

“EU”: Short for “Ethical” Union? The Role of Ethics in European Union Law

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Abstract	531
I. Introduction	532
II. Ethics and Morality – Lost in Translation?	536
III. EU Institutions’ Attitude Towards Ethics	539
IV. Member States’ “Umbrella Philosophy”	541
V. Individuals as Addressees	545
1. The Consequences of Unethical Practice and Behaviour (Continued)	545
2. Category of Non-Interference	547
3. Determination of Content	549
4. Analysis	561
VI. Not Only Filling a Gap	563
1. EU Methodology	564
2. Human Rights and Values, Not Religion	565
3. And the Task of Determining Ethics Goes to ...	570
4. Talk, Then Walk the Talk (Importance of Dialogue and Openness)	572
5. Limitations	574
VII. Conclusion	575

Abstract

In various (binding and non-binding) legal documents, the European Union (EU) refers to “ethics” and “morality”, without providing a definition or even referring to a common understanding. However, if a certain activity is qualified as “unethical”, there can be important consequences, such as stringent ethics reviews in case of the use of human stem cells under the “Horizon 2020” program, or, under the same program, the exclusion from

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funding, or, under the “EU Patient Mobility Directive”, no right to cross-border healthcare, to name but a few. This article focuses both on EU Primary and Secondary law, with a special emphasis on the latter. I will argue that in a lot of cases, ethics is (only) used in order to avoid interference of the EU in Member States’ competences, especially in sensitive fields, like abortion. However, there are also examples where the relevant content is determined, either by Ethics Committees and/or Code of Conducts, either at EU or at national level. Nevertheless, other situations remain undetermined. I will further argue that the determination of ethics should be carried out by referring to the EU’s values and fundamental rights, especially the “corner stone” of human dignity.

I. Introduction

At first sight, the EU’s approach to ethics can best be described by its motto “United in diversity”.¹ On the one side, the Treaty on European Union (TEU)² draws inspiration “from the cultural, religious and humanist inheritance of Europe”³ and the EU Charter of Fundamental Rights (CFR)⁴ which refers to the Union’s “common values”⁵ and “spiritual and moral heritage”.⁶ On the other side, the CFR requires the EU to respect “the diversity of the cultures and traditions of the peoples of Europe as well as the national identities of the Member States”.⁷

The current EU’s framework program for research and innovation (Horizon 2020) provides, for example, that “[t]he use, if any, of human stem cells, be they adult or embryonic [...] is subject to stringent [*sic!*] ethics re-

¹ Art. I-8, para. 3 (and 4th recital) Treaty Establishing a Constitution for Europe (not entered into force), Official Journal (O.J.) 2004, C 310/11. Although the symbols have been removed and not transferred into the Treaty of Lisbon, O.J. 2007, C 306/1, 16 Member States have declared their commitment to the motto (and the other symbols) in a joint declaration; O.J. 2007, C 306/267.

² Consolidated Version of the Treaty on European Union, O.J. 2012, C 326/13.

³ 2nd recital TEU.

⁴ Consolidated Version of the Charter of Fundamental Rights of the European Union, O.J. 2012, C 326/391.

⁵ 1st recital CFR.

⁶ 2nd recital CFR.

⁷ 3rd recital CFR. See also 6th recital, Art. 3, para. 3 subpara. 4 and Art. 4, para. 2 TEU. In the context of stem cell research, the Commission has concluded from this provision that “each Member State retains its full prerogative to legislate on ethical matters”; European Commission, Report on Human Embryonic Stem Cell Research, SEC (2003) 441 final 3.4.2003, 12.

view”.⁸ In the same context, a corresponding regulation provides that “[a] proposal which contravenes ethical principles or any applicable legislation [...] may be excluded from the evaluation, selection and award procedures at any time”.⁹ In the context of the EU Patient Mobility Directive (PMD), this form of cross-border healthcare is limited by the fact that the PMD may not “undermine the fundamental ethical choices of Member States”.¹⁰ These are only some examples¹¹ that raise a number of important questions: Is there a definition or at least a certain form of understanding as to what has to be understood by “ethical”?

The already mentioned EU’s common values¹² also entail “the rule of law”.¹³ According to the European Commission’s recent Communication¹⁴, one (formal)¹⁵ element of the rule of law is *legal certainty*, which, according to the European Court of Justice (ECJ)¹⁶, requires amongst other things that “legislation must be clear and predictable for those who are subject to it”.¹⁷ Hence, one might wonder, if EU legislation is “clear and predictable” enough to refer to undetermined concepts.

⁸ 31st recital Regulation 1291/2013/EU Establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020), O.J. 2013, L 347/104 (Regulation Establishing Horizon 2020). See also the Declaration of the Commission, O.J. 2013, C 373/12 (Framework Programme), according to which the “Commission proposes to *continue* with the *same ethical framework* for deciding on the EU funding of human embryonic stem cell research as in the 7th Framework Programme” (emphases added).

⁹ Art. 13, para. 3 Regulation 1290/2013/EU Laying Down the Rules for Participation and Dissemination in “Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)” (Regulation Horizon 2020 Rules for Participation), O.J. 2013, L 347/81. Also according to Annex 4.1.15 Commission Recommendation 2008/345/EC on a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research, O.J. 2008, L 116/46, “N&N research funding bodies should *not fund* research in areas which could involve the violation of fundamental rights or *fundamental ethical principles*” (emphases added).

¹⁰ 7th recital Directive 2011/24/EU on the Application of Patients’ Rights in Cross-border Healthcare, O.J. 2011, L 88/45.

¹¹ See V., 1.

¹² Art. 2 TEU.

¹³ Cf. *A. v. Bogdandy/M. Ioannidis*, Systemic Deficiency in the Rule of Law: What It Is, What Has Been Done, What Can Be Done, CML Rev. 51 (2014), 59, 62 et seq.

¹⁴ European Commission, A New EU Framework to Strengthen the Rule of Law, COM (2014) 158 final 11.3.2014, 4 and Annex 1.

¹⁵ *P. Craig*, Formal and Substantive Conceptions of the Rule of Law: An Analytical Framework, P.L. 55 (1997), 467, 467 “the clarity of the ensuing norm (was it sufficiently clear to guide an individual’s conduct so as to enable a person to plan his or her life, etc.)”.

¹⁶ In this article I will use the abbreviation “ECJ” only for the Court of Justice in the sense of Art. 19, para. 1 TEU.

¹⁷ ECJ Case 212 to 217/80 EU:C:1981:270 margin number 10 – *Meridionale Industria Salumi and Others*. See also Venice Commission, Report on the Rule of Law, CDL-AD(2011)003rev, 10 et seq.; and ECtHR, *L.H. v. Latvia*, 52019/07, para. 47 (“the rule of law,

However, the objective of this paper is not to assess the concept of ethics in EU law against this principle of the rule of law.¹⁸ The objective of this article is rather to depict and analyse the *status quo* of ethics and morality in EU law.¹⁹ Is there a common understanding of ethics, based on a certain philosophical approach, and how does EU law relate to ethics?

Thus, while it is clear that the EU has developed from an economic vehicle (initially coal and steel) to a political Union (also safeguarding fundamental rights), the question remains, as to whether the Union is also based on a principle of “the rule of ethics”.

Therefore, this article focuses on EU Primary and Secondary law, where those terms occur in different binding and non-binding documents. As the research wants to find out about the status quo of ethics and morality in EU law, it follows an inductive approach and portrays those documents where the relevant legislator explicitly²⁰ referred to those concepts, and, last but not least, clusters and analyses them in order to answer the following questions.

- How and at which level is this concept determined? Even below the threshold of a possible theoretical conflict with the rule of law, is the legal situation “formulated with sufficient precision to enable the individual to regulate his or her conduct”,²¹ or does it remain undetermined in the end?
- Do ethics occur in EU law in a uniform or, rather, a sector specific way?
- Although it is not the main objective, the question is whether there is a common understanding of ethics based on a certain philosophical approach.

Where appropriate, this article also takes into account relevant ECJ case-law and opinions of the European Group on Ethics in Science and New Technologies (EGE).²²

After a general introduction (II.), I will first focus on EU institutions²³ (III.), followed by Member States (IV.), and finally individuals (V.) as ad-

which [...] means that the domestic law must be formulated with sufficient precision and must afford adequate legal protection against arbitrariness”).

¹⁸ Such a research question would face different challenges and require a separate paper.

¹⁹ The article will mainly focus on ethics, as this term is used more often; See V.

²⁰ For an analysis of implicit traces of ethics in EU law see *I. Manners*, *The Normative Ethics of the European Union*, *Int'l Aff.* 84 (2008), 45.

²¹ Venice Commission (note 17), 10.

²² Those opinions are accessible at the following (meanwhile archived) webpage: *EGE*, *Opinions, Studies and General Activity Reports*, <<http://ec.europa.eu>> (accessed 31.3.2015).

dressees of ethical requirements. Especially in the latter category, I will analyse those approximate 75 (binding and non-binding) documents of Secondary²⁴ law that contain the term of ethics / ethical, and/or morality / moral.²⁵

The research mainly focused on documents that are still in force and excluded those, for example, in the field of research programs, which have been replaced by others.²⁶

The EU with its 28 Member States comprises 24²⁷ official languages.²⁸ The factual working languages of the EU institutions are mainly English, French (especially at the ECJ) and German, with a dominance of English in recent years.²⁹ However, it is important to keep in mind that according to settled case-law “the different language versions are all equally authentic” and that an interpretation of EU law “thus involves a comparison of the different language versions”.³⁰

That is why the research consisted in a database search using the terms “ethic*” and “mora*”, focusing mainly on English (as the most important factual working language). However, also the German and French language versions were taken into account. Where language versions differed, the research also envisaged the other languages spoken (Spanish) – or at least passively understood (Italian) – by the author.

²³ This term is used in a broad sense, so surpassing the enumeration of Art. 13, para. 1 TFEU.

²⁴ Amongst the documents examined, there have also been some implementing Secondary EU law (i.e. Tertiary EU law), see V., 3., (1a) and (3).

²⁵ See II.

²⁶ Hence, this disclaimer mainly applies to Secondary law.

²⁷ Including Croatian, since 1.7.2013; O.J. 2012, L 112/1, 25.

²⁸ According to Art. 55, para. 1 TEU and Art. 358 TFEU the Treaties (Primary law) are “equally authentic” in each of these 24 languages; the same is true for Secondary law, comprising 24 “official languages and the working languages of the institutions of the Union”; Council Regulation No 1 Determining the Languages to be Used by the European Economic Community, O.J. 1958, P 17/385, as amended by O.J. 2013, L 158/1, 71. According to Art. 4 leg. cit. “[r]egulations and other documents of general application shall be drafted in the official languages”.

²⁹ Therefore, the aforementioned 24 working languages do not correspond with Brussels’ (or Strasbourg’s) reality.

³⁰ ECJ Case 283/81 EU:C:1982:335 margin number 18 – *CILFIT v. Ministero della Sanità*.

II. Ethics and Morality – Lost in Translation?

In the context of legal protection of biotechnological inventions, the relevant EU directive refers to “ethical or moral principles supplement[ing] the standard legal examinations under patent law”.³¹ As both terms are used at the *same time*,³² it seems that they have a different meaning; however, it is unclear how they relate to each other.

Lawyers are used to working with definitions. When stepping into the world of philosophy, one has to accept that there are no official definitions. It is not primarily for lawyers to define the terms of ethics and morality. However, at the interface of these two disciplines, there is a need to shed some light on these terms by referring to reliable understandings.

Ethics is essentially seen as a “branch of philosophy dealing with what is morally right or wrong”,³³ or as “the philosophical study of the moral value of human conduct and of the rules and principles that ought to govern it”.³⁴

Morality, on the other hand, is described by *Beauchamp* and *Childress* in the following way:³⁵

“In its most familiar sense, the word *morality* [...] refers to norms about right and wrong human conduct that are so widely shared that they form a stable social compact. [...] We learn about morality as we grow up, and we learn to distinguish the part of morality that holds for everyone from moral norms that bind only members of specific communities or special groups [...]”.

Hence, in a very simplified way, one can say that ethics is the theoretical / philosophical approach (*Thomas von Aquin’s “scientia ethica, quam nos morale dicimus”*³⁶ or *Cicero’s “philosophia moralis”*³⁷) to morality, and the latter referring to factual³⁸ rules (“mores”) and codes of conduct in a specif-

³¹ 39th recital Directive 98/44/EC on the Legal Protection of Biotechnological Inventions, O.J. 1998, L 213/13.

³² ECtHR, *S.H. and others v. Austria*, 57813/00, para. 94 (“sensitive moral or ethical issues”) and 97 (“sensitive moral and ethical issues”); emphases added. In 38th (etc.) and 39th recitals Directive 2010/63/EU on the Protection of Animals Used for Scientific Purposes, O.J. 2010, L 276/33, the terms ethical and moral are used in “neighboring recitals”.

³³ Merriam-Webster, Ethics, <<http://www.merriam-webster.com>> (accessed 31.3.2015).

³⁴ Collins, Ethics, <<http://www.collinsdictionary.com>> (accessed 31.3.2015).

³⁵ *T. Beauchamp/J. Childress, Principles of Biomedical Ethics*, 2013, 2 et seq.; no emphases added.

³⁶ *H. Reiner, Ethisch*, in: J. Ritter/K. Gründer/G. Gabriel, *Historisches Wörterbuch der Philosophie*, 2007, Vol. 2, 809, 809.

³⁷ *J. Ritter, Ethik*, in: J. Ritter/K. Gründer/G. Gabriel, *Historisches Wörterbuch der Philosophie*, 2007, Vol. 2, 759, 760.

³⁸ *H. Reiner* (note 36), 809.

ic (cultural, territorial and temporal) social system (“*morem esse communem consensum omnium simul habitantium, qui inveteratus consuetudinem facit*”).³⁹

In the context of a Union with 24 different languages⁴⁰, it is important to follow a linguistically⁴¹ holistic approach. As we have just seen, ethics and morality, in theory, have a different meaning and therefore it is astonishing if they are used differently in different language versions. What reads “[c]onsumers in the Community would, in addition, find it *morally* unacceptable that their increased use of biofuels could have the effect of destroying biodiverse lands” in the English⁴² version, refers to *ethics* (“ethisch inakzeptabel”) in the German version.⁴³ However, as those terms are generally distinguished, we can assume that this wording is based on *imprecise translation* and without further significance. The same might hold true for the case of the already mentioned Directive 98/44/EC⁴⁴, which refers to the “ethical or moral principles recognised in a [*sic!*] Member State”,⁴⁵ whereas the German version uses the plural (“in den Mitgliedstaaten”).⁴⁶ Thus following the principle of equally authentic language versions, in the end one will have to follow a “majority rule”. Although this will be the compelling solution, it might sound funny if only the English version of a code of conduct (relating to transactions in transferable securities) declares the code’s objective as “to establish standards of ethical behaviour on a Community-wide basis”, whereas the other language version examined only refer to loyal behaviour (for example, FR: “comportement loyal”).⁴⁷

³⁹ G. Jüssen, Moral, moralisch, Moralphilosophie, in: J. Ritter/K. Gründer/G. Gabriel, Historisches Wörterbuch der Philosophie, 2007, Vol. 6, 146, 149.

⁴⁰ See I.

⁴¹ According to the limitation mentioned above, this will be English (EN), German (DE), French (FR), Spanish (ES) and Italian (IT).

⁴² Emphasis added. Similar in FR, ES, IT.

⁴³ 11th recital Directive 2009/30/EC Amending Directive 98/70/EC As Regards the Specification of Petrol, Diesel and Gas-oil and Introducing a Mechanism to Monitor and Reduce Greenhouse Gas Emissions [etc.], O.J. 2009, L 140/88. For a similar example see also ECJ Case C-267/95 EU:C:1996:468 margin number 53 – *Merck*, (“ethical obligations” vs. “moralische Verpflichtungen”).

⁴⁴ See note 31, 39th recital.

⁴⁵ Similar in FR, ES, IT.

⁴⁶ According to *F. de Witte*, Sex, Drugs & EU Law: The Recognition of Moral and Ethical Diversity in EU Law, CML Rev. 50 (2013), 1545, 1558, “the preamble to Directive 98/44 speaks of the respect for the ethical or moral principles recognized in a Member State, [...] and the European Parliament long halted the decision-making process by referring to the irreconcilable differences of opinion between the Member States, highlighting that it should be for States and their citizens to make their own assessments of these divisive moral questions”.

⁴⁷ Annex Commission Recommendation 77/534/EEC Concerning a European Code of Conduct Relating to Transactions in Transferable Securities, O.J. 1977, L 212/37.

There are other examples of differences in translation which can be clustered into a (less problematic) category, where the term “ethical” is just explicitly missing – but to some degree implicitly included – in another language version.

A first example refers to the degree to which substances can be tested on animals, where only the German version refers to ethics⁴⁸, whereas a similar idea is worded in different ways in English (“can humanely be allowed”;⁴⁹ similarly in ES), and the French (and IT) version referring to the degree of pain suffered by the animal (FR: “sans que cela fasse trop souffrir l’animal”).⁵⁰ A second example refers to doping, where the use of drugs in sport is denounced as “unsporting behaviour” in the English version, whereas all the other examined versions refer to the ethics of the sport (for example, ES: “contrario a la ética deportiva”).⁵¹ Therefore, in both cases, the result might be the same, but the wording is different. The same is true, if the term code of conduct (“Verhaltenskodex”) is used in one version (DE), whereas the other languages examined use the term code of ethics, and so on.⁵² In another case, a systematic way of interpretation can help, if only one language version refers to a “culture of ethics”⁵³, however, according to the heading⁵⁴, it is clear, that also the other language versions (only referring to the “culture for the organization”) have the same meaning.

Concerning ethical rules of a *professional nature*, one has to be aware of the fact that professional rules in one language version (DE: “standesrechtlichen Regeln”) can clearly refer to “rules of professional ethics” in other versions.⁵⁵ Again, the impression of inconsistent translation arises, if elsewhere in the very same directive (on recognition of professional qualifications) the word ethics is then used in all the language versions examined, without obvious reason.⁵⁶ If this inconsistency of the German version is

⁴⁸ DE: “ethisch verantwortbar”.

⁴⁹ On humanism, see VI., 2.

⁵⁰ Annex, Part B.4, 1.4.2.3 Regulation 440/2008/EC Laying Down Test Methods Pursuant to Regulation 1907/2006/EC on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), O.J. 2008, L 142/1, as amended by O.J. 2014, L 247/1.

⁵¹ Annex I Resolution of the Council [etc.] on Community Action to Combat the Use of Drugs, Including the Abuse of Medicinal Products, Particularly in Sport, O.J. 1990, C 329/4.

⁵² FR: “code de déontologie”, ES: “el código deontológico”, IT: “codice ético”; Annex, 3.1 Council Decision 2008/210/EC on the Principles, Priorities and Conditions Contained in the European Partnership with Albania and Repealing Decision 2006/54/EC, O.J. 2008, L 80/1.

⁵³ DE: “Kultur der Ethik”.

⁵⁴ “Ethics and integrity policies”.

⁵⁵ EN, FR, ES, IT. 11th recital, Art. 36, para. 3 Directive 2005/36/EC on the Recognition of Professional Qualifications, O.J. 2005, L 255/22; as amended by O.J. 2013, L 354/132.

⁵⁶ Art. 31, para. 6 (b), Art. 40, para. 2 (b), Art. 57 (a) Directive 2005/36/EC (note 55).

later avoided (in a directive amending the aforementioned one)⁵⁷ (DE: “Standesregeln und berufsethische Regeln”), then this can be seen as an argument in favour of a mere translation error.⁵⁸ No difference in translation can be analysed, if ethics and ethos are used in different languages, where the latter term refers to the firm tenor of any profession.⁵⁹

To summarize, we can say that the general rule to take into account not only one language version of course also helps in case of the language inconsistencies in this context. However, in case of fundamental concepts like ethics, more clarity and coherence would be desirable.⁶⁰ Still, it can also rest unclear if these language versions that are “united in diversity” are due to imprecise translations (for example, somewhere in a very comprehensive annex), or are the result of debates on principles.

III. EU Institutions’ Attitude Towards Ethics

First of all, we have to shed some light on the role of ethics in the EU’s institutions. In this context, one finding can be anticipated: none of the three main institutions (Commission, Parliament and Council) themselves have explicitly incorporated ethics or morality into their Rules of Procedure (ROP), and the same is true for the Court of Justice.

⁵⁷ Art. 57b, para. 1 Directive 2013/55/EU Amending Directive 2005/36/EC on the Recognition of Professional Qualifications [etc.], O.J. 2013, L 354/132.

⁵⁸ Also in this context of professional rules there is another example, where a systematic interpretation has to be applied, in order to get around language inconsistencies; 9th recital Directive 2006/43/EC on Statutory Audits of Annual Accounts and Consolidated Accounts [etc.], O.J. 2006, L 157/87, as amended by O.J. 2014, L 158/196. For another example with divergent German terminology see 99th, 113th and 114th recitals, Art. 25 Directive 2006/123/EC on Services in the Internal Market, O.J. 2006, L 376/36.

⁵⁹ *J. Ritter* (note 37), 813 (“feste Grundhaltung irgendeines Berufsstandes”). EN: “generally accepted principles of medical ethics” (also FR, ES, IT); DE: “allgemein anerkannten Grundsätze des ärztlichen Berufsethos”; Annex I, Part II.6 Directive 2006/43/EC (note 58).

⁶⁰ In that context, according to point 31 of the Interinstitutional [EP, Council and Commission] Agreement on Better Law-making, O.J. 2003, C 321/1, the “European Parliament and the Council will make all appropriate arrangements for improving the scrutiny carried out by their respective departments of the wording of texts adopted under the codecision procedure, with a view to avoiding any inaccuracies or inconsistencies”; and according to the Joint Declaration [of the same three institutions] on Practical Arrangements for the Codecision Procedure, O.J. 2007, C 145/5, “[n]o changes shall be made to any agreed texts without the explicit agreement, at the appropriate level, of both the European Parliament and the Council” (point 41), after “the agreed text [has been] finalised by the legal-linguistic services of the European Parliament and of the Council acting in close cooperation and by mutual agreement” (point 40).

Only the Parliament's ROP⁶¹ mention ethics twice; but, first, merely mentioning "ethical questions related to new technologies" as one of the competences of the Committee on Legal Affairs,⁶² and, second, concerning the Commission's obligation to seek Parliament's opinion when revising the "Code of Conduct for Commissioners".⁶³ Thus, with regard to the Commission, ethics cannot be found in the ROP, but at least in this latter distinct document,⁶⁴ not only regulating ethical issues with regard to independence and dignity, but also providing an ad hoc ethical committee, which can be requested by the president "to deliver opinions on any general ethical question concerning the interpretation"⁶⁵ of this code.⁶⁶

The question remains, as to whether "good behaviour", if not guaranteed on an ethical or moral basis, is "at least" stipulated (to whatever degree) on a legal basis. This can be answered in the affirmative for the Parliament,⁶⁷ (in addition to the above mentioned code also) for the Commission⁶⁸ and the Court of Justice.⁶⁹ No such legal provision can be found in the Council's⁷⁰ and in the European Council's⁷¹ ROP.⁷²

Nevertheless, there are institutions that do mention "ethics" in their respective rules. The European Investment Bank follows a combined institu-

⁶¹ European Parliament's Rules of Procedure, 8th parliamentary term (January 2015).

⁶² Annex VI, XVI, European Parliament's Rules of Procedure (note 61).

⁶³ Annex XIII (also published in O.J. 2010, L 304/47), II, European Parliament's Rules of Procedure (note 61).

⁶⁴ European Commission, Code of Conduct for Commissioners, <<http://ec.europa.eu>> (accessed 31.3.2015).

⁶⁵ European Commission, Code of Conduct for Commissioners (note 64), para. 2.3.

⁶⁶ For the new *Junker* Commission, the so called "Mission letters" of the President to the single Commissioners (e.g. <<http://ec.europa.eu>>, accessed 31.3.2015) address ethics (under the heading "Our Principles: Ethics and Transparency") in the following way: "We must abide by the highest possible professional and ethical standards at all times. [...] I expect all of us to honour both the word and the spirit of the Code". *J. Dratwa*, How Values Come to Matter at the European Commission, *Politique Européenne* 45 (2014), 86.

⁶⁷ Rule 11 and Annex I European Parliament's Rules of Procedure (note 61), ("Code of Conduct for Members of the European Parliament with Respect to Financial Interests and Conflicts of Interest").

⁶⁸ Rules of Procedure of the Commission, Annex "Code of Good Administrative Behaviour for Staff of the European Commission in their Relations with the Public", O.J. 2000, L 308/26, as amended by O.J. 2011, L 296/58.

⁶⁹ Art. 4 Rules of Procedure of the Court of Justice of 25.9.2012, <<http://curia.europa.eu>> (accessed 31.3.2015): "I swear that I will perform my duties impartially and conscientiously; I swear that I will preserve the secrecy of the deliberations of the Court".

⁷⁰ Rules of Procedure of the Council, O.J. 2009, L 325/36, as amended by O.J. 2014, L 358/25.

⁷¹ Rules of Procedure of the European Council, O.J. 2009, L 315/51.

⁷² Of course, one has to keep in mind that both of those institutions are most likely bound by their respective national standards.

tional and substantive approach, by having established an “Ethics and Compliance Committee”, which “shall rule on any potential conflict of interest” based on legal – not ethical – provisions.⁷³ Also the European Central Bank (ECB) follows a combined approach for the TARGET2-Securities Board, consisting of a code of conduct and an Ethics Officer.⁷⁴ The code of conduct contains well known principles such as avoidance of conflicts of interest (plus an obligation of notification in such situations), confidentiality, transparency and openness, an obligation of information and sanctions in the case of non-compliance. The Ethics Officer can be contacted by members in order to seek advice on an ad hoc basis.⁷⁵ The ECB itself has just recently established an Ethics Committee which shall provide advice on questions of ethics on the basis of individual requests.⁷⁶ Likewise, the European Anti-Fraud Office (OLAF) follows a substantive only approach for their Supervisory Committee, requiring the members to act independently, neither seeking nor taking instructions from others, not to deal with matters where they have a personal interest, to demonstrate confidentiality, and to adhere to an obligation of notification if any such situation occurs.⁷⁷

IV. Member States’ “Umbrella Philosophy”

In the context of the Internal Market, Member States are on an exceptional basis, allowed to restrict the free movement of goods based on grounds of “public morality, public policy [and so forth]” (Art. 36 Treaty on the Functioning of the EU, TFEU).⁷⁸ However, the Treaties do not provide a legal definition of this concept of “public morality”.

In the *Conagate* case, the ECJ had to deal with this “reason of justification” in a case of import of “inflatable dolls which were clearly of a sexual

⁷³ Art. 11, para. 4 Decision of the Board of Governors on the Amendment of the Rules of Procedure of the European Investment Bank to Reflect the Entry Into Force of the Treaty of Lisbon and of the New Statute of the Bank, O.J. 2011, L 266/1. See also European Investment Bank, Integrity Policy and Compliance Charter, <<http://www.eib.org>> (accessed 31.3.2015).

⁷⁴ Annex III, Decision 2012/235/EU of the European Central Bank on the Establishment of the TARGET2-Securities Board [etc.], O.J. 2012, L 117/13.

⁷⁵ Annex III, 5 Decision 2012/235/EU (note 74).

⁷⁶ Art. 4, para. 1 Decision 2015/433/EU of the European Central Bank Concerning the Establishment of an Ethics Committee and its Rules of Procedure, O.J. 2015, L 70/58 (referring to O.J. 2002, C 123/9 and O.J. 2010, C 104/8).

⁷⁷ Art. 4 OLAF Rules of Procedure of the OLAF Supervisory Committee, O.J. 2011, L 308/114.

⁷⁸ Consolidated Version of the Treaty on the Functioning of the European Union, O.J. 2012, C 326/47.

nature and other erotic articles” from Germany.⁷⁹ The relevant UK authority ordered the forfeiture of these goods and the national court referred the case to the ECJ, asking what is to be understood by public morality within the free movement of goods. The ECJ left it to the Member States to apply their understanding of public morality, as long as they do not follow a principle of public double morality.⁸⁰

Consequently, what we can learn from this case is the fact that the ECJ, other than in the case of (almost)⁸¹ all other reasons of justification, abstains from providing an EU wide definition of public morality. Therefore, “in principle it is for each Member State to determine in accordance with its own *scale of values* and in the form selected by it the requirements of public morality in its territory”.⁸² In a manner of “judicial self-restraint”⁸³ the definition was therefore left to the Member States, as the ECJ did not want to enter this “slippery path”,⁸⁴ as long as their law is not discriminating or incoherent.⁸⁵

With the expanding case-law of the ECJ, some Member States sought to protect their nationally determined understanding of morality. A look at the timeline exhibits the contemporaneity of a famous Irish abortion case⁸⁶ (4.10.1991) and the Maastricht Treaty (signed on 7.2.1992), where one of the protocols to this Treaty provides an umbrella, protecting “Article 40.3.3 [right to life of the unborn] of the Constitution of Ireland”.⁸⁷ When Malta acceded to the EU in 2004, a similar protocol was annexed to the Accession Treaty, stating that “[n]othing [...] shall affect the application in the territory of Malta of national legislation relating to abortion”.⁸⁸ In the very same

⁷⁹ ECJ Case 121/85 EU:C:1986:114 margin number 2 – *Conegate v. HM Customs & Excise*.

⁸⁰ ECJ Case *Conegate* (note 79), margin number 20.

⁸¹ Only the “health and life of humans rank foremost among the assets and interests protected by the Treaty and that it is for the Member States to determine the level of protection which they wish to afford to public health”; ECJ Case C-171/07 EU:C:2009:316 margin number 19 – *Apothekerkammer des Saarlandes and Others*.

⁸² ECJ Case *Conegate* (note 79), margin number 14, emphasis added; see also: ECJ Case 34/79 EU:C:1979:295 margin numbers 15, 22 – *Henn and Darby*.

⁸³ See e.g. Advocate General *Bot* Case C-34/10 EU:C:2011:669 margin number 45 – *Brüstle*; ECJ Case C-506/06 EU:C:2008:119 margin number 38 – *Mayr*. The German Constitutional High Court, for example, referred to this concept as “abstinence of ‘doing politics’” (“Verzicht ‘Politik zu treiben’”); BVerfGE 36, 1, 14.

⁸⁴ *V. Hatzopoulos*, *Regulating Services in the European Union*, 2012, 160.

⁸⁵ In this context the ECJ applies a “reduced proportionality test”, which has also been described as only being “procedural”; see *F. de Witte* (note 46), 1570 et seq.

⁸⁶ ECJ Case C-159/90 EU:C:1991:378 – *Society for the Protection of Unborn Children Ireland v. Grogan and Others [SPUC]*.

⁸⁷ O.J. 1992, C 191/1, 94.

⁸⁸ O.J. 2003, L 236/1, 947.

round of accessions, Poland opted for a similar, yet different approach, which can be qualified as “less” in terms of legal significance, as Poland’s concerns were only taken into account in terms of a Declaration of that acceding state; however, at the same time, it can be seen as “broader”, in the sense that the wording states that “nothing [...] prevents the Polish State in regulating *questions of moral significance*, as well as those related to the protection of human life”.⁸⁹

With the entering into force of the Lisbon Treaty⁹⁰ (1.12.2009), the previously only solemnly proclaimed⁹¹ CFR became legally binding.⁹² In this context, Poland seemed to fear that the CFR⁹³ “might be used to challenge its freedom to regulate the availability of abortions, euthanasia and same-sex marriage”.⁹⁴

Therefore, the final act of the 13.12.2007 signed Lisbon Treaty contained a declaration by Poland on the CFR, whereby “[t]he Charter does not affect in any way the right of Member States to legislate in the sphere of *public morality*, family law, as well as the protection of *human dignity* and *respect for human physical and moral integrity*”.⁹⁵ Some Member States, those present at the time of accession, were united in a position diverse to the Polish one, by underlying in a joint declaration “that the Declarations attached to this Final Act cannot be interpreted or applied in a way contrary to the obligations of the Member States arising from the Treaty and Act of Accession”.⁹⁶

As we have seen, EU Primary law addressing Member States does not comprise the term ethics. Still, there are a few cases⁹⁷ where it refers to (public) morality.

⁸⁹ See note 88, 983; emphasis added; see also 978.

⁹⁰ Treaty of Lisbon (note 1).

⁹¹ O.J. 2000, C 364/1 (Nice, 7.12.2000) and O.J 2007 C 303/1 (Strasbourg, 12.12.2007).

⁹² Art. 6, para. 1 TEU.

⁹³ For the application of the CFR on Poland and the United Kingdom see Protocol 30, O.J. 2007, C 306/156 et seq.; see also ECJ Cases C-411/10 and C-493/10 EU:C:2011:865 margin numbers 116 et seq. – *N. S. and Others*; *A. Arnull*, Protocol (30) on the Application of the Charter of Fundamental Rights of the European Union to Poland and the United Kingdom, in: S. Peers/T. Hervey/J. Kenner/A. Ward, *The EU Charter of Fundamental Rights: A Commentary*, 2014, 1595 et seq.

⁹⁴ *A. Arnull* (note 93), 1601.

⁹⁵ O.J. 2007, C 306/1, 270, emphases added.

⁹⁶ See note 88, 983; and noting “that the Commission subscribes fully to the above”.

⁹⁷ The “spiritual and moral heritage” (2nd recital CFR) has already been mentioned. The CFR further mentions the “physical, mental, moral or social development” in the context of the prohibition of child labor and protection of young people at work (Art. 32, para. 2); in the German version “moral” is translated with “sittliche”, whereas the French, Spanish and Italian correspond with the English one. Last but not least, Art. 165, para. 2 TFEU refers to the

According to the ECJ, morality has a cultural, a regional and a temporal component. While morality changes over the years (evolutionary character),⁹⁸ it is different from country to country (“in its territory”) and is based on certain values (“in accordance with its own scale of values”). That is why the ECJ, in a way of judicial self-restraint, has accepted the Member State’s competence in determining their understanding of morality. This morality (as mentioned in Art. 36 TFEU), is a *public* one, so in a way collective and in this context defined by public authorities, not by individuals.

Member States’ competence to determine their understanding of public morality is only limited, yet not actively determined. First, it is limited, if it proves to be a form of double moral or discrimination⁹⁹; or, second, if the national law (or administrative practice) is incoherent. The ECJ’s approach in this context can be qualified as balanced, or as achieving an Aristotelian golden mean.¹⁰⁰

The reaction of some Member States in the wake of this generally expanding – but still balanced – approach of the ECJ can be qualified as an “umbrella philosophy”, trying to establish a “principle of non-interference” of EU law with their nationally determined morality. In this field of negative integration¹⁰¹ (application of EU fundamental freedoms by the ECJ), only a negative (defending) way of dealing with morality (not even with ethics) can be observed.

Accordingly, the next chapter will focus on positive integration (harmonization of national law by means of EU legislation) mainly addressing individuals. I will analyse, in which context (sectors) and in which directives and regulations the terms of ethics and morality occur. Furthermore, I will focus on the question if at all, and to what degree, the content of the relevant concept of ethics or morality can be determined in a “clear and pre-

“physical and moral integrity of sportsmen and sportswomen”; in the German version “moral” is translated with “seelisch” (so rather referring to the soul), whereas the French, Spanish and Italian, again, correspond with the English one. In the latter situation, the EU can take action against doping; see e.g. ECJ Case C-519/04 P EU:C:2006:492 margin number 43 – *Mecca-Medina and Majcen v. Commission*, referring to “ethical values in sport”.

⁹⁸ See VI.4.

⁹⁹ ECJ Case C-542/09 EU:C:2012:346 margin number 41 – *Commission v. Netherlands*, (“according to settled case-law, discrimination can arise only through the application of different rules to comparable situations or the application of the same rule to different situations”).

¹⁰⁰ *Ch. Megone*, Aristotelian Ethics, in: R. Chadwick, *The Encyclopedia of Applied Ethics*, 2012, 189 et seq., 197 (“The virtuous state of character lies in a mean relative to us”).

¹⁰¹ According to *C. Baudenbacher/F. Bremer*, *European State Aid and Merger Control in the Financial Crisis*, *Journal of European Competition Law & Practice* 1 (2010), 267, “[t]his distinction was first made by the Dutch economist Jan Tinbergen”.

dictable” manner, so providing a positive and not only a negative (non-interference) understanding.

V. Individuals as Addressees

Other than in the examples identified so far, where we have seen that only the term (public) moral(ity) has been exerted, in the following chapter it is mainly the term ethic(al) that occurs.

1. The Consequences of Unethical Practice and Behaviour (Continued)

In the introduction we have already seen some examples of those practical consequences (no funding, stringent ethics review, no patient mobility), arising in cases of unethical practice and behaviour.

One very important ethical obligation arising in the field of bioethics is the issue of good clinical practice, which is defined as “a set of internationally recognised ethical and scientific quality requirements which must be observed for designing, conducting, recording and reporting clinical trials that involve the participation of human subjects”.¹⁰² Clinical trials have to be “scientifically sound and guided by ethical principles in all their aspects”.¹⁰³ Furthermore in the field of medical devices, a favourable opinion of the relevant ethics committee can be required.¹⁰⁴

¹⁰² Art. 1, para. 2 Directive 2001/20/EC on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Relating to the Implementation of Good Clinical Practice in the Conduct of Clinical Trials on Medicinal Products for Human Use, O.J. 2001, L 121/34; will be repealed by Regulation 536/2014/EU on Clinical Trials on Medicinal Products for Human Use [etc.], Art. 4 (*et passim*), O.J. 2014, L 158/1 (the new definition of “good clinical practice” can be found in Art. 2, para. 2 subpara. 30).

¹⁰³ Art. 2, para. 3 Commission Directive 2005/28/EC Laying Down Principles and Detailed Guidelines for Good Clinical Practice as Regards Investigational Medicinal Products for Human Use, as well as the Requirements for Authorization of the Manufacturing or Importation of Such Products, O.J. 2005, L 91/13. See also *V. Stühlinger/M. Hackel*, Research Ethics Committees in the Field of Health-Related Human Research, *European Journal of Health Law* 21 (2014), 387.

¹⁰⁴ Art. 15 (*et passim*) Directive 93/42/EEC Concerning Medical Devices, O.J. 1993, L 169/1, as amended by O.J. 2007, L 247/21. See also Art. 10, para. 2 subpara. 2 Council Directive 90/385/EEC on the Approximation of the Laws of the Member States Relating to Active Implantable Medical Devices, O.J. 1990, L 189/17; as amended by O.J. 2007, L 247/21; repeal proposed by COM (2012) 542 final 26.9.2012.

Not only in the strict medical field, but also in a broader health related field, ethics can create obligations, so for example in case of food labelling, where labelling requirements can refer to situations “where a food may give rise to ethical or religious concerns”.¹⁰⁵

In the context of the already mentioned Horizon 2020 program, we find an interesting consequence which, first, does not result in an obligation, but a kind of veto right for the Commission, and which, second, has an external¹⁰⁶ perspective; according to this provision:¹⁰⁷

“The grant agreement may provide that the Commission or the relevant funding body may *object* to transfers of ownership or to grants of an exclusive licence to third parties established in a *third country not associated* with Horizon 2020, if it considers that the grant or transfer is not in accordance with the interests of developing the competitiveness of the Union economy, or is *inconsistent with ethical principles* or security considerations”.

Although legally not binding, according to the European Charter for Researchers, researchers should not only “adhere to the recognised *ethical practices* and *fundamental ethical principles*”, but also “need to be aware that they are accountable [on] ethical grounds, towards society as a whole”.¹⁰⁸

¹⁰⁵ Art. 13, para. 2 (b) Regulation 1829/2003/EC on Genetically Modified Food and Feed, O.J. 2003, L 268/1; as amended by O.J. 2008, L 97/64; amendment proposed by COM (2013) 265 final 6.5.2013.

¹⁰⁶ Art. 4, para. 3, Art. 8, para. 4, 22nd recital Council Directive 2009/50/EC on the Conditions of Entry and Residence of Third-country Nationals for the Purposes of Highly Qualified Employment, O.J. 2009, L 155/17, entails an external *paternalistic* perspective, as in order to guarantee ethical recruitment policies, Member States should not issue “blue cards” in order to avoid a brain-drain in developing countries, especially in the health sector.

¹⁰⁷ Art. 44, para. 3 Regulation 1290/2013/EU (note 9) (emphases added). For a similar provision see also Art. 7, para. 2 Regulation No 1314/2013/Euratom on the Research and Training Programme of the European Atomic Energy Community (2014-2018) Complementing the Horizon 2020 Framework Programme for Research and Innovation, O.J. 2013, L 347/948. Other examples make sure that research carried out outside the Union is equally ethical: Art. 14, para. 1 Regulation 1290/2013/EU (note 9); Art. 8, para. 3 (ib) and Annex I, 8th recital Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use, O.J. 2001, L 311/67, as amended by O.J. 2012, L 299/1; Annex I, 2b (*et passim*) Decision 556/2014/EU on the Participation of the Union in a Second European and Developing Countries Clinical Trials Partnership Programme (EDCTP2) Jointly Undertaken by Several Member States, O.J. 2014, L 169/38.

¹⁰⁸ Annex Commission Recommendation 2005/251/EC on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers, O.J. 2005, L 75/67 (emphases added).

At last, although stepping into a very specific field (fisheries),¹⁰⁹ so called end-users¹¹⁰ are “responsible for correct and appropriate use of the data with regard to scientific ethics”.¹¹¹

Thus, as we can see, unethical practice or behaviour can have important consequences and this raises the question: What has to be understood by ethics? Before we proceed to this question and how the content of this term is determined, we can also identify, similarly to what we have seen above,¹¹² a category where ethics is primarily used to serve as a national protection shield of non-interference.

2. Category of Non-Interference

One noteworthy example of such a protection shield can be found in Horizon 2020 concerning embryonic stem cells. As we have seen in the introduction, the use of human stem cells is “subject to stringent ethics review”; this provision continues by stating that “[n]o project involving the use of human embryonic stem cells should be funded that does not obtain the necessary approvals from the Member States”.¹¹³ Also in the context of Horizon 2020, ethics is attributed to the national level, when participants have to “comply with national legislation, regulations and ethical rules in the countries where the action will be carried out”.¹¹⁴

A similar provision can be found in the directive on in vitro diagnostic medical devices, which – apart from referring to the Biomedicine Conven-

¹⁰⁹ Council Regulation 199/2008/EU Concerning the Establishment of a Community Framework for the Collection, Management and Use of Data in the Fisheries Sector and Support for Scientific Advice Regarding the Common Fisheries Policy, O.J. 2008, L 60/1.

¹¹⁰ Art. 2 (i) Council Regulation 199/2008/EU (note 109), “means bodies with a research or management interest in the scientific analysis of data in the fisheries sector”.

¹¹¹ Art. 22, para. 1 (c) Council Regulation 199/2008/EU (note 109).

¹¹² See IV.

¹¹³ 31st recital (see also Art. 19, para. 4) Regulation 1291/2013/EU (note 8).

¹¹⁴ Art. 23, para. 9 Regulation 1290/2013/EU, (note 9). See also Declaration No 34 on Art. 163 TFEU, O.J. 2007, C 306/261: “The Conference agrees that the Union’s action in the area of research and technological development will pay due respect to the fundamental orientations and choices of the research policies of the Member States”.

tion¹¹⁵ – emphasizes that “national regulations relating to ethics continue to apply”.¹¹⁶

The wording is even stronger in case of genetically modified food and organisms, where reference is made to “the competence [*sic!*] of Member States as regards ethical issues”.¹¹⁷

Another recent example is the already mentioned case of patient mobility. After a long series of cases decided by the ECJ based on the freedom of services, the European legislators finally decided to take control. However, as the definition of a service follows a very broad concept, some Member States feared the application of this directive to sensitive issues “like euthanasia, DNA-testing or IVF”.¹¹⁸ It had not been the Council of Ministers, but the European Parliament, that, at a very early stage of the legislative procedure, proposed amendments making clear that “[n]o provision of this Directive should be interpreted in such a way as to undermine the fundamental ethical choices of Member States”.¹¹⁹ This was strengthened by emphasizing that “[n]otwithstanding those common values it is accepted that Member States take different decisions on ethical grounds as regards the availability of certain treatments and the concrete access conditions [and that this] Directive is without prejudice to ethical diversity”.¹²⁰ The text of the finally adopted directive states that “[n]o provision of this Directive should be interpreted in such a way as to undermine the fundamental ethical choices of Member States”.¹²¹ The question remains, as to whether this principle of non-interference has to be interpreted in a narrow sense, as it requires “fundamental” ethical choices.

¹¹⁵ Council of Europe, Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, C.E.T.S. No. 164.

¹¹⁶ 33rd recital (see also Art. 1, para. 4 and Art. 9, para. 4 subpara. 2) Directive 98/79/EC on In Vitro Diagnostic Medical Devices, O.J. 1998, L 331/1, as amended by O.J. 2011, L 341/50.

¹¹⁷ 42nd recital Regulation 1829/2003/EC (note 105); 57th recital (see also Art. 29, para. 1) Directive 2001/18/EC on the Deliberate Release into the Environment of Genetically Modified Organisms [etc.], O.J. 2001, L 106/1, as amended by O.J. 2015, L 68/1.

¹¹⁸ *W. v. Hoof/G. Pennings*, Extraterritorial Laws for Cross-Border Reproductive Care: The Issue of Legal Diversity, *European Journal of Health Law* 19 (2012), 187, 194.

¹¹⁹ 6th recital European Parliament Legislative Resolution on the Proposal for a Directive of the European Parliament and of the Council on the Application of Patients’ Rights in Cross-border Healthcare, O.J. 2010, C 184 E/368.

¹²⁰ 14th recital European Parliament Legislative Resolution, (note 119); for those values mentioned, see O.J. 2006, C 146/1.

¹²¹ 7th recital Directive 2011/24/EU, (note 10). 53rd recital (see also Art. 11, para. 1 subpara. 3) *leg. cit.*, also states that the principle of “recognition of prescriptions from other Member States should *not affect any professional or ethical duty* that would require pharmacists to refuse to dispense the prescription” (emphasis added).

In the context of the legal protection of biotechnological inventions the TRIPs Agreement foresees the possibility to exclude from patentability inventions, if it is against ordre public or morality.¹²² When making use of this possibility, the directive makes clear that “ordre public and morality correspond in particular to ethical or moral principles recognised in a Member State”.¹²³

Again, before drawing our attention to the question of what are fundamental ethical choices, we have to take one step back and have to see, how (and by whom) the content of those terms of ethics is determined.

3. Determination of Content

An analysis of the examined documents displays that the content can either be determined, by (1.) ethics committees or (2.) codes of conduct, in both cases either at (a.) EU or (b.) national level.¹²⁴ Determination can also take place by (3.) references to other (international) documents. We will then see (4.) a category, where some hints are provided regarding the content or understanding of ethics, and, finally, (5.) a category, where ethics remains undetermined.

(1a.) Starting from a *vertical* perspective at the EU level, it is also possible to identify from a *horizontal* perspective the relevant institution in charge of determining the understanding of ethics. It is neither the Council of Ministers, nor the European Parliament, which is in charge of this task.¹²⁵ In Horizon 2020 it is the Commission¹²⁶ that “shall systematically carry out ethics reviews for proposals raising ethical issues” by verifying “the respect of ethical principles and legislation”.¹²⁷ From a procedural perspective, this “process of the ethics review [has to be] as transparent as possible”.¹²⁸ Fur-

¹²² 36th recital Directive 98/44/EC, (note 31).

¹²³ 39th recital Directive 98/44/EC, (note 31). The linguistic ambiguities in this context (singular vs. plural) have already been mentioned (note 45). 9th recital Directive 2001/18/EC (note 117), also refers to “ethical principles recognised in a Member State”.

¹²⁴ Of course, further determination of ethics can also take place throughout ordinary implementation of directives: e.g. Art. 21, para. 1 Directive 2006/43/EC (note 58).

¹²⁵ Of course, both institutions together (based on a proposal of the Commission) can issue EU Secondary law referring to ethics, as we have already seen. See also VI, 3.

¹²⁶ I will not further elaborate on examples of Comitology, where the Commission takes implementing measures on professional ethics, as for example, in 9th recital, Art. 21, para. 2 Directive 2006/43/EC (note 58), except for referring to international documents; see V, 3., (3).

¹²⁷ Art. 14, para. 1 Regulation 1290/2013/EU (note 9).

¹²⁸ Art. 14, para. 2 Regulation 1290/2013/EU (note 9). See also Art. 18, para. 6 according to which “[t]he *grant agreement* shall, where appropriate, contain provisions ensuring the

ther details implementing this legal requirement can be found on the Commission's webpage, describing the different steps (ethics self-assessment by the applicant, followed by an ethics screening and an ethics assessment by ethics experts).¹²⁹ An institution not mentioned in this "Regulation Horizon 2020 Rules for Participation", is the already mentioned European Group on Ethics in Science and New Technologies (EGE). Also according to the "Regulation Establishment Horizon 2020", the EGE opinions "should [only] be taken into account".¹³⁰

Following the Group of Advisers on the Ethical Implications of Biotechnology (GAEIB) which was created in November 1991, the EGE was established in December 1997.¹³¹ According to its current mandate, EGE is an "independent, pluralist and multidisciplinary" body of 15 members appointed *ad personam* who's task is to "advise the Commission on ethical questions relating to sciences and new technologies, either at the request of the Commission or on its own initiative".¹³² So far,¹³³ EGE has issued 28 (legally non-binding) opinions which, amongst other documents and relevant information, are accessible on its webpage.¹³⁴ Several of these opinions have been taken into account in the EU's legislative process,¹³⁵ although EGE's role has been seen very critically,¹³⁶ also as regards its composition. EGE's 15 members are appointed not by the college of 28 Commissioners,

respect of *ethical principles*, including the establishment of an *independent ethics board* and the right of the Commission to carry out an ethics audit by independent experts" (emphases added).

¹²⁹ For more details see European Commission, Horizon 2020 Online Manual Ethics, <<http://ec.europa.eu>> (accessed 31.3.2015).

¹³⁰ 29th recital Regulation 1291/2013/EU (note 8). Similar in 18th recital Regulation 1314/2013/Euratom (note 107).

¹³¹ For EGE's history and additional details see *A. Plomer*, The European Group on Ethics: Law, Politics and the Limits of Moral Integration in Europe, *E.L.J.* 14 (2008), 839, 841; *M. Tallacchini*, Governing by Values. EU Ethics: Soft Tool, Hard Effects, *Minerva* 47 (2009), 281, 287 et seq.

¹³² Art. 2 and Art. 3, para. 2 Commission Decision 2010/1/EU on the Renewal of the Mandate of the European Group on Ethics in Science and New Technologies, *O.J.* 2010, L 1/8.

¹³³ Valid as of March 2015.

¹³⁴ See note 22.

¹³⁵ E.g. 19th recital Directive 98/44/EC (note 31); 6th recital Commission Recommendation 2008/345/EC (note 9); 28th recital Regulation 1394/2007/EC on Advanced Therapy Medicinal Products [etc.], *O.J.* 2007, L 324/121, as amended by *O.J.* 2010, L 348/1; 33rd recital Directive 2004/23/EC on Setting Standards of Quality and Safety for the Donation, Procurement, Testing, Processing, Preservation, Storage and Distribution of Human Tissues and Cells, *O.J.* 2004, L 102/48, as amended by *O.J.* 2009, L 188/14.

¹³⁶ *A. Plomer* (note 131).

but by the president of the Commission only.¹³⁷ Based on this mandate¹³⁸ and the current decision of appointment¹³⁹ the present 15 members will serve until January 2016.

Notwithstanding this criticism, there are several legislative documents referring to EGE in different ways. One year after its establishment in 1997, Directive 98/44/EC on biotechnological inventions, provided that EGE “evaluates all [*sic!*] ethical aspects of biotechnology”.¹⁴⁰

In the field of Genetically Modified Organisms (GMOs), Directive 2001/18/EC on the deliberate release into the environment of GMOs ruled that “the Commission *shall*, on its own initiative or at the request of the European Parliament or the Council, *consult any committee* it has created with a view to obtaining its advice on the ethical implications of biotechnology, *such as* [EGE]”.¹⁴¹ Such consultation has to be “conducted under clear rules of openness, transparency and public accessibility”¹⁴² and “with a view to obtaining advice on ethical issues of a general nature regarding the deliberate release or placing on the market of GMOs”.¹⁴³ Always keeping in mind the fact that EGEs opinions are not legally binding, the wording in Regulation 1829/2003/EC on genetically modified food and feed is alleviated, as the “Commission, on its own initiative or at the request of a Member State, *may* consult [EGE] or any other appropriate body”.¹⁴⁴ Not as regards to the procedure (consultation), but to the output, it was provided that the opinions have to be made “available to the public”.¹⁴⁵

(1b.) Continuing this vertical perspective, we can also find references to ethics committees referring to the *national* level. As mentioned above, several documents emphasize the “competence of Member States as regards ethical issues”,¹⁴⁶ so it is not surprising that after referring to EGE, Directive 2001/18/EC (deliberate release of GMO) emphasizes that “Member States should [also] be *able* to consult *any committee they have established* with a view to obtaining advice on the ethical implications of biotechnolo-

¹³⁷ Art. 3, para. 1 Commission Decision 2010/1/EU (note 132).

¹³⁸ Art. 6 and Art. 1 Commission Decision 2010/1/EU (note 132).

¹³⁹ Decision 2011/115/EU of the President of the European Commission on the Appointment of the Members of the European Group on Ethics in Science and New Technologies for its Fourth Mandate, O.J. 2011, C 12/9.

¹⁴⁰ 44th recital and Art. 7 Directive 98/44/EC (note 31).

¹⁴¹ Art. 29, para. 1 Directive 2001/18/EC (note 117) (emphases added).

¹⁴² Art. 29, para. 2 Directive 2001/18/EC (note 117).

¹⁴³ 57th recital Directive 2001/18/EC (note 117).

¹⁴⁴ Art. 33, para. 1 Regulation 1829/2003/EC (note 105).

¹⁴⁵ Art. 33, para. 2 Regulation 1829/2003/EC (note 105).

¹⁴⁶ 57th recital Directive 2001/18/EC (note 117).

gy”.¹⁴⁷ The same is true for clinical trials, where Regulation 536/2014/EU emphasizes that “[i]t should be *left to the Member State* concerned to *determine the appropriate body or bodies* to be involved in the assessment of the application to conduct a clinical trial and *to organise the involvement of ethics committees* within the timelines for the authorisation of that clinical trial”.¹⁴⁸

The term ethics committee is defined as “an *independent* body established in a Member State in accordance with the law of that *Member State* and empowered to give *opinions* for the purposes of this Regulation, taking into account the views of laypersons, in particular patients or patients’ organisations”.¹⁴⁹ As Regulation 536/2014/EU is going to replace Directive 2001/20/EC,¹⁵⁰ it is interesting to see the changes with regard to ethics committees, one difference being the definition of an ethics committee. The new definition is more general, that is less detailed, (“give opinions for the purposes of this Regulation”), and does not provide requirements for the members, as the directive¹⁵¹ did previously (“consisting of healthcare professionals and non-medical members”). At least the new regulation provides that “the views of laypersons, in particular patients or patients’ organisations”¹⁵² have to be taken into account.

As already mentioned, a favourable opinion of the relevant ethics committee can also be required in the field of medical devices, before manufacturers are allowed to commence certain clinical investigations.¹⁵³ Evaluation by and consultation with national or local ethics committees is also foreseen for nanosciences and nanotechnologies research,¹⁵⁴ or in the case of ionizing radiation.¹⁵⁵

So far, we have seen examples of specific ethics committees. In the field of advanced therapy medicinal products, the relevant regulation does not pro-

¹⁴⁷ 58th recital Directive 2001/18/EC (note 117) emphases added).

¹⁴⁸ 18th recital (emphases added).

¹⁴⁹ Art. 2, para. 2 subpara. 11 Regulation 536/2014/EU (note 102); see also Art. 4, Art. 44, para. 3, *et passim*.

¹⁵⁰ Art. 2 (k) Directive 2001/20/EC (note 102), “responsibility [...] to protect the rights, safety and wellbeing of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, expressing an opinion”.

¹⁵¹ For further details see also 6th recital and Art. 6 Commission Directive 2005/28/EC (note 103).

¹⁵² See also 18th recital Regulation 536/2014/EU (note 102), for further details.

¹⁵³ Directive 93/42/EEC (note 104); Council Directive 90/385/EEC (note 104).

¹⁵⁴ Annex, 4.1.7 and 4.1.9 Commission Recommendation 2008/345/EC (note 9).

¹⁵⁵ Art. 55, para. 2 (e) Council Directive 2013/59/Euratom Laying Down Basic Safety Standards for Protection against the Dangers Arising from Exposure to Ionising Radiation [etc.], O.J. 2014, L 13/1.

vide for a specific ethics committee. Nonetheless, ethics is (only) one of the competences to be covered in the composition of the “Committee for Advanced Therapies”.¹⁵⁶

A combined approach of both EU (the role of the European Commission has already been described) and national ethical scrutiny can be found in Horizon 2020, where participants are not only obliged to “comply with *national* legislation, regulations and *ethical rules* in the countries where the action will be carried out”, but also “[w]here *appropriate*, [to] seek the *approval* of the *relevant national or local ethics committees* prior to the start of the action”.¹⁵⁷

Hence, as we have seen, ethics committees can not only issue opinions on request or on their own initiative (for example, EGE), but can also play a decisive role in authorization procedures, not only for research grants, but also for manufacturing processes.

One task of ethics committees can also be to issue codes of conduct. Codes of conduct have the clear advantage that they are more detailed than just a general reference to ethical standards.

(2a.) At EU level¹⁵⁸ we find the already mentioned “Code of Conduct for responsible nanosciences and nanotechnologies research” which, however, is not exclusively¹⁵⁹ on ethics. “This Recommendation provides Member States with an instrument to undertake further initiatives to ensure safe, ethical and sustainable nanosciences and nanotechnologies research in the European Union”.¹⁶⁰ So, ethics is only part of the general principles mentioned therein.

Again at EU level, we find another (non-binding) recommendation, the already mentioned European Charter for Researchers, which, apart from referring to recognized ethical principles and so forth, also requires researchers to “adhere to [...] ethical standards as documented in the different *national, sectoral or institutional codes of ethics*”¹⁶¹. It therefore does not create a code of conduct, but just refers to existing ones, also at *national* level.

¹⁵⁶ 11th recital and Art. 21, para. 2 Regulation 1394/2007/EC (note 135).

¹⁵⁷ Art. 23, para. 9 Regulation 1290/2013/EU (note 9) (emphases added).

¹⁵⁸ For some examples of institutional codes of conduct at EU level see III.

¹⁵⁹ In Annex, 3.1 Council Decision 2008/210/EC (note 52), we find reference to a “code of ethics for the prisons system”.

¹⁶⁰ 13th recital Commission Recommendation 2008/345/EC (note 9).

¹⁶¹ Annex section 1 Commission Recommendation 2005/251/EC (note 108) (emphases added). Cf. also Annex Commission Recommendation 77/534/EEC (note 47), “The code’s objective is to establish standards of ethical behaviour on a Community-wide basis [...]”

(2b.) After those two examples of non-binding recommendations, we also find an *obligation* for the Member States regarding the transposition of EU directive against child pornography, according to which Member States have to undertake preventive action “such as the drawing up and reinforcement of a *code of conduct* and self-regulatory mechanisms in the tourism industry, the setting-up of a *code of ethics*” and so forth.¹⁶² Although the transposition of the directive into national law is binding in itself, the Member States enjoy thus some flexibility as regards the form and methods of achieving this goal.

In the case of the EU services directive, we find a provision which encourages “the setting up of codes of conduct, in particular, by professional bodies, organisations and associations at Community level”. Similar to the case of the example of nanosciences, this code of conduct is also not only about (professional) ethics.¹⁶³

(3.) Accordingly, after ethics committees and codes of conduct, determining the content of ethics, we proceed to another category, which comprises references to other international documents.

In the field of good clinical practice and medical devices, reference is made to the “Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects”, adopted by the World Medical Association.¹⁶⁴ Although the references vary in wording (“as for instance reflected in [...]”;¹⁶⁵ “[c]linical trials shall be conducted in accordance with [...]”;¹⁶⁶ “[c]linical investigations shall be made in accordance with [...]” and it is “mandatory that all measures relating to the protection of human subjects are carried out in the spirit of [...]”;¹⁶⁷ “in accordance with the ethical principles that are reflected, for example, in [...]”)¹⁶⁸ this Helsinki Declaration has the advantage not only of having been elaborated at a “worldwide” basis, but also of providing relatively detailed rules as regards to ethical behaviour. Of course it has to be acknowledged that EU law can only refer to

¹⁶² 33rd recital Directive 2011/92/EU on Combating the Sexual Abuse and Sexual Exploitation of Children and Child Pornography [etc.], O.J. 2011, L 335/1 (emphases added).

¹⁶³ 114th recital Directive 2006/123/EC (note 58). The 113th recital is also about ethics, however in this case those codes of conduct (drawn up by “interested parties” at EU level) are only mentioned insofar as they have to be “compatible with legally binding rules governing professional ethics and conduct in the Member States”.

¹⁶⁴ World Medical Association, WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects, <<http://www.wma.net>> (accessed 31.3.2015).

¹⁶⁵ 2nd recital Directive 2001/20/EC (note 102).

¹⁶⁶ Art. 3, para. 2 Commission Directive 2005/28/EC (note 103).

¹⁶⁷ Annex 7, 2.2 Council Directive 90/385/EEC (note 104); also Annex X, 2.2 Directive 93/42/EEC (note 104).

¹⁶⁸ Annex I, 8th recital Directive 2001/83/EC (note 107).

such detailed guidelines if they exist and have been elaborated by an acknowledged body in the relevant field.

One example already mentioned also falls into this category, namely, the directive on in vitro diagnostic medical devices, which for ethical issues with regard to “the removal, collection and use of tissues, cells and substances of human origin”, refers to the Council of Europe’s Biomedicine Convention.¹⁶⁹

It is also worth mentioning the example of the directive on statutory audits, which requires adherence to “highest ethical standards”.¹⁷⁰ In this context, it’s the Commission’s task to “adopt implementing measures on professional ethics as minimum standards [and when] doing so, it *might consider* the *principles* contained in the International Federation of Accountants (IFAC) Code of Ethics”.¹⁷¹ So, the Commission is invited to take this international code into account.

Last but not least, there is also one example, where in the context of biocidal products reference is made to “internationally accepted ethical standards”, without further guidance of how these standards are defined.¹⁷²

(4.) Apart from ethics committees, codes of conduct and references to international documents, we can also cluster one category, where EU law¹⁷³ itself provides some information *ex ante* as to what is seen as ethical.¹⁷⁴

In the context of placing of proprietary medicinal products on the market, we find an example of a clear statement as to what is seen as unethical and what should be the consequences: “[S]ince a full placebo comparison will not often be feasible or ethically acceptable in convulsive epilepsy, it is important in the later phases of evaluation to carry out controlled (randomized) clinical trials [...]”.¹⁷⁵ Also in the field of medicinal products for human use we find some thoughts on the treatment of control groups against the background of ethical considerations: “Thus it may, in some instances, be more pertinent to compare the efficacy of a new medicinal product with

¹⁶⁹ See note 115. Art. 1, para. 4 Directive 98/79/EC (note 116).

¹⁷⁰ 9th recital Directive 2006/43/EC (note 58).

¹⁷¹ 9th recital Directive 2006/43/EC (note 58).

¹⁷² Annex IV, 1.1.3 Regulation 528/2012/EU Concerning the Making Available on the Market and Use of Biocidal Products, O.J. 2012, L 167/1, as amended by O.J. 2014, L 103/22.

¹⁷³ There are also examples, where EU Secondary law just refers to another of its kind, mainly to Directive 2001/20/EC (note 102); that is the case for the following examples: Art. 8, para. 3 (ib) and Annex I, 8th recital Directive 2001/83/EC (note 107); 16th recital Regulation 1394/2007/EC (note 135).

¹⁷⁴ For one example (Regulation 440/2008/EC) already described in respect of language ambiguity (note 50).

¹⁷⁵ Annex IX, 6 Council Recommendation 87/176/EEC Concerning Tests Relating to the Placing on the Market of Proprietary Medicinal Products, O.J. 1987, L 73/1.

that of an established medicinal product of proven therapeutic value rather than with the effect of a placebo”.¹⁷⁶ The same directive also exempts applicants from certain documentation if “it would be contrary to generally accepted principles of medical ethics to collect such information”.¹⁷⁷

In Horizon 2020 actions falling within the scope of “Regulation Horizon 2020 Rules for Participation” should “be in conformity [...] with ethical principles, which include avoiding any breach of research integrity”.¹⁷⁸ In addition, Art. 19 (entitled “Ethical principles”) of “Regulation Establishment Horizon 2020”, after stipulating that “[a]ll the research and innovation activities carried out under Horizon 2020 shall comply with ethical principles [and human rights]”, excludes the following fields of research from funding: Human cloning for reproductive purposes, modification of the genetic heritage of human beings and “research activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer”.¹⁷⁹ This can be seen as a European consensus with regard to bioethics, although one could argue that this provision is “only” about funding and not about the legality of these activities.

Although this paper is based on a broad understanding of bioethics, the examples mentioned so far always referred to humans. Nonetheless, there are also examples where the beneficiaries of ethical or moral principles are not humans, but animals, plants or the environment.¹⁸⁰ Especially animals are protected by ethical principles in different fields.

Bearing some resemblance to human dignity,¹⁸¹ the directive on the protection of animals used for scientific purposes asserts that animals “have an *intrinsic* value which must be respected”.¹⁸² As a practical consequence arising from this approach, “animals should always be treated as sentient creatures and their use in procedures should be restricted to areas which may ultimately benefit human or animal health, or the environment”, and their use “for scientific or educational purposes should therefore only be considered where a non-animal alternative is unavailable”.¹⁸³ This directive pro-

¹⁷⁶ Annex I, Part I, 5.2.5.1 Directive 2001/83/EC (note 107).

¹⁷⁷ Annex I, Part II, 6 Directive 2001/83/EC (note 107).

¹⁷⁸ 9th recital Regulation 1290/2013/EU (note 9).

¹⁷⁹ Art. 19, para. 3 Regulation 1291/2013/EU (note 8).

¹⁸⁰ Annex, 3.2 Commission Recommendation 2008/345/EC (note 9) (“not harm or create a biological, physical or moral threat to people, animals, plants or the environment, at present or in the future”).

¹⁸¹ See VI., 2.

¹⁸² 12th recital Directive 2010/63/EU (note 32) (emphasis added); and further refers to “the ethical concerns of the general public as regards the use of animals in procedures”.

¹⁸³ 12th recital Directive 2010/63/EU (note 32).

vides even more detailed statements with respect to the practical consequences of the intrinsic value of animals, as there are restrictions for the use of non-human primates.¹⁸⁴ Due to ethical considerations the directive also sets a maximum threshold of permissible pain and therefore prohibits “the performance of procedures that result in severe pain, suffering or distress, which is likely to be long-lasting and cannot be ameliorated”.¹⁸⁵

Apart from this directive, ethical considerations concerning animals are also the reason why mass slaughtering has been declared as being, amongst other things, “ethically questionable”,¹⁸⁶ or, why in certain circumstances there can even be an “ethical duty to kill productive animals”.¹⁸⁷

After a mere declaration annexed to the Maastricht Treaty¹⁸⁸ and a protocol annexed to the Amsterdam Treaty,¹⁸⁹ Art. 13 TFEU now entails a horizontal clause according to which both the EU and the Member States shall “pay full regard to the welfare requirements of animals”, because animals are “sentient beings”.¹⁹⁰ In Horizon 2020, this Art. 13 TFEU is addressed in the context of respect for “fundamental ethical principles” with the practical consequence that “the use of animals in research and testing should be reduced, with a view ultimately to replacing their use”.¹⁹¹

Leaving the field of bioethics, the already mentioned directive on statutory audits provides another example pertaining to this category where some understandings of the practical consequences of ethics are provided. After stating that statutory auditors should adhere to “the highest ethical stand-

¹⁸⁴ 17th recital Directive 2010/63/EU (note 32): “Due to their *genetic proximity* to human beings and to their *highly developed social skills*, the use of non-human primates in scientific procedures raises *specific ethical* and practical *problems* in terms of meeting their behavioural, environmental and social needs in a laboratory environment”. (emphases added).

¹⁸⁵ 23rd recital Directive 2010/63/EU (note 32). All those ethical considerations have to be taken into account for project evaluation (38th recital; Art. 38, para. 2 [d]).

¹⁸⁶ Para. 18 Court of Auditors, Special Report No 1/2000 on Classical Swine Fever, Together With the Commission’s Replies, O.J. 2000, C 85/1: “mass slaughtering is expensive, ethically questionable, wasteful of food resources and may destroy genetically valuable animals”.

¹⁸⁷ 12th recital Council Regulation 1099/2009/EC on the Protection of Animals at the Time of Killing, O.J. 2009, L 303/1, amendment proposed by COM (2013) 265 final 6.5.2013.

¹⁸⁸ O.J. 1992, C 191/103.

¹⁸⁹ O.J. 1997, C 340/110.

¹⁹⁰ As protocols also pertain to EU Primary law, the transfer from protocol to Treaty provision had more of a symbolic than a legal significance. Neither the declaration nor the protocol had entailed this rationale that animals are sentient beings.

¹⁹¹ 29th recital Regulation 1291/2013/EU (note 8). Similar in 18th recital Regulation 1314/2013/Euratom (note 107). Animal welfare “and other ethical issues” are also addressed in Annex I, Part III, 2.2.3 Council Decision 2013/743/EU Establishing the Specific Programme Implementing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) [etc.], O.J. 2013, L 347/965.

ards”, provides that they should be “subject to professional ethics, covering at least their public-interest function, their integrity and objectivity and their professional competence and due care”;¹⁹² further details have to be implemented by the Member States.¹⁹³

Last but not least, it is worth mentioning one example, where ethics is not determined by the EU, Member States and so forth on a collective basis, but by a single business entity. According to the Regulation on European social entrepreneurship funds, so called “[q]ualifying social entrepreneurship funds should invest in a manner consistent with *their* ethical investment strategy, for instance they should not undertake investments that finance the weapons industry, that risk breaches of human rights or that entail electronic waste-dumping”.¹⁹⁴

(5.) After having seen determination by ethics committees, codes of conduct, references to international documents and further information provided by EU law itself, we finally arrive at the last category, that is, EU law, where ethics remains *undetermined*.

Although this example has already been mentioned in the category of non-interference, if patients do not have a right to cross-border healthcare because the directive (codifying ECJ case-law on that issue) shall not “undermine the fundamental ethical choices of Member States”,¹⁹⁵ we could be satisfied because it is up to the Member States to determine their understanding of fundamentally unethical forms of treatment. However, this undetermined provision can have a significant impact on patients seeking cross-border healthcare.

Having mentioned this impact related argument, some of the following examples could be seen as being less of a problem. However, contrary to the previous example referring to the relevant entity to determine ethics in this regard (that is the Member States), the following examples provide no information whatsoever¹⁹⁶ on the understanding behind the term of ethics used in those documents, of both a binding and non-binding nature.

One example of a binding nature is about food law, where it has been acknowledged that scientific risk assessment alone might not provide all

¹⁹² 9th recital Directive 2006/43/EC (note 58).

¹⁹³ See note 124.

¹⁹⁴ 21st recital Regulation 346/2013/EU on European Social Entrepreneurship Funds, O.J. 2013, L 115/18.

¹⁹⁵ 7th recital Directive 2011/24/EU (note 10).

¹⁹⁶ For another recent example see: Annex IV, Commission Regulation (EU) 2015/445 Amending Regulation (EU) No 1178/2011 as regards Technical Requirements and Administrative Procedures Related to Civil Aviation Aircrew, O.J. 2015, L 74/1, just referring to “relevant ethical principles”.

necessary information for, but where also “societal, economic, traditional, ethical and environmental factors” have to be considered.¹⁹⁷ The reference to ethics might be very general (one factor amongst others to be taken into account), but does not mitigate the fact that the concept of ethics remains undetermined.

Another example refers to the European Council,¹⁹⁸ which expressed in its Stockholm presidency conclusions from 2001 the need to “strengthen the European biotechnology sector’s competitiveness”, while ensuring that this is “consistent with common fundamental values and ethical principles”.¹⁹⁹ Some could take the view that there is no need for a (purely) political document to provide detailed statements, nonetheless also in this case we lack further guidance as to the understanding of ethics.

The Council (of Ministers) resolution concerning fundamental health-policy choices is another example of a non-binding document, taking “only” note of some topics, “which warrant joint consideration”, such as “revision of medical studies syllabuses in order to incorporate the relevant economic, legal, *ethical* and social aspects necessary to ensure that practitioners dispense adequate health care”.²⁰⁰ Although there is no further information on what constitutes an ethical syllabus, the Member States’ competence²⁰¹ for both education and health might be the legally-based reason why this philosophical term should be defined by the Member States.

The same thought can hold true for other health related (non-binding) documents in the context of cancer screening²⁰² and hereditary illnesses²⁰³ on the one side, and for lifelong learning²⁰⁴ on the other.

Within the shared competence of the internal market,²⁰⁵ we find one example of a task in the public interest, which is about “doctors or veterinary

¹⁹⁷ 19th recital Regulation 178/2002/EC Laying Down the General Principles and Requirements of Food Law, Establishing the European Food Safety Authority and Laying Down Procedures in Matters of Food Safety, O.J. 2002, L 31/1, as amended by O.J. 2014, L 189/1.

¹⁹⁸ Art. 15 TEU.

¹⁹⁹ Part I, VI., 44 Presidency Conclusions, Stockholm European Council (23./24.3.2001).

²⁰⁰ Resolution of the Council [etc.] Concerning Fundamental Health-Policy Choices, O.J. 1991, C 304/5 (emphasis added).

²⁰¹ Art. 6 (a) and (e) TFEU.

²⁰² 10th and 23rd recitals Council Recommendation on Cancer Screening, O.J. 2003, L 327/34.

²⁰³ 5th recital Conclusions of the Council [etc.] on Hereditary Illnesses, O.J. 1992, C 148/3.

²⁰⁴ Annex (*passim*) Recommendation of the European Parliament and of the Council 2006/962/EC on Key Competences for Lifelong Learning, O.J. 2006, L 394/10.

²⁰⁵ Art. 4, para. 2 (a) TFEU.

bodies ensuring that their members conform to ethical or sanitary rules”.²⁰⁶ This example adds up to our list of undetermined references to ethics, where a possible solution could be to see those bodies in charge of defining those ethical rules.

Another (last) economic example derives from the financial crisis, where the Commission’s banking communication refers several times to “moral hazard”.²⁰⁷ Moral hazard is addressed in the context of burden-sharing in the following way:²⁰⁸

“The Crisis Communications clearly spell out that even during the crisis the general principles of State aid control remain applicable. In particular, *in order to limit distortions of competition* between banks and across Member States in the single market *and address moral hazard*, aid should be limited to the minimum necessary [...]. State support should be granted on terms which represent an *adequate burden-sharing* by those who invested in the bank.”

This last example of an undetermined reference is different. First, it is not about ethical principles, neither is it about public morality nor morality alone, but it is about moral hazard. Moral hazard in this context is furthermore not used in a way to attach concrete consequences to a certain behaviour; it can rather be seen as the “moral” justification why burden-sharing is a key concept in this reaction to supporting banks in the wake of the financial crisis. Most likely this undetermined term does not refer to EU, national, international or business determined understanding, but most likely to microeconomics, where moral hazard is defined by *Pindyck* and *Rubinfeld* in the following way: “[I]n general, *moral hazard* occurs when a party whose actions are unobserved affects the probability or magnitude of a payment.”²⁰⁹

They refer to moral hazard in situations of insurances (undue behaviour of the insured leading to a financial disadvantage for the insurance), or “job shirking”, both in situations where the (immoral) behaviour cannot be monitored.²¹⁰

²⁰⁶ Annex, 6 II, Commission Recommendation on Data Protection Guidelines for the Internal Market Information System (IMI), O.J. 2009, L 100/12.

²⁰⁷ Paras. 15, 40, 77 and 84 Communication from the Commission on the Application of State Aid Rules to Support Measures in Favour of Banks in the Context of the Financial Crisis (“Banking Communication”), O.J. 2013, C 216/1. In this context, see e.g. O.J. 2015, L 80, 1 and 49.

²⁰⁸ Para. 15 Communication from the Commission on the Application of State Aid Rules (note 207), (emphases added).

²⁰⁹ *R. Pindyck/D. Rubinfeld*, Microeconomics, 2013, 643.

²¹⁰ *R. Pindyck/D. Rubinfeld* (note 209), 628 et seq.

This concept could also be explained by referring to a situation caused by the immoral behaviour of a single body that is dangerous for a bigger group (society). Although there is a (micro)economic definition, it describes the situation but does not shed much light on which behaviour would be seen as moral or not. Whilst most people would agree to qualify the risky behaviour of certain banks to the detriment of taxpayers (whereas bonuses would still be paid, maybe also with the help of those taxpayers’ subsidies) as immoral,²¹¹ we still lack further clarity as to morality as such.

4. Analysis

Summing up the relationship of law and ethics can take place in different constellations.

It causes no major challenges if, firstly, a legal provision “only” refers to ethical (or moral) considerations as a *supporting argument*, why a certain legal solution has been chosen.²¹² In the context of language ambiguities (ethical vs. moral), we have already seen the example of Directive 2009/30/EC on gas emission which states that consumers “find it morally unacceptable that their increased use of biofuels could have the effect of destroying biodiverse lands”.²¹³ There are also examples that refer to ethical or moral concerns not of a specific group (for example, consumers), but in a broader way to concerns of the “general public”,²¹⁴ and other examples²¹⁵ that just refer to ethics without mentioning a certain group.

In a second category in this relationship we can identify coexistence of law and ethics (that is a parallel system), with Directive 98/44/EC on biotechnological inventions stating that “substantive patent law *cannot serve to replace* or render superfluous [...] compliance with certain ethical standards”²¹⁶ and that “ethical or moral principles *supplement* the standard legal examinations under patent law”.²¹⁷ Also the already mentioned Stockholm

²¹¹ For a good description see *M. Sandel*, Justice. What’s The Right Thing To Do?, 2010, 12 et seq.

²¹² Cf. also *M. Tallacchini* (note 131), 296 et seq.

²¹³ 11th recital Directive 2009/30/EC (note 43).

²¹⁴ See note 182.

²¹⁵ See note 51.

²¹⁶ 14th recital Directive 98/44/EC (note 31) (emphases added).

²¹⁷ 39th recital Directive 98/44/EC (note 31) (emphasis added). See also: ECJ Case C-377/98 EU:C:2001:523 margin number 80 – *Netherlands v. Parliament and Council*; Art. 2 (g) Commission Decision 2014/792/EU on the Early Warning System to be used by Authorizing Officers of the Commission and by the Executive Agencies, O.J. 2014, L 329/68.

Presidency Conclusions from 2001 in the context of the general wish of strengthening the European biotechnology sector's competitiveness emphasized the need to ensure "that those developments occur in a manner which is healthy and safe for consumers and the environment, and consistent with common fundamental values and ethical principles and in full compliance with the existing legislative framework".²¹⁸ Hence, also in this political document we can find a coexistence of law and ethics. In the field of transferable securities we find a noteworthy statement of the European Commission concerning the relationship of EU harmonization and ethics:²¹⁹

"In parallel with the work of harmonization by Directives, and without prejudice to this method which is the only one capable of attaining the objective of true European integration, the Commission is of the opinion that it could recommend to the Member States [...] that they should ensure the observation of certain basic principles [...] are already widely recognized in all the countries of Europe, but restating and applying them will help to create a common set of professional ethics in an ever-changing field".

Although the Commission acting as the main institution in charge of initiating new EU legislation (the so called "motor of integration") cannot weaken its competence in this field, it has opted for a parallel approach.

Closely linked to the previous category is a third one of so called *opening clauses* where legal texts refer to ethics or morality and therefore open the legal sphere for the philosophical one.

Theoretically, there would also be a fourth category, namely a clash of ethics and law which could lead to a discussion as it took place between law and justice. According to the *Radbruch* formula, for the sake of legal certainty, in principle "positive law, secured by legislation and power, takes precedence even when its content is unjust and fails to benefit the people, unless the conflict between statute and justice reaches such an intolerable degree that the statute, as 'flawed law', must yield to justice".²²⁰ *Radbruch's* formula was an attempt to challenge intolerable unjust law (for example, of the Nazi regime) by the principle of justice. *Radbruch's* approach has to be seen against the background of legal positivism, whereby law and morality have been strictly separated.²²¹ However, as the objective of this paper is to

²¹⁸ See note 199.

²¹⁹ Point 4 Commission Recommendation 77/534/EEC (note 47).

²²⁰ G. *Radbruch*, Statutory Lawlessness and Supra-Statutory Law (1946). Translated by Bonnie Litschewski Paulson and Stanley L. Paulson, Oxford J. Legal Stud. 26 (2006), 7.

²²¹ H. *Hart*, The Concept of Law, 1994, 268 put it this way "I argue in this book that though there are many different contingent connections between law and morality there are no necessary conceptual connections between the content of law and morality: and hence

depict and analyse the status quo of ethics and morality in EU law, this challenging task can be left aside.

Coming back to the third category, in EU law we do not have a strict separation between law on the one side and ethics and morality on the other, as we have seen many “opening clauses”. Those references in different legal documents to ethics and morality have been filled with life by ethics committees, codes of conduct, references to international documents and further information provided by EU law itself, or rest undetermined. For all of them but especially for the latter one, the question remains as to which understanding of ethics should be applied within the EU and how possible gaps have to be filled.

VI. Not Only Filling a Gap

As a preliminary remark we can identify different *beneficiaries* of the different references to ethics in EU law. The already mentioned Commission’s recommendation on responsible nanosciences and nanotechnologies research states that research activities have to be safe, ethical and sustainable and “should not harm or create a biological, physical or moral threat to people, animals, plants or the environment, at present or in the future”.²²² Thus, in this case we have multiple beneficiaries. We have also already seen examples of references to ethics emphasizing the “intrinsic value” of animals as beneficiaries.²²³ Concerning humans, special groups that have not been mentioned so far, are incapacitated subjects²²⁴ in respect of clinical trials on medicinal products for human use, and children,²²⁵ where specific ethical concerns might arise and should be addressed.

morally iniquitous provisions may be valid as legal rules or principles. One aspect of this separation of law from morality is that there can be legal rights and duties which have no moral justification of force whatever”.

²²² Annex, 3.2 Commission Recommendation 2008/345/EC (note 9).

²²³ See note 182.

²²⁴ Art. 10, para. 2 Regulation 536/2014/EU (note 102).

²²⁵ Annex XIV, 3.2.2 b Council Recommendation 87/176/EEC (note 175); 7th and 9th recitals Council Resolution on Paediatric Medicinal Products, O.J. 2001, C 17/1; Art. 10, para. 1 Regulation 536/2014/EU (note 102).

1. EU Methodology

What do parody and ethics have in common? Well, in both cases EU law uses those terms without providing a definition. Recently, the Court (Grand Chamber) ruled in this case on parody as follows:²²⁶

“It should be noted that, since Directive 2001/29 gives no definition at all of the concept of parody, the meaning and scope of that term must, as the Court has consistently held, be determined [1.] by considering its *usual meaning in everyday language*, while also taking into account [2.] the *context* in which it occurs and [3.] the *purposes* of the rules of which it is part [...]”.

Although the EU legislator could have determined ethics, it has implicitly delegated²²⁷ this task to the ECJ, which has to apply a literal interpretation, a systematic and a teleological one.²²⁸ In addition, those terms used in EU Secondary law have to be interpreted in line with EU Primary law,²²⁹ especially with the EU fundamental rights,²³⁰ while of course respecting the equally authentic status of all language versions.²³¹

Which implications does this involve for ethics? As a preliminary question we have to ask if this term is national or EU wide. In general, the ECJ favours an autonomous interpretation.²³²

The variety of documents entailing the term ethics does not allow for a uniform answer as to whether this term always has to be seen as an autonomous concept of EU law. Although we can also find autonomous and uniform concepts in those fields which can be attributed to the competence of the Member States,²³³ it has already been mentioned that the ECJ applies a judicial self-restraint in such sensitive issues of ethics.²³⁴ For a horizontal, that is cross-sector approach, a systematic and teleological interpretation

²²⁶ ECJ Case C-201/13 EU:C:2014:2132 margin number 19 – *Deckmyn and Vrijheidsfonds* (emphases added).

²²⁷ Of course the Member States are essentially free to correct ECJ case-law by changing Primary law; however, this is not possible for the EU institutions adopting EU Secondary law.

²²⁸ It would go beyond the scope of this paper to provide a comprehensive overview on the issue of interpretation in EU law; for a more detailed overview see: *J. Anweiler, Die Auslegungsmethoden des Gerichtshofs der Europäischen Gemeinschaften*, 1997.

²²⁹ ECJ Case C-137/11 EU:C:2012:593 margin number 46 – *Partena*.

²³⁰ ECJ Case C-305/05 EU:C:2007:383 margin number 28 – *Ordre des barreaux francophones and germanophone*; Advocate General *Trstenjak* Case C-40/11 EU:C:2012:296 margin number 53 – *Iida*.

²³¹ See note 30.

²³² ECJ Case C-287/98 EU:C:2000:468 margin number 43 – *Linster*.

²³³ ECJ Case C-173/09 EU:C:2010:581 margin number 40 – *Elchinov*.

²³⁴ See note 83.

will not be very helpful, as, first, those two ways of interpretation only apply in a sectoral way (that is in the context of the specific relevant legal document). Second, a teleological interpretation will most likely just lead us to the realization, that “good” behaviour should be promoted.²³⁵ In case of very broad terms such as ethics, also the usual meaning in everyday language (that is literal) will not be too useful. What remains is therefore the requirement to interpret Secondary EU law in a manner consistent with primary law, especially with the EU’s fundamental rights.²³⁶

2. Human Rights and Values, Not Religion

There are several documents, especially recent ones in the context of Horizon 2020 and nanotechnologies research that refer both to (fundamental) ethical principles and human rights²³⁷ (and here especially the CFR²³⁸). However, this in itself can only be seen as an indication but not a reason, as to why human rights and the CFR should play a key role in the following argumentation.

In a report on the CFR, requested by former Commission president *Romano Prodi*, EGE has put it this way: “[T]he respect of the *dignity* of the human person is at the *root* of the *ethics* of science and new technologies *as well as* of human rights”.²³⁹ Although this document is not binding, this quotation reflects a key link between these two spheres, the ethical and the legal one. The thesis of this paper, on how to determine ethics, is based on this idea. I therefore argue that in those cases where EU law refers to ethics, the latter has to be understood based on the EU’s values²⁴⁰ and fundamental rights.²⁴¹

²³⁵ For most of the examined documents, a systematic interpretation will not provide enough clarity on the understanding of ethics.

²³⁶ For the issue of different language version, see II.

²³⁷ Annex, 4.1.15 Commission Recommendation 2008/345/EC (note 9); Annex I, Part III, 7.3 and 7.6 Council Decision 2013/743/EU (note 191).

²³⁸ 9th recital Regulation 1290/2013/EU (note 9); Art. 19, para. 1 Regulation 1291/2013/EU (note 8); Art. 10, para. 1 Regulation 1314/2013/Euratom (note 107).

²³⁹ EGE Report on the CFR related to technological innovation, CHARTE 4370/00, 11 (emphases added).

²⁴⁰ In this paper it is not possible to explain all values in depth, so I will concentrate on the key concepts.

²⁴¹ Irrespective of the well-known differences, for this paper, the terms human rights and fundamental rights can be treated synonymously. In some earlier cases (i.e. before Art. 2 TEU), the ECJ had referred to the Member States’ values (note 82). Nevertheless, nowadays and in this context, we need to refer to the EU’s values.

The EU's values are enshrined in Art. 2 TEU:²⁴²

“The Union is founded on the values of respect for *human dignity*, freedom, democracy, equality, the rule of law and respect for *human rights*, including the rights of persons belonging to minorities. These values are common to the Member States in a society in which pluralism, non-discrimination, tolerance, justice, solidarity and equality between women and men prevail”.

The EU's fundamental rights, on the other hand, have been shaped by various documents, the ECJ case-law (also taking into account the jurisprudence of the Strasbourg court), and have finally been codified in the CFR.²⁴³

In the argumentation of this paper, human dignity plays a key role. According to the explanations relating to the CFR, human dignity²⁴⁴ is “not only a fundamental right in itself but constitutes the *real basis* of fundamental rights” and “is part of the *substance* of the rights laid down in this Charter”.²⁴⁵ Apart from being mentioned as one of the EU's values, human dignity plays a key role in the CFR within Title I (Dignity) as the Charter's first article.²⁴⁶

This approach of filling the gaps of a philosophical term (ethics) used in legal texts from a legal perspective could be criticized by arguing that philosophical terms (ethics) should be defined by philosophers, according to philosophical methods. Nevertheless, I am convinced that references in legal texts to ethics and morality have to be seen within the limitation that those philosophical concepts necessarily have to be reflected within the legal order itself;²⁴⁷ in other words, concepts that cannot, in one or another way be traced in the legal order itself (and which therefore are alien to this legal order), consequently cannot come into consideration.

Still, the outcome of both approaches (legal vs. philosophical standpoint) might not be too different, as in literature the understanding of human dignity itself has been traced back to *Kant* and the idea that humans should be

²⁴² Emphases added.

²⁴³ For the current legal situation see: ECJ Opinion 1/13 EU:C:2014:2454 – *accession of the EU to the ECHR*; Editorial comments, *The EU's Accession to the ECHR – a “NO” from the ECJ!*, CML Rev. 52 (2015), 1.

²⁴⁴ For both a historic overview and good analyses see *R. Andorno, Human Dignity and Human Rights*, in: H. t. Have/B. Gordijn, *Handbook of Global Bioethics*, 2014, 45-57; see also the different contributions in: C. McCrudden, *Understanding Human Dignity*, *Proceedings of the British Academy* Vol. 192, 2014.

²⁴⁵ O.J. 2007, C 303/17 (emphases added).

²⁴⁶ “Human dignity is inviolable. It must be respected and protected”; Art. 1 CFR.

²⁴⁷ In this sense e.g. the Austrian Supreme Court (*Oberster Gerichtshof*) Case No. 3 Ob 45/12g, para. 4.6.1 (available at: <<http://www.ris.bka.gv.at>>).

treated as subjects and not as mere objects;²⁴⁸ although it is not the aim of this paper to trace all possible philosophers in EU integration, *Kant* is also associated with other aspects²⁴⁹ of EU integration (for example, promoting peace²⁵⁰).

In the previously mentioned report, EGE had also proposed that “the Charter should highlight the two basic ideas, which are hallmarks of European society: dignity and freedom”.²⁵¹ This idea has been rejected in the Convention drafting the CFR.²⁵² Notwithstanding the fact that freedom is also mentioned in Art. 2 TEU amongst the other EU values, my argumentation will primarily focus on human dignity.

The argumentation will not focus on religion, at least not in a direct way. In EU Secondary law on genetically modified food we do find some references to religion (“the labelling should give information about [...] any characteristic or property which gives rise to ethical or religious concerns”²⁵³), but not in terms of defining ethics. Although the 2nd recital TEU refers to “the cultural, religious and humanist inheritance of Europe”, this reference might be misleading; not taking into account the controversial discussions at the time the European Convention drafted the CFR. Those disputes²⁵⁴ concerning the way of referring to religion have been finally solved by deviating language versions referring to the “spiritual and moral heritage”, whereas only the German version refers to religion,²⁵⁵ and none of them to “God”.

Therefore, on the one side, the reference to the spiritual and moral heritage can neither be seen as a commitment to a single religion (for example, Christianity), nor to several religions (such as, Christianity, Judaism, while excluding Islam), and, on the other side, also atheists and agnostics should be seen as bearers of this heritage.²⁵⁶ Therefore, due to a lack of consensus, ethics in EU law cannot be filled with religion, but human dignity instead. Nonetheless it has to be mentioned that, apart from *Kant*, also “religious

²⁴⁸ M. Borowsky, Würde des Menschen, in: J. Meyer, Charta der Grundrechte der Europäischen Union, 2014, 96. Although it has been criticized that this in itself does not answer all possible questions, the approach should be welcomed.

²⁴⁹ M. Borowsky (note 248), 96.

²⁵⁰ J. Meyer, Präambel, in: J. Meyer, Charta der Grundrechte der Europäischen Union, 2014, 68.

²⁵¹ EGE (note 239), 8 (and 11).

²⁵² M. Borowsky (note 248), 119.

²⁵³ 22nd recital (*et passim*) Regulation 1829/2003/EC (note 105).

²⁵⁴ J. Meyer (note 250), 58 et seq., 70.

²⁵⁵ 2nd recital CFR (“In dem Bewusstsein ihres geistig-religiösen und sittlichen Erbes”).

²⁵⁶ J. Meyer (note 250), 71.

constitutionalism” had some influence and inspired the concept of dignity.²⁵⁷

The approach of applying the EU’s values and human rights, but not religion, is somehow also confirmed by some Eurobarometer surveys. During the last years, peace, respect for human life and human rights have constantly been ranked top in terms of *personal* values of Europeans, and peace, human rights and democracy in terms of values *representing the EU*, while religion has been constantly ranked very low in both categories.²⁵⁸

Reference has already been made to the Kantian idea that humans should be treated as subjects but not as objects. This understanding of human dignity forbids making someone who is of basic human traits the *object* of EU or national legislative-action.²⁵⁹ Therefore, humans shall never be considered as only a means to an end.²⁶⁰ This can be seen as a rejection of utilitarianism (“the greatest good for the greatest number”), where one human could be deemed to serve a purpose for the greatest good.²⁶¹ For all those reasons, human dignity has been proposed as a regulatory principle especially in the field of bioethics.²⁶² If we can agree to resort to human dignity (also, but not only, in order to fill those gaps that result due to undetermined references to ethics in legal texts), we still have to be aware of and accept that this will not answer all possible questions.

Title I CFR does not only entail human dignity (Art. 1), the right to life (Art. 2), prohibition of torture and inhuman or degrading treatment or pun-

²⁵⁷ For further details see: S. Moyn, *The Secret History of Constitutional Dignity*, available at SSRN: <<http://ssrn.com>>; S. Moyn, *The Secret History of Constitutional Dignity*, in: C. McCrudden, *Understanding Human Dignity*, Proceedings of the British Academy Vol. 192, 2014, 95. Also EGE (note 239), 4 mentions that the European multiculturalism is “moderated by the Graeco-Latin and Judeo-Christian traditions”. On Jewish law and human dignity see D. Sinclair, *Feticide, Cannibalism, Nudity and Extra-Legal Sanctions*, in: L. Moscovitz, *The Manchester 2008 Conference Volume*, 2010, 262, 285, 294.

²⁵⁸ Eurobarometer 77 (2012), 9 and 12; Eurobarometer 74 (2010), 32 and 33; Eurobarometer 72 (2009), Vol. 2, 148 and 152; Eurobarometer 69 (2008), 1. Values of Europeans, 15 and 22; Eurobarometer 66 (2007), 28.

²⁵⁹ M. Borowsky (note 248), 96; L. Nordenfelt, *Dignity*, in: R. Chadwick, *The Encyclopedia of Applied Ethics*, 2012, 800 et seq., 800: “All people have this dignity to the same degree, that is, people are equal with respect to this kind of dignity. It is significant that human dignity cannot be taken from the human being as long as he or she is alive”.

²⁶⁰ M. Borowsky (note 248), 96; L. Nordenfelt (note 259), 802.

²⁶¹ B. Eggleston, *Utilitarianism*, in: R. Chadwick, *The Encyclopedia of Applied Ethics*, 2012, 452 et seq.; M. Sandel (note 211), 31 et seq.; 110.

²⁶² M. Borowsky (note 248), 96. This goes hand in hand with the reference to the humanist inheritance (note 3), as humanism is defined as “any philosophical perspective that assigns preeminent value to human beings, their experiences, their interests, and their rights”; E. Steelwater, *Humanism*, in: R. Chadwick, *The Encyclopedia of Applied Ethics*, 2012, 674 et seq., 674.

ishment (Art. 4) and prohibition of slavery and forced labour (Art. 5), but also the right to integrity of the person (Art. 3):²⁶³

“1. Everyone has the right to respect for his or her physical and mental integrity.

2. In the fields of medicine and biology, the following must be respected *in particular*:

(a) the *free and informed consent* of the person concerned, according to the procedures laid down by law;

(b) the prohibition of *eugenic practices*, in particular those aiming at the selection of persons;

(c) the prohibition on making the *human body* and its parts as such a *source of financial gain*;

(d) the prohibition of the *reproductive cloning* of human beings”.

This provision has the advantage of not only providing quite detailed instructions as to what would be seen as being against integrity, but also for allowing for future developments to be taken into account in the interpretation of those four examples (“argumentum” : “in particular”).

Last but not least, two comments: Although this approach refers to the EU’s values and the fundamental rights (with human dignity as a key element), this approach cannot only be used in the case of humans as beneficiaries of ethics, but also for animals,²⁶⁴ plants and the environment, if we take a broad understanding of environmental protection (Art. 37 CFR²⁶⁵). If this understanding should exclude animals, they would at least be protected by those examples of EU law mentioned so far. Second, if this thesis applies for those situations where EU legal provisions refer to ethics, the question remains as to whether this concept would not have to be seen in a broader sense, that is, where there are no references of EU law to ethics.²⁶⁶

²⁶³ Emphases added.

²⁶⁴ Unlike the previous statement that Utilitarianism is not really in line with the principles as they are reflected in EU law, referring to animals as “sentient” creatures (note 190) has some similarities with Utilitarianism (“all sentient creatures are objects of moral concern”; *B. Eggleston* [note 261], 455).

²⁶⁵ According to *B. Rudolf*, Artikel 37, in: J. Meyer, Charta der Grundrechte der Europäischen Union, 2014, 558 et seq., 562, the notion of environment comprises air, soil, water, flora and fauna, humans and the environment created and shaped by humans and animals (but no pets).

²⁶⁶ However, what is clear from the legal perspective is the fact that the EU’s values (Art. 2 TEU) are not restricted to the scope of EU law as in the case of the CFR. For the expansion beyond the wording of Art. 51, para. 1 CFR (i.e. that the CFR is binding for the Member States “only when they are *implementing* Union law”; emphasis added) see ECJ Case C-617/10 EU:C:2013:105 margin number 21 – *Åkerberg Fransson*, (“The applicability of European Union law entails applicability of the fundamental rights guaranteed by the Charter”).

3. And the Task of Determining Ethics Goes to ...

Based on the idea to shape the understanding of ethics (and morality) by referring to the EU's values and fundamental rights (with special emphasis on human dignity), the question remains, as to who should be in charge of this task.

Also here I argue that this question has to be answered by taking into account the legal framework. From a vertical perspective, as already suggested earlier, the vertical distribution of competences (Art. 2-6 TFEU) between the EU and its Member States has to play a decisive role. If sectoral policies, like public health or education, fall within the Member State's competence (and the EU is therefore only allowed to "support, coordinate or supplement the actions of the Member States"), then it will mainly be the Member States to fill the terms of ethics with life. In doing so, the Member States of course have to take into account the EU's values, fundamental rights and especially human dignity. Apart from that it can of course not be excluded that in an "ever closer union"²⁶⁷ ethics is not going to become an increasingly European issue.

If, from a vertical perspective, the EU shall have this task, then the question remains as to which institutions shall be responsible. As we have seen, EGE's task is to advise the Commission²⁶⁸ and its 15 members are appointed by the president of the Commission, not even the college of 28 Commissioners. According to the current mandate, "Parliament and the Council may [only] draw the Commission's attention to questions which they consider to be of major ethical importance".²⁶⁹ This interinstitutional relationship²⁷⁰ at a horizontal level can also be found in the context of the deliberate release of GMO, where the "Commission shall send to the European Parliament and the Council every year, a report on the ethical issues referred to in Article 29(1)^[271]".²⁷² In another context we have also seen the Commission's obligation to seek Parliament's opinion when revising the "Code of Conduct for Commissioners".²⁷³

Consequently, based on this fact the question can be raised, if it would be better to install an advisory ethics body that supports *all* three major EU

²⁶⁷ Art. 1, para. 2 and 13th recital TEU; 1st recital TFEU; 1st recital CFR.

²⁶⁸ Commission Decision 2010/1/EU (note 132).

²⁶⁹ Art. 2 Commission Decision 2010/1/EU (note 132).

²⁷⁰ For a good overview on those tensions see *A. Plomer* (note 131), 842 et seq.

²⁷¹ I.e. consultation of EGE etc.; mentioned in note 141.

²⁷² Art. 31, para. 8 Directive 2001/18/EC (note 117).

²⁷³ See note 63.

institutions involved in the decision-making process.²⁷⁴ As the current 15 EGE members are going to serve until January 2016, we will see how the new Commission’s president (*Jean-Claude Juncker*) is going to deal with this question. Will he initiate an advisory body for all three institutions mentioned, is the number of members going to be increased, how is this body going to be composed, and so forth?²⁷⁵

Last but not least, one should not disregard the ECJ.²⁷⁶ As we have seen earlier, there is definitely a need to provide clarifications, as such general terms seem to provide a common basis, which nevertheless can lead to diametrically opposed solutions in concrete situations.²⁷⁷ Asking a legal court to provide clarification regarding a philosophical term can seem strange, but it is necessary to find clarification regarding references to ethics contained in legal texts. Also, we can observe a tendency of judicial self-restraint (not concerning political questions but) concerning ethics, where courts try to find well-balanced solutions in such sensitive issues.

All these ways of determining ethics mentioned so far are top-down. In a Union based on the rule of law and following the democratic principle, those ethical standards cannot be disconnected from law and of course also cannot circumvent the principle of democracy. In other words, determining the content of legal texts by transferring competences to committees of a very small number of people can be problematic in terms of lacking democratic legitimacy.²⁷⁸ In addition to those top-down elements, there will also be a need to address this issue from bottom-up, as it has been emphasized in many of the documents scrutinized herein.

²⁷⁴ On the one side this could enhance legitimacy, but on the other, some diversity in respect of three advisory bodies could also be fruitful.

²⁷⁵ A similar discussion took place concerning the Commission’s “chief scientific adviser”; see *D. Keating*, Should the EU Scrap Scientific Advice?, *European Voice* 17.8.2014 (online); *D. Keating*, Juncker Scraps Chief Scientific Adviser Post, *European Voice* 13.11.2014 (online); *Charlemagne*, The Battle of the Scientists, *The Economist* 20.12.2014, 37.

²⁷⁶ *P. Grossi*, Europe’s Message about Law and Its Vitality, *European Business Law Review* 25 (2014), 349, 356 refers to the ECJ as “an industrious workshop in which prestigious jurists are in the search for *values* on which to build *principles*, capable of providing sound foundations for legal situations which are vital for European citizens’ lives”.

²⁷⁷ E.g., while some could use human dignity in order to oppose euthanasia, others could argue in favor of “dying in dignity”. See also *G. Pennings*, Legal Harmonization and Reproductive Tourism in Europe, *Reproductive Health Matters* 13 (2005), 1, 5; *Ch. Megone* (note 100), 203 (“Rarely will these general considerations determine precisely what must be done in particular circumstances”).

²⁷⁸ Cf. also *M. Tallacchini* (note 131), 284, 290, 296.

4. Talk, Then Walk the Talk (Importance of Dialogue and Openness)

In the context of nanotechnologies research, the relevant Commission's recommendation states that it should "also be used as an instrument to *encourage dialogue at all governance levels* among policy makers, researchers, industry, ethics committees, civil society organisations and society at large with a view to *increasing understanding* and *involvement* by the general public in the development of new technologies".²⁷⁹ A similar invitation addressed to the Member States and the Commission "to pursue activities aimed at initiating a *dialogue* on ethical issues in relation to science and technologies at the European, national, regional and local levels" can be found in the Council Resolution on women in science.²⁸⁰ Comparable examples can also be traced in Horizon 2020.²⁸¹

However, stimulating dialogue is not enough. Closely related to this, some documents demand for ethics as a minimum requirement with regard to education and training (for example, concerning the protection of animals,²⁸² professional ethics²⁸³ and so forth²⁸⁴), while certain documents promote ethics in terms of lifelong learning.²⁸⁵ In some fields we can also find an institutionalized exchange of information on ethics by contact points, assistance centres and so forth.²⁸⁶ In a more general way, raising

²⁷⁹ Point 8 Commission Recommendation 2008/345/EC (note 9).

²⁸⁰ 18th recital (see also 19th recital) Council Resolution on Science and Society and on Women in Science, O.J. 2001, C 199/1 (emphases added).

²⁸¹ Annex I, Part V, 2 Regulation 1291/2013/EU (note 8); Annex I, Part V, f Council Decision 2013/743/EU (note 191).

²⁸² Art. 23, para. 3 i.c.w. Annex V, Directive 2010/63/EU (note 32); Art. 95, para. 3 (b) European Commission, COM (2013) 265 final 6.5.2013.

²⁸³ Art. 31, para. 6 (b), 36, para. 3 and 40, para. 3 (b) Directive 2005/36/EC (note 55); respectively Directive 2013/55/EU (note 57); see also Art. 8, para. 1 (j) Directive 2006/43/EC (note 58).

²⁸⁴ Annex, 3.2 Council Decision 2008/210/EC (note 52). Commission Implementing Regulation 1244/2014/EU laying down rules for the implementation of Regulation 375/2014/EU establishing the European Voluntary Humanitarian Aid Corps: Art. 13, para. 1, Art. 9, para. 7 i.c.w. Annex II, point 8.

²⁸⁵ Directive 2013/55/EU (note 57): 15th recital and Art. 3 (l); Annex I, Part I, 3.1 Council Decision 2013/743/EU (note 191); Resolution of the Council [etc.] (note 200); Annex, 3.B Recommendation 2006/962/EC (note 204).

²⁸⁶ For exchange of information on ethics between contact points see Art. 57a Directive 2005/36/EC (note 55); respectively now Art. 57b, para. 1 Directive 2013/55/EU (note 57); see also 60th recital Directive 2001/18/EC (note 117).

awareness²⁸⁷ and understanding²⁸⁸ of ethics is also an issue. Also the availability of EGE’s opinions and public accessibility has been stressed.²⁸⁹

Summarizing, we have availability and exchange of information, dialogue both *at* and also *between* different levels, between different stakeholders,²⁹⁰ in order to increase understanding and involvement. These measures will be important to enhance bottom-up dialogue, which is of utmost importance in the field of ethics.²⁹¹

Other than what has been mentioned so far, what are the additional tools? Within Title II TEU (provisions on democratic principles) we find, *inter alia*, an “open, transparent and regular dialogue” between EU institutions on the one side and representative associations and civil society at the other (Art. 11, para. 2 TEU), broad consultations to be carried out by the Commission with parties concerned (Art. 11, para. 3 TEU), and the new EU citizen’s initiative (Art. 11, para. 4 TEU,²⁹² Art 24, para. 1 TFEU). The latter could be used for agenda setting in this context, unless the proposed citizens’ initiative falls manifestly outside the framework of the Commission’s powers to submit a legislative proposal, or if it is manifestly abusive, frivolous or vexatious, or if it is manifestly contrary to the EU’s values.²⁹³

In addition to this active involvement, the already mentioned Eurobarometer²⁹⁴ surveys could be used as a way of monitoring (passive) citizens’ attitudes in a certain field in the future:²⁹⁵

²⁸⁷ Recommendation 2006/962/EC (note 204): Annex, 4 and 7; Annex, 4.3.2 Commission Recommendation 2008/345/EC (note 9).

²⁸⁸ Annex I, Part III, 7.3 Regulation 1291/2013/EU (note 8).

²⁸⁹ Art. 33, para. 2 Regulation 1829/2003/EC (note 105), (“The Commission shall make these opinions [of EGE etc.] available to the public”); Art. 29, para. 2 Directive 2001/18/EC (note 117), (“[The outcome of the consultation of EGE etc.] shall be accessible to the public”).

²⁹⁰ Art. 17 TFEU also mentions an “open, transparent and regular dialogue” with churches, religious associations or communities and philosophical and non-confessional organizations; see also O.J. 1997 C 340/133.

²⁹¹ EGE (note 239), 4 (“Pluralism, tolerance, and open dialogue about cultural and moral differences constitute therefore a distinctive sign of the European idea”).

²⁹² “Not less than one million citizens who are nationals of a significant number [7 out of 28] of Member States may take the initiative of inviting the European Commission, *within the framework of its powers*, to submit any appropriate proposal [i.e. to change Secondary, not Primary law] on matters where citizens consider that a legal act of the Union is required for the purpose of implementing the Treaties” (emphasis added). See also Regulation 211/2011/EU on the Citizens’ Initiative, O.J. 2011, L 65/1, as amended by O.J. 2014, L 148/52.

²⁹³ Art. 4, para. 2 Regulation 211/2011/EU (note 292) (situations, where registration will be refused by the Commission).

²⁹⁴ See note 258.

²⁹⁵ Advocate General *Bot*, Case C-34/10 EU:C:2011:669 margin number 48 – *Brüstle*; see also Advocate General *Cruz Villalón*, Case C-364/13 EU:C:2014:2104 margin number 25 –

“Consequently, in my view, the solution which I propose or the solution adopted by the Court will apply only at the time it is established. Advances in knowledge may lead to it being modified in future”.

In the same way that Advocate General *Bot* has formulated it in the context of biotechnological inventions concerning the legal perspective (that he has separated from the ethical one),²⁹⁶ also in the field of ethics, not only dialogue, but a *constant* dialogue is of utmost importance. This is especially due to the evolutionary character in ethics which has been underlined by many documents.²⁹⁷ One example is research that is seen as unethical and which therefore shall not be financed under Horizon 2020, as aforementioned.²⁹⁸ The same Art. 19 on “ethical principles” also refers to a review of unethical research activities “in the light of scientific advances”.²⁹⁹

In summary, dealing with ethics is not only important at EU level, but involving citizens and other stakeholders is essential for a holistic approach in this field. However, if citizens are engaged and “have a talk”, then this input should also be taken into account as far as possible (“walk the talk”).

5. Limitations

The suggested idea of filling the identified gaps with the EU’s values and human rights, especially human dignity and the right to integrity, can however not provide detailed information as regards the gaps identified earlier in this paper. In other words, it can only lead the way, but not predict the final outcome on a specific ethical question.³⁰⁰

International Stem Cell Corporation; ECtHR, *S.H. and others v. Austria* (note 32), para. 97 (“sensitive moral and ethical issues against a background of fast-moving medical and scientific developments”).

²⁹⁶ Advocate General *Bot*, Case *Brüstle* (note 295) margin number 45.

²⁹⁷ Annex I, Part VI, 3.3 (f) Regulation 1291/2013/EU (note 8); Council Decision 2013/743/EU (note 191): Annex I, Part V (“Rapid advances in contemporary scientific research and innovation have led to a rise of important ethical, legal and social issues that affect the relationship between science and society”) and Annex I, Part III, 1.5.2 (“need to support the development of relevant methods for assisting the assessment of ethical aspects”); Annex XIII, 3 (e) Council Recommendation 87/176/EEC (note 175); 33rd recital Directive 2004/23/EC (note 135) (the opinions of EGE “will be sought in the future whenever necessary”); 19th recital Council Resolution (note 280); Annex, 4.2.7 Commission Recommendation 2008/345/EC (note 9).

²⁹⁸ See V., 3., (4).

²⁹⁹ Art. 19, para. 5 Regulation 1291/2013/EU (note 8).

³⁰⁰ Similar *R. Andorno* (note 244), 53 (“Human dignity is not a magic word that, when uttered, will immediately solve all the complex dilemmas posed by medical technology.”).

As already mentioned, we can identify a process where ethical issues play an ever increasing role, yet where this process will lead to is unknown. This contribution focused on the role of ethics (and morality) in Primary and Secondary EU law and is therefore no more than one jigsaw piece of the greater puzzle.

What still waits for exploration would be the role of ethics in agreements concluded by the EU and/or the Member States with third countries and/or international organizations, as well as a detailed analysis of ethics in ECJ case-law. It would also be worth comparing the role of ethics from the Commission’s proposals throughout the legislative procedure until the finally adopted legal acts by the Council and European Parliament.³⁰¹ Closely related to the EU, it would also be worth focusing on EFTA and EEA documents and the case law of the EFTA Court, in order to get a more holistic European picture. Once this would be achieved, it would also be worth stepping one level down to the 28 Member States plus the three³⁰² EEA-states (Norway, Iceland and Liechtenstein) national legal orders and not only focus on their self-contained understanding of ethics, but also the way they deal with ethical questions of European provenance.

VII. Conclusion

“Ethics” and “morality” occur in a variety of different documents, both of EU Primary and Secondary law, in the latter category pertaining to different sectors. Although a good majority of them are related to bioethics, the question as to whether there is a common understanding of ethics is difficult to answer due to a lack of a recognizable coherent concept, especially in EU Secondary law. Ought there to be a coherent concept? Yes, if we take the stipulations in EU Primary law (values, fundamental rights, the “spiritual and moral heritage”, “the cultural, religious and humanist inheritance”) seriously, then such a coherent concept should be developed, at least since those provisions came into force. What we have clearly seen is a non-coherent usage of “ethics” and “morality”, not only based on the common theoretical understanding of those two terms, but also in comparison between different language versions.

³⁰¹ *A propos* European Parliament, it would also be worth exploring the role of ethics in Parliamentary questions in the EU.

³⁰² Plus one, if also including Switzerland (linked to the EU by means of several bilateral agreements).

As we have seen, ethics has been determined by ethics committees, codes of conduct, references to international documents, further information provided by EU Secondary law itself, and was left undetermined in other cases.

As mentioned earlier, the objective of this paper was not to assess the concept of ethics in EU law against this principle of the rule of law; the objective was rather to crystallize the status quo. Even below that threshold of getting into conflict with the rule of law, a certain degree of legal uncertainty can pose different problems. Nevertheless, in those cases of missing determination, possible ways of closing the gaps could be identified, for example, by referring to the vertical distribution of competences (EU vs. Member States).

Can we conclude that the EU is based on a “rule of ethics”? This question is very difficult to answer, but there is a tendency to attach more and more importance to ethics in EU law. Even if the concept gets more united, it still has to be qualified as equally diverse, especially taking into account different approaches in the 28 Member States. Nevertheless, this ethical diversity can be seen as a chance, if it is respected and used in an ethical dialogue³⁰³ while shaping a European understanding of ethics. In other words, the spiritual and moral heritage and the cultural, religious and humanist inheritance (to some extent Aristotelian and Kantian) can be used for the future process of shaping a more coherent concept of ethics in the EU.

If some examples of EU Secondary law referred to the “competence” of the Member States in terms of ethics, this has to be seen in the light of the EU’s values and fundamental rights. As mentioned earlier,³⁰⁴ the fundamental rights are binding within the scope of EU law, whereas the EU’s values are binding only based on the mere fact of EU membership. In some cases reference was made to “fundamental” ethical choices of Member States, which can be seen as a narrow interpretation of Member State’s discretion in this field. However, we have also seen some examples, both in Primary and Secondary law, of less ambitious “umbrella clauses”. Ethics should definitely be more than a mere substitute for a kind of subsidiarity principle.

The ECJ submits itself to a judicial self-restraint in sensitive fields like ethics and tries to solve the different tasks at the interface of law and ethics

³⁰³ EGE (note 239), (confirmed) at 13 (“The respect for different philosophical, moral or legal approaches and for diverse national cultures is essential to the building of Europe”); see also G. Pennings, Reproductive Tourism as Moral Pluralism in Motion, *Journal of Medical Ethics* 28 (2002), 337, 340; G. Pennings (note 277), 7.

³⁰⁴ See note 266.

by concentrating on the legal perspective.³⁰⁵ This self-restraint does not apply to the legislators in the EU, the Commission, the Parliament or the Council. Those institutions can help shape ethics in the EU under the umbrella of EU values and fundamental rights, based on advice from ethics bodies, different forms of dialogue and other bottom-up initiatives; especially, but not only, in the field of bioethics.

While this paper could hopefully depict the status quo, as a first step, and answer some questions in this context, we have seen a lot of questions that remain unanswered. Consequently, this contribution can be seen as one piece of the puzzle, in essence, a research agenda where I hope that others will contribute to this process.³⁰⁶

³⁰⁵ E.g. Advocate General *Cruz Villalón*, Case *International Stem Cell Corporation* (note 295) margin numbers 28, 38 et seq. did refer to ethics, but not the Court (ECJ Case C-364/13 EU:C:2014:2451 – *International Stem Cell Corporation*).

³⁰⁶ Inspired by *G. Cohen*, *Medical Tourism: The View from Ten Thousand Feet*, Hastings Center Report (March-April 2010) 11, 11.

