review* 61 (1998), p. 652, that states that 'these initiatives seem often not so much to integrate different views as simply aggregate them, and in so aggregating them afford science a voice which is regarded as more authoritative, and indeed more legitimate, than that of others'. According to the author, a new theory of decision-making mechanisms is needed: 'The call that is being made here is not simply for the broadening of participation in regulation, however, but for regulators to adopt a different role: that of facilitators, of negotiators'.

requirements aim to legitimise the decision-making process in the sense of both lay and expert participation, but also to verify its performance compared with its aims, context and results achieved. An example is represented by the implementation within the medical–scientific context of general means of preventive analysis of regulation, regarding expected effects of regulation by comparing different regulatory solutions.[31] *Ex ante* evaluation, especially when integrated by consultative and participatory mechanisms, may increase the adequacy of regulatory intervention, and also its transparency and feasibility.

Law-implementation and law-evaluation process. Law provides formalised mechanisms through which its performance may be evaluated, in the light of potential reforms and adaptation to scientific, ethical and social developments. Accordingly, this phase performs a twofold function: on the one hand, the monitoring one; on the other hand, the evaluative one. The means for monitoring and evaluation may be both general and specific. General mechanisms include the regulatory impact assessment.[32] This is based on a set of criteria that can usefully be applied to ART regulation: level of knowledge of regulatory contents; level of implementation of regulatory content; adequacy of regulatory intervention, through the evaluation of the accomplishment of regulatory goals and effects on persons involved and finally, identification of possible means for increasing regulatory performances. Regarding the context-specific means for the evaluation of the law, these include periodic/annual reports, provided by executive or administrative bodies (Italy) or, alternatively, by delegated technical bodies/authorities, independent from both the Executive and the Parliament (France and Spain). When monitoring/evaluation powers are delegated to independent bodies, they are generally accompanied by authorisation and sanctioning functions, such as in the UK (Human Fertilisation and Embryology Authority (HFEA)) and France (National Agency on Biomedicine). Systematic, compulsory and periodic monitoring and evaluation is a necessary and unavoidable characteristic of the process, for guaranteeing its effectiveness and feasibility. This power must be assigned by law to technical (expertise) and independent (accountability and fairness) bodies, according to predefined procedures, and linked with complementary powers (i.e. inquiry function), which serve as preliminary conditions for effective development of the evaluative function. It may also have a merely cognitive nature, when the legislature is not bound by its outcome; or, conversely, an effective binding nature. When the power to propose recommendations for further legislative reforms is provided, the indirectly binding nature of the evaluation function increases: not in the sense of requiring a duty to accept every recommendation, but to demonstrate that the latter has been taken into consideration within the reform process.

31. See J. Verschuuren (ed.), *The Impact of Legislation: A Critical Analysis of Ex Ante Evaluation* (Leiden, The Netherlans: Martinus Nijhoff Publishers, 2009).
32. Recently, from a general perspective, see C.A. Dunlop, M. Maggetti, C.M. Radaelli and D. Russel, 'The Many Uses of Regulatory Impact Assessment: A Meta-Analysis of EU and UK Cases', *Regulation and Governance* 6(1) (2012), pp. 23–45.

As stressed at the beginning of this section, a set of substantial indexes integrates procedural requirements. The latter represent a precondition for the former, as they aim to provide institutional mechanisms that can guarantee the adequacy, efficacy and effectiveness of statutory intervention.

Substantial indexes can be described as follows:

Legal definition of scientific notions. The law provides legally binding 'definitions' of scientific/biological notions (e.g. the 'embryo'), which contribute to specifying the concrete area of both regulatory implementation and limitation of medical/research activity. This index helps clarify the existing link between procedural and substantial indexes. The appropriateness of the definitions used depends on the level of scientific knowledge assumed within the decision-making process, in order to make them as acceptable, coherent and feasible as possible. The more decision-making process is participative and inclusive, the more this kind of regulatory means will be able to perform its function. It is also linked with the need for periodical evaluation of the scientific soundness of the law, as scientific knowledge is constantly developing. Possible positive outcomes of this index face preliminary questions which, if not addressed, might undermine its function. First, scientific adequacy of legal definitions is an unavoidable prerequisite. The legislature must guarantee, when deciding to insert legal definitions within the law, that these are grounded on existent, feasible and verified medical-scientific data, which can assure their scientific soundness. A different question concerns the margin of political discretionary power to be afforded to the legislature. It may be recognised as having full discretion in choosing, among different scientific alternatives, the one to be inserted within a legal definition; or, conversely, the legislature may clash with concrete burdens, represented by the need for delegating these definitions to ad hoc technical independent bodies. A connected issue is the identification of subjects entitled to perform this function of providing definitions. The legislature, as stressed before, is democratically legitimated and therefore it might be the more appropriate body for approaching highly social and ethical sensitive issues. It might be desirable that judges be involved in this process. Even if not democratically legitimated, the judiciary's expertise within the judicial process and their case-by-case approach may mean that their involvement in this function is beneficial. Independent authorities, although poorly democratically legitimated, are useful for ensuring the feasibility of definition of scientific/biological concepts due to their ownership of technical and scientific expertise. At the same time, regulatory means provided for authorities are usually flexible and temporary (i.e. reports, guidelines, general authorisations), which can adapt their content to ongoing scientific progress more adequately than legislative sources.

A different question is raised by the so-called 'time factor'.[33] The time when the decision is taken is crucial in determining the content of a definition, its soundness and feasibility. This is not a matter of margin of discretionary power when defining scientific concepts. It is related to the level of scientific knowledge available at the time of legislative intervention. Accordingly, the former become a preliminary condition for legitimacy of legislative intervention. It entails that the legislature may be called on both to clarify scientific sources and explain the reasons behind political choices. This last issue

33. See ECtHR case law, case *S.H. v. Austria*, Grand Chamber.

shows the connection with the following substantial index, the so-called 'updating clause': it is functional for a continuous and periodic updating of legislative content, in the light of possible scientific-technological developments, which can guarantee – among other – periodic adaptation of statutory definitions.

Temporal validity/updating clause. In this case, the law provides a parliamentary duty to analyse, evaluate and eventually reconsider its own content, on the ground of its implementation and efficacy, its consistency with scientific, but also social, ethical and economic development, and its adaptability to new scientific knowledge. The temporal validity clause may increase the connection[34] between regulatory tools and regulated context. Although under a common framework, the mechanism may vary in terms of its compulsory and binding nature. It can provide temporal validity clauses, which predefine a time-limit within which the legislature is called upon to review and reform the law, by means of a new statutory intervention which substitutes the previous one (e.g. as in Israel). In this case, the mechanism is both compulsory and binding: when the term has passed, the law loses its own validity, passing on to the legislature the duty to act to fill the regulatory gap. A more flexible interpretation of this means is conceivable. A temperate approach requires a duty for the periodic check of legislative contents, eventually providing for statutory reform on the ground of its performances (France and Canada).[35] Unlike the rigid approach previously described, in the latter case, if the term expires without an evaluation process being activated, it does not imply a loss of legislative validity: therefore, it is 'at the disposal' of the national legislature, that may choose whether or not comply with it. However, this flexible approach may be strengthened by a number of procedural burdens, to be complied with by the legislature before reforming the law. This might include a duty to consult ad hoc technical bodies; to build up a consultative framework involving not only expertise but also both stakeholders and society; to provide for periodic reports on implementation and impact of regulation. Conclusively, this index seems to balance the need for guaranteeing scientific soundness of regulation on the one hand and the necessary margin of discretion to be reserved for national legislatures.

Legislative reference to expertise and scientific data/lex artis. The law makes use of indeterminate concepts or clauses referring to *lex artis*, scientific data and medical standards

34. See R. Brownsword, *Rights, Regulation, and the Technological Revolution*; Above 'Embryonic Stem Cell', note 2.

35. See the Canadian Assisted Human Reproduction Act (S.C. 2004, c. 2) and the role of the clause providing the review of the Act every 3 years. Section 72 states that 'The administration of this Act shall, within three years after the coming into force of section 21, be reviewed by any committee of the Senate, the House of Commons or both Houses of Parliament that may be designated or established for that purpose. The committee shall undertake a comprehensive review of the provisions and operation of this Act and shall, within a year after the review is undertaken or within such further time as the Senate, the House of Commons or both Houses of Parliament may authorize, submit its report on the review including a statement of any changes to this Act or its administration that the committee recommends'. See, particularly, A. Campbell, 'A Place for Criminal Law in the Regulation of Reproductive Technologies', *Health Law Journal* 10 (2002), p. 89.

(i.e. the number of embryos producible and transferable to the wombs), that must be specified by ad hoc bodies or physicians. By means of this regulatory solution, the legislature seems to delegate concrete determination of statutory content to subjects entitled to implement it in concrete cases. This regulatory technique is useful when regulating areas characterised by flux in scientific–medical knowledge. The fluidity of regulatory objects also influences regulatory tools, which must be integrated by clauses referring to expertise in a broad sense in order to be effectively enforceable. It gives regulatory structure a means through which to adapt to scientific change without reforming its own formal content. It guarantees a prompt reaction in terms of regulation, without activating the traditional law-making process: from this perspective, there seems to be an evident link with the procedural index aimed at increasing *ex post* expertise participation (see above). Through this mechanism, the legislature does not renounce its regulatory power. On the contrary, by including both institutional (ad hoc bodies) and individual subjects (physicians) involved in law-implementation, it seeks to increase the efficacy of regulatory intervention, balancing the call for legal certainty and the need for normative flexibility.

Classifying national regulatory regimes: 'procedure-oriented', 'hybrid' and 'value-oriented' models

After describing classificatory indexes, it is appropriate now to apply them to analysed national legal systems. Indexes have been applied to each legal system, in order to analyse whether, how and how much they are implemented at the national level. We can now derive three main regulatory models: (a) the 'value-oriented' approach; (b) the 'hybrid' (intermediate) approach; (c) the 'procedure-oriented' approach. Two aspects come into view at the general level: on the one hand, all the analysed systems activate legislative sources; on the other, transversality among the traditional-level families is detectable when classifying them. The distinctive element of each regulatory model becomes evident: the theory and function of statutory source and its connection with other concurring regulatory tools (professional ethics codes; guidelines of professional organisations and international boards or scientific societies; self-regulation).[36]

'Procedure-oriented' approach: the case of Spain

A 'procedure-oriented' approach is shared by two legal orders that differ in both their legal and cultural background. These are the UK[37] and Spain. Both systems fulfilled almost every index, so it is possible to conclude that they have systematised them within their own

36. According to S. Gevers, 'Health Law in Europe: From the Present to the Future', *European Journal of Health Law* 15 (2008), p. 264, 'While the emergence of this so called self-regulation is a general phenomenon, it seems to be especially prominent in the health field, where the power of the professions has always been substantial and where many issues are too complicated or developing too fast to be captured in other than very general statutory provisions'.
37. See M.H. Johnson, 'The Regulation of Human Embryo Research in the UK: What Implications for Therapeutic Research?', in J. Gunning ed. *Assisted Conception. Research, Ethics and Law* (Dartmouth: Ashgate, 2000), pp. 120.

regulatory processes. It is more appropriate, in order to underline transversality among legal families, which characterises classification, to focus on the Spanish legal context more than the UK one, as the former belongs to the 'civil law' family such as Italy and France. This might strengthen the theoretical assumption of the proposed classificatory mechanism.

Spain was one of the first European countries to regulate ART. Its first legislative intervention in the field dates back to 1988, when the Spanish Parliament enacted Law no. 35/1988.[38] Since the beginning, the Spanish legislature has enforced a regulatory mechanism centred on a continuous involvement of expertise. The Law of 1988 was preceded by a consultative process in which an ad hoc, independent and interdisciplinary commission (the so called *Comisión Palacios*) provided Parliament with a set of recommendations that were then received into the statutory text. This method was applied repeatedly when Parliament decided to reform the legislation, such as happened in 2003 and most recently in 2006.[39] Both reforms, as expressly recognised during the parliamentary debates, were grounded on opinions given by the National Commission on ART. The same procedure took place for the Law on Biomedical Research,[40] in which hESC research is regulated. The role of expertise as an expression of the regulatory function of science also stems from the law-implementation process. The law builds a comprehensive institutional structure founded on different technical entities that are recognised with a specially qualified function based on impartiality, independence, technical capacity and professional competency.[41] The structure comprises the National Commission on ART (endowed with consultative binding power on both new ART and research with embryos), the Spanish Committee on Bioethics (endowed with consultative and propositional functions) and the Commission for the Guarantees on the Donation and Use of Human Cells and Tissues (responsible for the compulsory evaluation of research projects on hESC).[42] Therefore, the Spanish system is characterised by both the

38. See I. Alkorta Idiakez, 'Los Derechos Reproductivos de Las Españolas. En Especial, las Técnicas de Reproducción Asistida', *Derecho Sanitario* 11 (2003), p. 172.
39. Law no. 14/2006. On the legal development of ART regulation in Spain, see I. De Melo-Martín, 'Assisted Reproduction Technology in Spain: Considering Women's Interest', *Cambridge Quarterly of Healthcare Ethics* 18(3) (2009), pp. 228.
40. no. 14/2007.
41. See Explanatory Notes provided by Law 16/2007 on Biomedical research.
42. Article 38 enumerates the Commission's functions: (a) To assure the scientific, ethical and legal guarantees that may be demanded in relation to the research mentioned in Article 35 and to annually evaluate the results; (b) To provide, upon request of the State health authorities and the autonomous communities, reports on biomedical research with human embryonic cells and tissues and their clinical applications in the field of regenerative medicine; (c) To provide a compulsory report on research projects that require trans-border flows of embryonic material. See F. Fonseca Ferrandis, 'La Investigación en Materia de Terapia Celular Como Objeto de Intervención Administrativa. ¿Qué Hay Que Hacer Para Investigar en España con Células Troncales de Origen Embrionario', *Revista de Derecho y Genoma Humano* 32 (2010), pp. 98–99.

appointment of independent bodies for reporting and assessing Parliament and the delegation of law-implementation to ad hoc commissions listed above.

If we consider *substantive* classificatory criteria, the Spanish regulatory regime provides a set of definitions. Among others, especially relevant is the distinction between 'pre-embryo' defined as 'in vitro embryo formed by the group of cells resulting from the progressive division of the fertilized egg from fertilisation up to 14 days later'[43] and 'embryo', intended as 'a phase of embryonic development from the moment in which the fertilised ovocite is found in the uterus of a woman until the beginning of organogenesis and which ends 56 days from the moment of fertilisation, with the exception of the computation of those days in which the development could have been stopped'.[44] It is also possible to find a systematic reference to scientific and clinical best practices. The number of embryos that can be produced is reserved to the physician's discretion – and the number of embryos that can be transferred into the womb (a maximum of three) is determined by international scientific standards.[45] This political option – scientifically grounded – guarantees a reasonable space open to both expertise and autonomy of physicians directly involved in ART application.

The 'hybrid' model: the case of France

France represents a paradigmatic example of what can be defined as a 'hybrid' approach. This model represents the concrete proof of a convergence towards a procedural approach within the analysed jurisdictions. The French system recognises a high level of protection for the embryo, which leads to apparently controversial choices, such as prohibiting hESC research but allowing it exceptionally, under a set of requirements and conditions to be fulfilled by every research project.[46] At the same time, it is grounded in a progressive strengthening of consultation and participation mechanisms within both decision-making (the *États généraux de la bioéthique*, see below) and law-implementation (the National Agency on Biomedicine). Law no. 2011-814 on

43. Law no. 14/2006, article 2.
44. According to Law no. 14/2007, article 3. See the English version of the Law, available at the website of the Inter-University Chair in Law and the Human Genome (Available at: http://www.catedraderechoygenomahumano.es/images/novedades/Spanish%20Law%20on%20Biomedical%20Research.pdf (accessed September 2012)).
45. Article 3 of Law 14/2006.
46. Critically, with regard to this approach, S. Hennette-Vauchez, 'Words Count: How Interest in Stem Cell Has Made the Embryo Available: A look at the French Law of Bioethics' (*Medical Law Review* 17 (2009), pp. 59 -60). Recently the French Senate approved a Bill that will amend the Law n° 2011-814 with regard to embryo and hESC research. It is actually discussing within the French National Assembly and aims at substituting the current system of prohibition with regulated exceptions with a more liberal approach based on an authorisation system under a predefined set of conditions and requirements (see Proposition de loi tendant á modifier la loi n° 2011-814 du 7 juillet 2011 relative á la bioéthique en autorisant sous certaines conditions la recherche sur l'embryon et les cellules souches embryonnaires, n. 473, December 2012).

Bioethics,[47] following a process of progressive empowerment, has metabolised expertise and society participation within its law-making process.[48] According to the law, the French Parliament must organise the *États généraux de la bioéthique* every time it intends to reform the Act. At the same time, the National Agency on Biomedicine has been delegated the power to authorise hESC research, in a way similar to that enforced within the 'procedure-oriented' model. According to the 2011 Law on Bioethics, the National Agency fulfils a number of both consultative, co-decisional, monitoring and authorisation functions. These include participating in the development and application of regulations and standards of good practice and recommendations for activities under its jurisdiction; providing information to Parliament and the Government on the development of knowledge and techniques for activities within its jurisdiction and offering guidelines and measures they ask for; monitoring evaluating and, if necessary, controlling medical and biological activities. As such, it is the recipient of annual reports of institutions and organizations within its areas of competence, focusing in particular on the possible consequences of medically assisted procreation on the health of people who use them and on children. It seems, at least formally, that most of the functions described are dedicated to expertise participation in the law-implementation process, especially by means of technical independent bodies.

Moreover, both decision-making and law-implementation mechanisms have been institutionalised by law. On the one hand, any reform has to be preceded by a public debate by means of the *États généraux de la bioéthique*,[49] which in any case has to be convened every 5 years. The decision-making process, conceived as a multilayered and multidisciplinary consultative method (i.e. by means of the *États généraux de la bioéthique* at least every five years, as outlined above), has been incorporated into the law, accompanied and integrated by a set of evaluative and informative means (reports to political subjects, Parliament and Government, public information) which acquire the nature of mandatory requirements.

Accordingly, the participative nature of the decision-making process evolves, from being a voluntary option, to a compulsory mechanism which the legislature has to implement when reforming the law. On the other hand, an entire Chapter of the Law on bioethics is dedicated to the 'Application and evaluation of the Law on Bioethics'.[50] According to this Chapter, every 6 years the *Office parlementaire d'évaluation des choix scientifiques et technologiques* must evaluate the implementation of the Law,[51] to check

47. The so called Law on Bioethics: Law no. 94-653, July, 1994, '*relative au respect du corps humain*'; and Law no. 94-654, July, 1994, '*relative à l'assistance médicale à la procréation, au diagnostic prénatal et au don et à l'utilisation des éléments et produits du corps humain*'.
48. On the effective outcomes of the *États généraux de la bioéthique*, see – among others – P. Merviel, R. Cabry, E. Lourdel, F. Brasseur, A. Devaux and H. Copin, 'La Révision de la loi de Bioéthique: Analyse Comparative des Contributions de Différents Organismes Publics ou Professionnels. Assistance Médicale à la Procréation, Recherche sur l'embryon et les Cellules Souches, Banque de Sang du Cordon Ombilical', *Gynécologie Obstétrique and Fertilité* 37 (2009), pp. 733–741.
49. Article 46.
50. Chapter IX.

its adequacy according to social, scientific and ethical developments. Furthermore, this Chapter also provides an 'updating clause', according to which the French Parliament has a duty to re-examine the law at least every 7 years, on the grounds of the results of a set of reports and consultations required by law (primarily the report of the *Office parlementaire d'évaluation des choix scientifiques et technologiques*).

The 'value-oriented' approach: the case of Italy

A 'value-oriented' approach represents the alternative model to the 'procedure-oriented' one. This model does not provide either institutional mechanisms for consulting expertise and society within the decision-making process, or ad hoc bodies entitled to authorise, monitor and sanction functions within law-implementation, such as happens in both the 'procedure-oriented' and the 'hybrid' systems. The value oriented approach provokes, as the case of Italy seems to confirm, negative effects on the scientific consistency of the law, as its political content lacks scientific and technical evidence that might orient and ground it. Within this regulatory system, statutory law is considered the exclusive normative tool when regulating science-related fields. It means that alternative sources (such as self-regulation, professional ethics codes and best practices) are excluded or suppressed. As we will see when the legislature's attitude aims at excluding a regulatory function for expertise, the judiciary intervenes by restating the relationship between the legislation and physicians' professional autonomy, based on scientific and medical expertise.

Embryo protection, starting from fertilisation, is the absolute goal of the Italian legislation. The Legislature tries to achieve this by means of a rigid but nigh unenforceable criminal sanctioning structure.[52] This seems to be a regulatory option that readily clashes with the constitutional framework, as traditionally constitutions recognise the coexistence of different interests and rights, without providing a rigid predefined hierarchy between them.[53] The aim of the legislature might be to accommodate differences, by providing context-specific regulatory assets in which every involved interest may find a reasonable and proportionate protection, even when it must yield to prevailing counter-interests.

As already mentioned, Italy represents a paradigmatic case of such an approach. When the Italian Parliament passed the Law on ART, no. 40/2004, it fulfilled almost none of the procedural or substantive criteria outlined above. With regard to procedural indexes, no ad hoc commissions or advisory bodies were appointed by Parliament before

51. Article 47.
52. According to R. Deech and A. Smajdor, *From IVF to Immortality – Controversy in the Era of Reproductive Technology* (New York: Oxford University Press, 2007), p. 209, 'the law introduces a set of prohibitions rather than constructing a general regulatory framework for the conduct of assisted reproduction and/or research'.
53. See R.C. Post and R.B. Siegel, 'Democratic Constitutionalism', in J.M. Balkin and R.V. Siegel, eds. *The Constitution in 2020* (New York: Oxford University Press, 2010), p. 27, who recognise that 'paradoxically, the possibility of disagreement about the Constitution's meaning preserves constitutional authority'.

the beginning of the legislative making process and very few hearings took place during the latter. Furthermore, Law no. 40/2004 does not provide either law-making or law-enforcing and law-evaluation criteria. On the one hand, the law does not provide for any obligation to open the decision-making process to society or expert participation, as happens in France. On the other hand, the Italian system does not provide any mechanisms facilitating expertise involvement during law-implementation, as happens in any of the other analysed legal systems (both 'procedure-oriented' and 'hybrid').

If we consider substantive indexes, things do not seem to change. Law no. 40/2004 does not contain a set of definitions that can circumscribe its application and support interpreters when applying it. This absence drives evident inconsistency within the same statutory architecture. For instance, the same legal entity that is defined '*concepitus*' in article 1 is then identified as 'embryo' in articles 13 and 14, regulating embryo research and ART application. This inevitably produces at least a feeling of legal uncertainty and approximation, which is particularly concerning in a field such as embryo research, where normative soundness and clarity are crucial in order to understand which kind of research is permitted, and especially when the law aims at protecting the embryo by means of a severe criminal sanctioning system. Italian Law does not provide an 'updating clause', even though it prescribes that the Guidelines on ART provided by the Health Ministry have to be renewed every 3 years, in line with any scientific development which may occur (article 7).

What is the outcome of such a 'value-oriented' approach? There are two immediate consequences, one directly influencing the content of regulation, the other affecting the law-implementation phase. On the one hand, if we agree with the assumption according to which there exists a direct connection between the method of law-making and its regulatory outcome, the 'value-oriented' approach produces an (almost) never-ending list of prohibitions and duties directed to both couples and medical practitioners.[54] A non-exhaustive list of these is provided below:

a. prohibition from withdrawing consent after the time of fertilisation;
b. absolute ban on gametes donation;
c. prohibition of any research or experimentation with embryos, except with therapeutic or diagnostic purposes aimed at protecting the health and biological development of the same embryo
d. ban on the production of embryos for research purposes;
e. ban on any selection for eugenic purposes;
f. duty to produce no more than three embryos;
g. duty to transfer into the womb every produced embryo at the same time;
h. absolute ban on cryopreservation;
i. and prohibition of PGD/ hESC research.

This regulatory structure corresponds to the express political will of the Italian legislature: according to article 1 of Law 40/2004, it consists of protecting embryos, together

54. See in general terms T. Caulfield, L. Knowles and E.M. Meslin, 'Law and Policy in the Era of Reproductive Genetics', 414, that considers 'simple bans and prohibitions (...) an inappropriate means of regulating behavior in this complex and dynamic area'.

with all other involved subjects. Accordingly, it has built up a very strict regulation, in order to avoid any risk for embryo development in both ART application and embryo/hESC research. However, if we move from the *voluntas legis* to its implementation, the landscape notably changes, revealing an 'unharmed' legislature, which has been unable to provide a regulatory structure that is effectively enforceable.

When considering the list proposed above, it is possible to conclude that none of those legislative means has been fruitful in achieving the legislative aim of gaining an absolute protection of the in vitro embryo. A brief description of the case law provoked by Law 40 will clarify this conclusion. The prohibition on withdrawing consent after fertilisation has been relaxed and then substantially overridden by the Italian Ministry of Health. The Ministry provides Guidelines on ART (2004 and 2008) stating that, in any case, transfer of embryos cannot be imposed. With regard to the absolute ban on gamete donation for reproductive purposes, a question having this as its object is pending before the Italian Constitutional Court, as it is questioned whether it can be considered consistent with the Constitution (particularly with regard to the principle of equality; right to found a family; right to health; principle of proportionality and reasonableness).

The way in which ART must be applied is also regulated by Law 40. Article 14 provides both a limitation on the number of embryos producible in each cycle (maximum of three) and a duty to transfer every produced embryo by means of a single transfer. It also prohibits cryopreservation of embryos, except due to the need to protect woman's health for reasons that cannot be predicted at the time of fertilisation. It builds a very strict regulatory regime, which directly affects the professional autonomy of physicians and adaptation of ART implementation to each concrete case. This system has been quashed by the Italian Constitutional Court, which has declared the unconstitutionality of both the limit on producible embryos and the duty of single transfer, as they violated both the right to health of the woman involved and physicians' professional autonomy.[55] Accordingly, it also relaxed the absolute ban of cryopreservation, as it is now up to physicians to decide the number of embryos to be produced and, most importantly, to be transferred to the woman's womb. This leads to the consequence that all non-transferred embryos will be legitimately cryopreserved, in all those cases in which a woman's personal and health conditions do not recommend transferring the embryo, according to medical evidence and best practices. Therefore, the regulatory structure built by article 14 has been completely reassembled by the Italian Constitutional Court in order to make it consistent with the constitutional framework.

The process of rewriting Law 40 is not limited to article 14. The case of PGD also comes into view.[56] PGD is not expressly regulated by the law, which provides quite contradictory regulatory elements in this context. On the one hand, it introduces the ban on any embryo selection for eugenic purposes (article 13). On the other hand, article 7 allows the couple to be informed not only about the number of embryos but also about

55. See decision no. 151/2009.

56. See P. Hanafin, 'Cultures of Life: Embryo Protection and the Pluralist State', in M. Freeman, ed. *Law and Bioethics. Current Legal Issues* (New York: Oxford University Press, vol. 11, 2008).

their health conditions. This extravagant mix of prohibitions and rights, in the absence of a specific rule governing PGD, has led to confusing case law, in which different, even opposite, decisions have been reached, on the grounds of the same regulatory system. Accordingly, from a judiciary interpretation which stated the incompatibility of PGD with Law 40/22004, case law has moved towards an 'open' approach, according to which PGD is allowed, even if under (non legislatively) predefined conditions and requirements. Case law has probably moved a long way from the original legislative purpose, but it is due to a scientifically infeasible and constitutionally inconsistent regulatory regime, which has led to a substantial rewriting of the law by the judiciary.[57] Interestingly enough, it happens in a 'civil law' system, in which the rule of *stare decisis* does not apply. It inevitably provokes legal uncertainty, which affects both the protection of personal rights, such as the right to health, and the activity of professionals involved in ART application. The exclusion of expertise from both the decision-making and the law-implementation seems to produce an 'awkwardness effect', due to the lack of an essential source that is able to both orient and legitimise political choices. This, as an indirect consequence, transfers to the judiciary the function, primarily belonging to the legislature, of accommodating legislative rules to constitutional principles, within a (scientifically) inadequate and (legally) contradictory statutory regime.[58]

Converging by procedures: the integration by specialisation of different regulatory tools

In conclusion, we can try to answer the preliminary question posed at the end of the first section of this article, on the grounds of the outcomes of the comparison. Is there a connection between fulfilment of the procedural and substantive indexes and legislative content? At first sight, it is possible to conclude that implementation of described indexes can

57. Last 28th of August, 10th Section of European Court of Human Rights, in the case of *Costa and Pavan v. Italy* (application no. 54270/10), held, unanimously, that Law 40/2004 violates article 8 (right to respect for private and family life) of the European Convention on Human Rights, as it incoherently prohibits PGD while authorising medically assisted termination of pregnancy if the foetus shows symptoms of genetically transmissible disease (see available at: www.hudoc.echr.coe.int (accessed September 2012)). The European Court agrees with a strict interpretation of the Italian law on 'Human Assisted Reproduction' (Law no. 40 of 2004), according to which genetic preimplantation diagnosis ('embryo screening') is forbidden. According to Italian law, married couples may have access to assisted reproductive technologies (ARTs) exclusively in order to overcome infertility or sterility: accordingly, ARTs are not available for preventing a couple from transmitting genetically transmissible diseases to the child. On this decision, see S. Penasa, 'The Italian Law on assisted reproductive technologies no. 40 of 2004 facing the EuropeanCourt of Human Rights: the case of *Costa and Pavan v. Italy*', *Revista de Derecho y Genoma Humano/Law and the Human Genome Review* 37 (2012), pp. 155–178.

58. G. Ponzetto and P. Fernandez, 'Case Law vs. Statute Law: An Evolutionary Comparison', *Journal of Legal Studies* 73(2) (2008), p. 391, recognise that 'inefficient rules are more likely to be litigated and subsequently improved by case law', referring to the concept of 'endogenous litigation'.

favour a convergence towards similar rules within different national legal systems, as the case of hESC research seems to demonstrate. When having enforced procedural mechanisms similar to those applied by 'procedure-oriented' systems (UK and Spain), France has enacted a regulatory framework that is grounded on both common regulatory mechanisms (delegation of authorisation and control powers to independent technical bodies, such as the HFEA in the UK and the National Agency on Biomedicine in France) and similar contents, although the space open to research in this field remains different in each country.[59]

It is easier now to clarify why integration between the content of legislation and the method of decision-making might be constructive when classifying different regulatory systems. The procedural approach may integrate the one based on regulatory contents in a twofold sense. On the one hand, it guarantees predictability of national legislative choices. If we agree on recognising a 'cause–effect' mechanism between the concrete characteristics of the decision-making process and its outcomes, it is possible to conclude that the more the indexes are fulfilled, the more the system will enforce a 'procedure-oriented' approach and this drives towards specific legislative content. Accordingly, the extent to which a particular system fulfils the proposed indexes, may make it possible to predict: (a) which kind of regulation will be substantially enforced in each national legal system, by considering the characteristics of the decision-making process and (b) whether the regulation will be consistent with the Constitution, effectively enforceable and consistent with the scientific context to which it has to be applied. On the other hand, the classification provides a set of criteria that can be enforced by national legislature when regulating ART, reasonably assuming that their fulfilment will lead to more feasible, effective and consistent regulation. At the same time, it may lead to the achievement of a common regulatory framework within the European context, derived from sharing common deliberative methods more than directly imposing common regulatory contents.

Actors, procedures, sites and systems in law making

The comparison conducted in this article has shown the need for new methods of law-making in the field of ART. It involves:

The actors of law-making. The legislature is not the exclusive regulatory subject. It must be integrated with other actors, which may not be directly democratically legitimated, but come from the inside of the regulated context and provide a concurrent source of legitimacy.[60] This is the case with self-regulation, when the legislature delegates directly to

59. Interestingly enough, the French model seems to show a direct link among the strengthening of indexes fulfilment and a more open regulatory content. In the field of human embryonic stem cell research, the space allowed for this kind of research has been broadened: not only research aimed at achieving therapeutic progresses (such as happens according to the previous version of the Law on Bioethics, 2004) may be authorized, but also research aimed at making any medical progress. Therefore, the National Agency on Biomedicine will also authorize research projects with diagnostic and preventive aims.

60. As stressed by H. Somsen, 'Regulating Human Genetics in a Neo-Eugenic Era', in T. Murphy, ed. *New Technologies and Human Rights* (New York: Oxford University Press, 2009),

physicians or researchers a portion of regulatory power. This integration can also occur with the creation of technical bodies, which assist the legislature within both the law-making and the law-implementation processes.[61] In this regard, the cases of France, UK and Spain are particularly relevant in showing a common trend towards integration of regulatory sources;

The procedures of law-making. The traditional law-making process which exists almost entirely within parliamentary procedures must be questioned. Comparative analysis, with particular regard to the French and Spanish cases, seems to show that allowing non-parliamentary procedures which contribute to integrating the traditional one is consistent with constitutional principles in which parliament is the focal institution. In this case, in fact, parliament autonomously decides to use its own democratic mandate to empower and legitimate the role and function of alternative bodies, in both law-making and law enforcement.[62] By analysing recent law-making processes, such as the French General States of Bioethics, which preceded the reform of the Law on Bioethics (2010–2011), it is clear that parliament is the driving force but not the exclusive means through which regulation is produced. This approach that recognises procedures in which both expertise and stakeholders are systematically involved with decision-making has demonstrated that a comprehensive decision-making process is enforceable in different legal and cultural contexts.

The sites of law-making. If we renegotiate parliament's regulatory monopoly, we must also question the context in which decisions are taken. What is the role of decision-making sites other than the parliament? This leads to a principle of 'procedural subsidiarity', according to which the centrality of self-regulation has to be recognised, which is replaced with other sources only when it is incapable of guaranteeing a satisfactory level of rights protection. This principle has been developed also by the judiciary. The Italian Constitutional Court has systematically stated that the golden rule of medical activity is represented by the autonomy and accountability of medical professionals, that – always under patients' consent – act according to *lex artis* and best practice.[63] Accordingly, decision-making power has to be spread across different, integrated regulatory contexts, both *ex ante* (law-making) and *ex post* (law-implementation).

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p. 100, 'if democracy amounts more than translating populist anxieties and prejudices into policy, then a meta-regime that raises the publication and use of sound information to a central procedural requirement and facilitates deliberation is democracy reinforcing'.

61. B. Capps, 'Authoritative Regulation and the Stem Cell Debate', *Bioethics* 22(1) (2008), p. 50, refers to 'a number of mutually informative levels of procedure that maximise trust through transparency, accountability, and consistency in the process of decision-making', linking this structure directly with the constitutional context.
62. See S.D. Pattinson, *Medical Law and Ethics*, cited, p. 282, referring to Human Fertilisation and Embryology Authority.
63. See decision no. 282/2002; 151/2009.

The systems of law-making. Finally, linking together the previous three dimensions (actors, procedures and sites), we need to achieve original systems of law-making, starting from the assumption that sharing common deliberative methods proves to be more effective and viable in view of a convergence of national policies, rather than attempting to force this harmonizing process by means of legislation that does not take into account inevitable social, political and cultural differences.[64]

This is what has been defined as 'convergence by procedures': a common procedural approach that drives towards similar regulatory solutions. Regulatory content has to become the natural, physical outcome of the implementation of common procedural principles and methods. It is important to note that enforcing a 'procedure-oriented' approach does not imply renouncing regulatory substance. On the contrary, it gives the latter new sources of legitimacy and increases its scientific soundness, normative effectiveness and constitutional consistency, as the cases of Spain and France seem to show. The 'procedure-oriented' model does not lead to the so-called regulatory 'far-west'. The counter-proof is paradoxically provided by a very 'content-based' system, Italy. Even if it is based on a rigid 'value-oriented' approach, the Italian regulatory regime guarantees a lower level of both legal certainty and rights protection, when compared with the 'procedure-oriented' or 'hybrid' models. Accordingly, criticisms based on the weaker nature of procedural justification of regulatory intervention may be relaxed,[65] when considering that the enforcement of a 'procedure-oriented' approach may change regulatory focus from ethical–moral legitimacy to a 'rights-protection grounded' legitimacy. When ethical concerns substitute the goal of rights protection in the biomedical field, the outcome, as the case of Italy seems to show, is a weak regulation, unable to achieve its own declared objectives.

The 'integration by specialisation' model

The regulatory model that this article proposes is defined as 'integration by specialisation' of different regulatory tools. Within this model, the role of regulatory tools other than legislative ones is decisive, and places emphasis on the role of science and scientific knowledge as regulatory tools. The hypothesis here is that statutory law is a necessary but not sufficient regulatory source. It must coexist with other sources, traditionally not considered as legal sources in many States, such as professional ethics codes, self-regulation and case law.[66] The coexistence may be supportive or pathological. It may be pathological in the sense that statutory law can react with other sources by excluding

64. In general terms, C. Scott, 'Regulatory Governance and the Challenge of Constitutionalism', in D. Oliver, T. Prosser and R. Rawlings, eds. *The Regulatory State* (New York: Oxford University Press, 2010), pp. 17, recognises that 'one response to the diffusion of regulatory power is to seek the extension of traditional modes of control and accountability beyond state actors, as the alternative is to recognize diffusion not only in actors but also in modes of regulatory governance'.

65. For this kind of criticism, see R. Brownsword, 'Human Dignity, Ethical Pluralism, and the Regulation of Modern Biotechnologies', in T. Murphy, ed. *New Technologies and Human Rights* (New York: Oxford University Press, 2009), p. 40.

their feasibility and effectiveness (such as in Italy), or can be supportive by recognising the need for an integrated system of different sources, each one performing a specific function (such as in the UK, Spain and France). To determine whether coexistence is pathological or supportive a number of questions can be asked: is the interaction between different regulatory sources to be understood in the sense of reciprocal exclusiveness or mutual integration? What is the approach of the judiciary when it comes to verifying the enforceability of statutory law: does it differ based on whether the preliminary law recognises a space for other sources (self-regulation or professional ethics codes) or denies it? Does case law at both national and international levels recognise the need for a regulatory function of science and self-regulation?[67]

In order to answer these questions, it seems that, within what I call the 'integration by specialisation' model, a new dimension of the principle of reasonableness is emerging: this is the 'scientific reasonableness' of the law, which constitutes a fundamental theoretical ground for this regulatory approach. If we consider both national and international case law regarding legislative regulation of science, it seems that a scientific dimension of the reasonableness principle is developing.[68] The Italian Constitutional Court has consistently recognised the limits for legislative discretionary power which derive from scientific and experimental knowledge. As mentioned above, discretionary legislative intervention cannot be considered the exclusive regulatory tool when regulating medical treatments, as with regard to therapeutic activity, the golden rule is physician's autonomy and responsibility that, with patient's consent, makes professional choices grounded in the level of scientific development.[69] Therefore, the legislature, according to a subsidiarity perspective, is not the main regulatory tool emerging within the medical context. Science itself, in the form of self-regulation and expertise, acts as a direct regulatory tool. This does not mean that parliament has been excluded from regulating medical activity, but its intervention is limited and oriented by a set of both substantive and procedural criteria.

According to the principle of subsidiarity, parliaments may (or must) intervene when self-regulation is not able to guarantee a reasonable level of rights protection. On the other hand, even when entitled to intervene, statutory intervention on medical treatment adequacy may not derive exclusively from political discretionary power, but should be based on verification of available scientific knowledge and experimental evidence, acquired by technical bodies, either national or supranational, because of the essential importance that they hold for these purposes. Statutory intervention should be the result of such an examination.[70]

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66. D. Morgan, 'Regulating Reproductive Technologies: Ten Years Down The Tube?', in J. Gunning, ed. *Assisted Conception*, p. 182.
67. On this issue, see K. Syrett, 'Health Technology Appraisal and the Courts: Accountability for Reasonableness and the Judicial Model of Procedural Justice', *Health Economics, Policy and Law* 6 (2011), pp. 469–488.
68. See S. Penasa, 'La Ragionevolezza Scientifica Delle Leggi Nella Giurisprudenza Costituzionale', *Quaderni costituzionali* 4 (2009). See, from a partially different approach, S. Hennette-Vauchez, 'Reasonableness and Biolaw', in G. Bongiovanni, G. Sartor and C. Valentini, eds. *Reasonableness and Law* (New York: Springer, 2009), pp. 356.
69. Italian Constitutional Court, decision no. 151/2009.
70. See decisions no. 282/2002; 338/2003; 151/2009.

Legislatures, and also judges, are not best placed to intervene in evaluating the merit of medical–scientific options, due to a lack of expertise and should defer such a decision to technical bodies. Interestingly enough, both UK and Italian case law[71] seem to share this approach, by recognising that there is a regulatory area that has to be reserved for expertise (by means of both self-regulation and ad hoc technical bodies).[72] The Italian Constitutional Court expressly refers to a 'competences reserved for health scientific-technical bodies'.[73] Legislatures face a duty of method more than a duty of results, in the sense that the proposed regulatory framework, procedural, does not lead automatically to a predefined legislative result. It binds legislature to follow a law-making process that can guarantee the acceptability and feasibility of political choices, without previously defining them. Accordingly, the legislature can decide not to adhere to the scientific assessment provided during the decision-making: but it has to demonstrate that the assessment has been provided and, when overcoming it, it must provide reasonable arguments. Interestingly, a judicial convergence is also detectable. Although in very different legal frameworks, such as the national one on the one hand and the WTO on the other, judicial attitudes seem to be similar. On the one hand, there emerges an 'obligation to disclose the information upon which the decision was based'[74] and a legislative intervention limiting the freedom of private enterprise (in the case of genetically modified organisms), by applying the precautionary principle, can be constitutionally justified exclusively by showing that it is based on the verification of the state of the art of scientific knowledge, acquired by institutions and bodies delegated for this.[75] On the other hand, WTO legislation 'does oblige the political branch to offer reasons for deviating from scientific advice, and attaches conditions to the quality of such reasons'.[76] Therefore, this procedural model calls on 'politics to rationalize and articulate policy in a manner that allows for *ex ante* and *ex post* democratic deliberation and control'.[77]

Another relevant dimension of the principle of 'scientific reasonableness' seems to arise from international case law. Here, we can look to a recent case ruled on by the EctHR: the case of *S.H. and Others v Austria*. The case concerned gamete donation for in vitro fertilisation purposes and the ban that Austrian law on ART places on this practice. Two couples went before the ECtHR, asking for a declaration of incompatibility between the prohibition and article 8 (right to respect for private and family life) of the

71. See the decisions of the Italian Constitutional Court no. 185/1998; 188/2000.
72. See, for the UK, K. Syrett, 'Health Technology Appraisal and the Courts: Accountability for Reasonableness and the Judicial Model of Procedural Justice', p. 480; and, for Italy, R. Bin, 'Freedom of scientific research in the field of genetics', in R. Bin, N. Lucchi and S. Lorenzon, eds. *Biotech Innovations and Fundamental Rights* (New York: Springer, 2011), pp. 353.
73. Decision no. 188/2000.
74. K. Syrett, 'Health Technology Appraisal and the Courts', p. 481.
75. Italian Constitutional Court, decision no. 116/2006.
76. H. Somsen, 'Regulating Human Genetics in a Neo-Eugenic Era', p. 100, that argues that 'what is not accepted (. . .) is that members take measures without giving sound reasons'.
77. Somsen, 'Regulating Human Genetics'.

ECHR. The Grand Chamber dismissed the request (November 2011), overruling the previous decision of the First Section (April 2010), by recognising a broad margin of appreciation to Member States. The reasoning of the Grand Chamber is particularly relevant. The Grand Chamber of the ECtHR expressly stated that 'even if it finds no breach of Article 8 in the present case, the Court considers that this area, in which the law appears to be continuously evolving and which is subject to a particularly dynamic development in science and law, needs to be kept under review by the Contracting States'.[78] The Court appeared to impose on the Austrian Parliament the duty to 'keep the legislation under review' because of the particularly dynamic development characterising the field of ART. The Austrian Constitutional Court had also previously asked Parliament to take into account the developments of both medical science and consensus in society.[79] This may point to a common understanding of the law–science relationship at both a national and international level, at least with regard to the need for constantly adapting legislative regulation to scientific reality.

So what is the way forward? Reference to the scientific dimension of the principle of reasonableness inevitably recalls the 'accountability for reasonableness' theory for driving decisions on healthcare limit-setting and allocation of (limited) financial resources. Even if widely implemented, this framework is not free from concerns.[80] Notwithstanding, if we assume it as an efficient decision-making framework, it sounds paradoxical to exclude its enforcement within the law-making phase,which precedes allocative decisions and in which an integrated asset of different regulatory tools is called upon to provide a general legal framework for the healthcare system. Why not implement the principles connoting 'accountability for reasonableness' framework within the law-making process, when a general convergence towards substantially equivalent principles is emerging at both legislative and judicial levels? It should be necessary to adapt it to the peculiarities of law-making, but it may offer a common set of regulatory principles to be implemented by national legislatures when regulating science-related fields, such as ART.

Inevitably, every national system will adapt ART regulation to its own constitutional and cultural framework, but this comparative research has shown the existence of a general common trend towards harmonisation, linking together systems belonging to different legal traditions and cultural heritage (such as the UK and Spain). When agreeing to apply this method to policies on health care provision and not only on allocative decisions, law-making mechanisms have to integrate four requirements: (a) a *publicity* condition, which

78. para 118.
79. Para 117 As stated by the European Court, 'the Austrian Constitutional Court, when finding that the legislature had complied with the principle of proportionality under Article 8, Section 2 of the Convention, added that the principle adopted by the legislature to permit homologous methods of artificial procreation as a rule and insemination using donor sperm as an exception reflected the then current state of medical science and the consensus in society. This, however, did not mean that these criteria would not be subject to developments which the legislature would have to take into account in the future' (*S.H. and Others v Austria*).
80. See A. Friedman, 'Beyond Accountability for Reasonableness', *Bioethics* 22(2) (2008), pp. 101–112.

requires transparent and publicly accessible political decision procedures;[81] (b) a *relevance* condition, which calls for principle-based and evidence-based regulation, in order to assure that political decisions on the access to medical-therapeutic treatment are achieved fairly; (c) a *revision and appeals* condition, that requires dispute resolution mechanisms and political decision review (reassessment) mechanisms, based on new scientific achievement and (d) an *enforcement* condition, based on a control and scrutiny system of effective law-enforcement, by means of both independent technical bodies and public involvement.[82] One criticism linked to this theory is the lack of *ex ante* society and expertise involvement.[83] Therefore, two further elements seem to be necessary: The involvement of relevant parties in the decision-making process and the open and fair discussion of principles.[84] Interestingly enough, all conditions characterising 'accountability for reasonableness' theory seem to overlap with the main characters of the 'integration by specialisation' model which has been proposed in this article.[85]

The problems of how to legislate and how much to legislate, assume a clearer dimension. The 'procedure-oriented' approach recalls an 'integrated model', as is characterised by a mix of different regulatory sources each developing a determined function: statutory law providing for a set of general rules and principles to be enforced case-by-case by independent technical bodies (authorities) and integrated by self-regulation and professional ethics rules. On the one hand, law cannot infringe a regulatory space reserved to expertise and self-regulation, developing a subsidiary/complementary function. On the other hand, it has to recognise the integrative role of expertise within the decision-making process. This leads to a mutual integration of a plurality of regulatory tools, each legitimated to perform a content-specific normative function.

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81. R. Dresser, 'Stem Cell Research as Innovation: Expanding the Ethical and Political Conversation', *Journal of Law, Medicine and Ethics* 38(2) (2010), p. 332, applies deliberative democratic policy making also to the hESC research regulation.
82. K. Syrett, 'NICE and Judicial Review: Enforcing'Accountability for Reasonableness' Through the Courts?'; above note 55, p. 135.
83. Again, see A. Friedman, 'Beyond Accountability for Reasonableness', pp. 111–112.
84. L.M. Sabik and R.K. Lie, 'Principles vs. Procedures in Making Health Care Coverage Decisions: Addressing Inevitable Conflicts', *Theoretical Medicine and Bioethics* 29 (2008), p. 82.
85. The latter tries to introduce further conditions, which seem to lack within the 'accountability for reasonableness' framework, as stressed by many scholars: among others, see A. Rid, 'Justice and Procedure: How Does 'Accountability for Reasonableness' Result in a Fair Limit-Setting Decisions?', *Journal of Medical Ethics* 35 (2009), pp. 15–16, that refers to a lack of formal fairness and inclusiveness and representation.