The style of EU directives and the discourse of expert rationality

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Introduction

In this study, *the discourse of the European Union* (EU discourse) is defined as a body of texts that actualize three basic ideological assumptions, namely that EU Member States constitute an entity with an identifiable collective identity, that this entity has a coherent set of objectively delimited common interests, and that it can best be governed by pan-European institutions. To use Foucault's (1972) terminology, these three assumptions are epistemes – the underlying principles of what can be known and stated within the discursive formation of EU discourse. Also, these assumptions have underpinned one of the key political effects spawned by EU's ideology – integrationism.

In fact, as some scholars of European Union Studies contend (cf. Walters 2002), "European integration" is just a discursive construct that has been successfully advanced and naturalized to such a degree that it no longer seems ideological to most European citizens. However, with the shadow of the economic downturn and the separatist projects voiced by some key European players (notably the UK), the constructed nature of the concept of European integration is beginning to be exposed as a discursive ploy to legitimize the oversized EU administration and render its regulative powers pervasive in every sphere of European business and politics.

This study can be located within this recent trend in European Union Studies, albeit it takes a more language-oriented, stylistic, and discursive perspective. It

looks at the main administrative tool of EU governance aimed at integration – the directive, in order to discuss its stylistic properties and related discursive practices. Each directive is an elaborate, legally delimited, pan-European regulatory measure, a counterpart to an executive order, complete with a mechanism of persecution in case a given Member State fails in its implementation. It is hypothesized here that EC-originated, EP-ratified directives constitute specific realizations of the EU hegemonic discursive form of governance legitimization, namely that of the discourse of expert rationality.

The study first summarizes the main tenets of the EU's "governmentality" (Foucault 1991) in the historical context, as interpreted in Walters and Haahr (2005). Then the notion of expert rationality is explained and characterized with regard to the EU's administrative procedures, as well as operationalized in terms of its representative discursive properties. It is spotlighted how elitist expertise is likely to depart from social rationality and democratic deliberation. This will be followed by a discursive analysis of the composition, style, and rhetorical devices of a selected Directive (Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices).

Governmentality

According to Foucault (1991), the European Union's governance is an example of a specific political rationality – a particular "governmentality" based on the idea of integration through the steering of economic and social processes. When set beside other historical political models (e.g. sovereignty or balance of powers), its constructed and coincidental nature come into fuller view: it seems that other governance models could well be used for the project of integration as an alternative. The outcome of the accepted EU governmentality is that the management and control of economic, financial, commercial and, ultimately, social processes within the community has been assigned to EU's institutionalized administrative branch, which, as any bureaucracy in the Weberian sense (1967), tends to perpetuate itself.

In a similar vein, Walters and Haahr (2005: 34) stress that European integrationist governmentality is a historically situated and constructed rather than natural or universal process. Apparently, it is realized through a set of specific *discursive formations* (e.g. the discourse of peace and stability in the

Treaties of Paris and Rome, the discourse of liberty and security in the Schengen accords, the discourse of sustainability and competitiveness in the Treaty of Lisbon) that legitimize particular *technologies of governance* (e.g. co-operation, transparency, co-ordination, monitoring, and benchmarking). This governmentality is also rooted in the conception that power relations underlie all social relations within the European community and have a major influence on the formation of identities of European citizens. Indeed, it might seem that this particular governmentality works to project Europeans as increasingly insecure and anxious individuals who need administrators to regulate and control everything from border security, food safety and the stability of financial institutions, to educational priorities, the quality of asphalt, and the shape of cucumbers for sale.

Since the legitimacy of EU administration is not derived from mythology (i.e. historical, national, cultural, or religious master-narratives), it must be based on other premises. Walters and Haahr (2005: 43) point out that the EU project is ideologically traceable to the liberalism of high (mature) modernism (which was marked by the balance of self-regulation and elite pluralist leadership) with only some traces of postmodernist elements (e.g. civil society, networking, and feedback). It is rooted in the belief in a rational, non-conflictual pan-society, whose development and enterprise can be strategically planned. This brings us to the function of "expert rationality" as one of the principal mechanisms of legitimization of EU governmentality.

Expert rationality

It is beyond the scope of this study to review the history of the EU project. Suffice it to state that the modernist ramifications of the European Coal and Steel Community, of the European Community, and now largely of the European Union are predicated on the assumption that rational, progressive, and well-planned economic, political and social advancement must be guided from above by technocrats and experts, not national politicians or community leaders. As envisioned by Jean Monnet (1978), this rationality and ethos enabled the implementation of new forms of pan-European governance channeled towards reform and modernization. The rapid and steady technological progress that ensued in the post-war Europe and the planned social reforms were welcome

outcomes of that governance at first, but they are now approached more critically.

The early forms of technocratic rationality required that high officials were appointed, rather than elected, and that they worked in small teams within specific institutions to manage the European affairs, largely behind the backs of national politicians and public opinion. It was trusted that the proceedings of such technocracy would be pragmatic, apolitical, objective, gradual, and uncontroversial. Small teams were more creative and competent and needed to co-operate and co-ordinate their efforts. This gave rise to sector schema and empowered "commissions" with regard to specific aspects of European planning and management (Walters and Haahr 2005: 51–55). As a result, EU institutions began to work outside established power relations and were independent of existing decision-making bodies. It cannot be denied that this form of governmentality was marked by elitism, but, since the proceedings involved public consultations and commission hearings before decisions were issued and plans designed, technocracy could not be fairly criticized as undemocratic.

According to Scott (1998), one of the failures of such a technocratic order is that it requires an ever-growing administration to implement, monitor, evaluate and, if necessary, enforce the outcomes of the commissions' legal designs, economic strategies, as well as proposed social reforms. The small-team sector efforts and flexible collectives have been transformed into a more rigid and inflexible bureaucracy, with all its positive and negative consequences (cf. Weber 1967). Admittedly, the EU bureaucracy is more transparent and accountable than many other administrative bodies. However, in the post-industrial media-saturated world, the hegemonic ideology of expert rationality that permeates many EU institutions seems strikingly at odds with the currently popular ideologies of emancipated and empowered civil societies. As a result, the EU's deficits of democracy and its strategic planning, bordering on social engineering, become ever more apparent. It is by de-naturalizing the properties of the *discourse* of expert rationality that this study attempts to offer a critique of this ideology.

The discourse of expert rationality

In this study the discourse of expert rationality is operationalized as a set of fairly naturalized discursive strategies that project Europeans as in need of the

EU authorities and their expert consultants to identify issues, regulate activities, and implement plans related to pan-European enterprises. To paraphrase Walters and Haahr (2005: 12): the EU authorities are obliged to consult experts to identify what Europeans need and how best to meet those needs. This discourse can be characterized in terms of specific variables, which we discuss below.

For one, the discourse of expert rationality is one that most of all draws on legal, scientific and logical argumentation (cf. the neo-Aristotelian notion of logos, Cockcroft and Cockcroft 2005: 81–106), thus it can be assumed that various types of semantic references to legality, credibility, and knowledge will feature prominently. It is also expected that the questions of continuity and congruence will be foregrounded. The coherence of the exposition will need to be scrutinized, especially in terms of cause-and-effect relations superimposed on exposition. Reliance on such argumentation is likely to constitute an attempt to rationalize solutions and, through this, to underline the EU's effectiveness and agency.

Secondly, despite appearing to be based on democratic deliberation and social rationality, expert rationality can be characterized as fairly elitist and restrictive. For example, it is publicized that expert consultations were solicited, and whose expert opinions were considered, but not to what extent commissioners considered them, or if any opinions were rejected (Walters and Haahr 2005: 133–134). This kind of shortage of transparency will be likely to be balanced with a two-sided type of argument and sufficient qualification of statements. It will be crucial then to assess how external expert voices are incorporated into the argumentation, and how they are acknowledged or validated.

Thirdly, expert rationality is inherently paternalistic; thus it will be channeled towards identifying "what is needed" to be done. After all, it is experts who know best what societies need most. Linguistically, this is likely to be realized via presupposition, nominalization, and modality. The stress on needs, requirements, and obligations will turn attention to the EU's precautionary and long-term strategizing with regard to regulation. In an analysis of EU discourse, attention will need to be paid to the level of generality/specificity of information, as well as textual realizations of minute planning, together with the specification of all possible cases (conjunctions, enumerations, listings, and alternatives). The study will have to focus on suggestions that are offered to pre-empt problems and ensure timing for implementation. Under the guise of

removing barriers and uniformizing the law, new requirements and benchmarks will be set, probably to ensure "progress," "standards," "quality," "development," or other merits. As a result various linguistic features of the problem-solution formulae in the discourse will have to be analyzed.

Fourthly, as Walters and Haahr (2005: 136) remind us, in some areas of governance expert rationality will legitimize certain solutions with definitions of "the other." In economic discourse it is usually the forces of globalization, free market mechanisms or technological progress that require reactions. Expert rationality portrays them as unpredictable and uncontrollable processes, and thus in urgent need of regulation. The dominant logic of expertise is expected to be based on sizing up threats and identifying areas that need to be assessed. It often resorts to such discursive strategies as identifying "the enemy" and polarizing between "us" and "them" (othering), even if those are hypothetical, discursive entities.

The next questionable aspect of the discourse of expert rationality is connected to the recent tendency of EU authorities to remedy the alleged democratic deficits with more public consultations, social campaigns, and the fostering of deliberation in various (mediated) forms. However, propagating EU projects via various channels does not equal deliberation: legitimization of projects is often achieved through persuasion and rhetorical means rather than free exchange of arguments. This discursive strategy has been labeled "the voice of consensuality" (Molek-Kozakowska 2014 in press) and it is designed to render dialogue unnecessary by projecting the appearance of commonality of purpose, of shared identity and interests, and of collectively recognized trust in EU institutions' capacities to solve problems at all levels.

Directive as a genre

EU directives are legal acts that oblige Member States to implement internal regulations regarding a particular sphere of enterprise that would be compatible with specified pan-European requirements. The initiating memorandum, and subsequently, the text of a draft directive is prepared by the European Commission after consultations with its own and national experts. The draft is presented to the European Parliament and the Council of Europe, which is composed of relevant ministers of Member State governments. Initially, the

draft is open to evaluation and comment, with the EC responding to specific amendments or giving reasons for rejecting them; then the final version is presented for approval (or rejection) in a vote.

The directive sets a given time period for the implementation of the designed outcome or transposition of the national law, but often leaves the methods of implementation to the individual Member States. Directives become binding on a specified day, or, if not specified, twenty days after they are released. If a Member State fails to pass the required legislation, if the legislation does not adequately comply with the requirements of the directive, or if a Member State has transposed a directive in theory but fails to adhere to its provisions in practice, the Commission may initiate legal action against it in the European Court of Justice. Additionally, if a citizen of a Member State is adversely affected by the country's non-implementation of a given directive, they may sue it in European Court of Justice and seek compensation.

Until recently EU directives were overtly specific and technical, and required the transposition of rules of the Member States' markets, industries and government administration within particular sectors, e.g. pharmaceuticals, motor industry, waste disposal and recycling, or food safety. This was done in a long and complicated legal procedure of adaptation of national regulations, and hundreds of cases for non-implementations were filed. By contrast, the "new global directives" in operation since 2006 are constructed in such a way that they oblige the developers, producers and marketers of given products to identify and apply all relevant requirements before they apply for homogenized CE certificate and introduce the products to the EU market.

The genre of the directive can be claimed to represent an aspect of "the soft law" of EU governmentality. According to Walters and Haahr (2005: 176), after the strategic aims of the community have been defined centrally, the calendars are being coordinated to make implementation traceable. Then the measureable outcomes are set to be achieved and every now and then individual Member States are compared as far as the progress of implementation is concerned. In fact, it could be said that it is not the role of drafting the directives that matters most now, but all the technologies of monitoring, reporting, benchmarking, peer-review, and good practices that are developed by the EU bureaucracy to legitimize the system of governance based on rationally calculable variables.

The style of directives

The choice of Directive 98/79/EC of 27 October 1998 on *in vitro* diagnostic medical devices as an illustration of the discursive practices of expert rationality is not coincidental. Not surprisingly, medical and pharmaceutical industries have long been strongly regulated at the European level, considering the highly specialized nature of research and product development on the one hand, and the questions of public health and standards of welfare on the other. Secondly, this is a directive that evidences the discursive practices of EU integrationist regulatory measures aimed at both Member States and manufacturers (before the new global approach to directives was adopted). And yet, directive 98/79/EC has been modified only twice (in 2003 and 2009) to accommodate later regulations by the European Parliament and the Council (particularly connected with the powers of monitoring committees), not the newest technological developments in the field. Last but not least, it concerns a field of expertise (*in vitro* medical products and procedures) that, in a larger sense, is a part of different discursive formations: not only the regulatory, but also the medical, the economic, the ethical and the social discourses, whose epistemes could be said to inhere mutually exclusive or clashing ideological positionings. By keeping these tensions in mind, hopefully, it will be easier to defamiliarize the directive's stylistic conventions and demonstrate how the discourse of expert rationality is but one perspective, one strategy, one construct or one way of legitimizing EU directivity.

The full text of the directive can be found in the electronic archive of EU legislative acts, at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1998L0079:20090807:en:PDF. The text encompasses 43 pages and includes 1 title page, 5 pages of the preamble that specify the premises of the directive, 15 pages of the main body of the directive comprising 24 articles, and 22 pages comprising 10 annexes[1]. Indeed, the annexes are an indispensable part of the directive and are frequently referred to in the preceding articles. It might even be suggested that the annexes are of paramount importance when considering the EU's monitoring, controlling, and certifying powers. It is in the annexes that essential requirements for *in vitro* medical devices are specified

[1] In the analytic part these will be referred to as: T – title page, P – preamble, Art – article, An – annex, with the latter three references also specifying which number, point and instance is cited. For example Art 1: 2b refers to Article one, point two, instance b.

(An 1). They also list the documents a manufacturer needs to draw up to register a product in conformity with the directive (An 3), as well as the details of the quality assurance system that must be introduced by any manufacturer who aspires to be qualified to market *in vitro* medical devices (An 4). In addition, the annexes specify the rules for applying for EC-type examination that might be conducive to certification (An 5), the measures for EC verification of standards declared by the manufactures (An 6), the procedures for performance evaluation and re-evaluation (An 8), the criteria for the designation of notified bodies responsible for controlling the quality of devices and for carrying out inspections of manufacturing premises on behalf of the EU (An 9), and even the graphic design of CE marking affixed to certified products (An 10). These annexes, when interpreted in terms of the discursive practices enacted, can be said to help legitimize the EU's supervisory functions by projecting a vast and complex domain of the controlling mechanisms necessary in the context of medical industry. The sheer range of the instruments of control postulated in the directive make one "rational" conclusion inescapable: it is only at the European level of legal and technical control that the guarantee can ever be given of appropriate measures taken to limit any risks to the populace from unreliable manufacturers.

The preamble to the directive, as is the case with all directives, is used to frame the main objectives of the regulation and contextualize it within the EU legal space. It refers to the (then) EC Treaty (as a document that makes directives operational), to the European Commission's original proposal (as an executive document designed to realize EU's strategic aims), and to the expert opinions used to draft the directive, which in this case come from consultations with the Economic and Social Committee. Drawing from the generic conventions of legal accords, the preamble is fashioned as a list of 35 points that contain the main premises (explanations of motivations and reasons as well as legal framings) of this directive. All of the points are expressed with the anaphoric "whereas...", but, since sometimes there are more aspects in each point, there are as many as 64 clauses or phrases beginning with "whereas" altogether in this part of the directive. This might seem an elaborated and thorough attempt at "carving out" and verbalizing the legal grounds, rational arguments, and practical needs of this particular directive.

All the points aim at a legitimization of the directive's main purpose of "homogenization" of rules for the production and certification of *in vitro*

medical devices across the EU. The main intertextual means of legitimization here consist in referring to (1) various other directives and documents that had left the area of *in vitro* medical diagnostics unregulated, but which called for its future regulation; and (2) "a comparative survey of national legislations carried out on behalf of the Commission" (P, 2). The abovementioned survey produced the conclusion that homogenization is necessary, because "the existence of disparities creates barriers to trade" (P, 2). It should be noted that although the citing of expert opinions to justify a policy is not uncommon, directive EC/98/79 does not name any specific experts/organizations commissioned to conduct that survey. This might imply that no matter which expert body conducted the survey, it would have produced the same results, as "objective" and "rational" research is not likely to be biased in this respect.

As the directive's priority is the homogenization of rules pertaining to *in vitro* medical diagnostic materials, it is worth analyzing the order of EC's premises for this endeavor. This could reveal which arguments are treated as the most significant and valid. The first reason the rules should be homogenized is ensuring "smooth operation of the internal market" and "free movement of goods" (P, 1). The second reason is overcoming the diversity in legal provisions in individual Member States (P, 2,3). The next is ensuring that all patients and clinics are provided with equipment that has "a high level of health protection and attain(s) performance levels originally attributed to [it]" (P, 5). It is not until point 33 (out of 35) that the directive invokes the need to protect human rights and dignity, as well as "the integrity of the human person during the sampling, collection and use of substances derived from the human body" (P, 33). Although it is not always true that *a list* of preambular points coincides with *a hierarchy* of values and needs a given piece of legislation adheres to, or aims to satisfy, it can be concluded here that the questions of free market trade and product quality are foregrounded to a larger extent than those of e.g. social accessibility or ethics.

Additionally, the use of such expressions as "the human person" or "the human body" (P, 33) is reminiscent of the (currently dominant) discourse of evidence-based medicine (as opposed to the patient-centered therapeutic discourse), where medical performance is evaluated on the basis of statistical and objectified criteria, rather than with respect to an individual patient's unique constitution. This stylistic property is elaborated on below.

The preamble also very distinctly displaces any national legislation and locally used provisions in any Member States, binding them through the directive to comply with the requirements at the European level. For example, it is stated that "this objective [removing obstacles to trade] cannot be achieved in a satisfactory manner by other means by the individual Member States" (P, 3) and it is argued that "because they are essential, such requirements should replace the corresponding national provisions" (P, 6). Furthermore, it is claimed that "it is desirable to have harmonized standards in respect of the prevention of risks associated with the design, manufacture and packaging of medical devices" (P, 15) and that "it is appropriate that these particular specifications should be replaced by common technical specifications" (P, 17). It is interesting to note that, even though they are assertive and formal, these statements invite strong positive evaluation of the EC's directivity. However, this way of self-legitimizing through positive modifiers (e.g. "satisfactory," "desirable," "appropriate") is indirect, since the source of such evaluation is obscured through the use of passive or impersonal constructions. This implies that any *rational* person would agree to accept such priorities (cf. the voice of consensuality in Molek-Kozakowska 2014 in press). The use of deontic modal verbs (e.g. should, and cannot) in this co-text results in projecting a strong injunction as to what needs to be done and obliges Member States to follow the directive to prevent any further "risks."

What is more, point 15 of the preamble recognizes such European committees as the European Committee for Standardization and the European Committee for Electrotechnical Standardization as the most authoritative bodies in the process of standardizing the procedures and certifying the products in the area of *in vitro* diagnostics. This is yet another practice of validating the role of pan-European administrative bodies over any Member State's national institutions, implying that it is only experts at the "central" level of governance that can satisfactorily oversee the harmonization of rules, issue information and certify accomplishments. Van Leeuwen (2008: 113) calls this type of legitimization in terms of goals, uses and effects *instrumental rationalization*, and claims that such discursive strategies often involve the technique of "expert authorization" of specific solutions.

Article 1 is devoted to specifying the technical meaning of the directive's key terms. Here the subject of the directive, as used in its title, is delimited in a way that resembles definition in scientific discourse with the use of medical jargon,

and with *genus proximum* and *differentia specifica*, which involve extensive enumerations of elements and functions:

> 'in vitro diagnostic medical device' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information: concerning a physiological or pathological state, or concerning a congenital abnormality, or to determine the safety and compatibility with potential recipients, or to monitor therapeutic measures. (Art 1: 2b)

It should be remembered that the Latin phrase *in vitro,* which means in artificial laboratory conditions outside of a living organism, has been used to refer to some of the most advanced (and controversial) medical procedures developed so far, including transplantation, reconstruction, artificial insemination, and cloning. In this text, it is used 35 times and only three times without the collocates of "*in vitro* (diagnostic) (medical) devices." This might indicate that the questions of the ethics of *in vitro* or the status of the human donor/patient is again largely beyond the scope here, the central focus being the quality and safety of the diagnostic equipment. This, in turn, is the evidence of directives being largely focused on technicalities that are to answer to practical concerns and preclude larger deliberations. In other words, directives specify all the circumstances of "how to do it" as opposed to "why to do it" or "whether to do it". This could be interpreted as a pragmaticist dimension of expert rationality.

This technical nature of directivity is stylistically instantiated with examples of medical jargon that falls within the boundaries of the discourse of evidence-based medicine, as revealed in this list of purposes that *in vitro* medical devices can be put to:

– diagnosis, prevention, monitoring, treatment or alleviation of disease,

– diagnosis, monitoring, treatment, alleviation or compensation for an injury or handicap,

– investigation, replacement or modification of the anatomy or of a physiological process,

– control of conception (Art 1: 2a)

In this perspective, patients are largely bracketed out of the activities of the medical professionals. The discourse of evidence-based medicine is concerned with diseases, injuries, handicaps, physiological processes, and conception, which "objectifies" human beings (cf Murawska, 2012). At the same time

doctors' responsibilities and acts are presented as nominalizations (complete entities, impossible to locate in space and time and without specified beneficiaries). For example, the phrase "modification of the anatomy" reduces a complex sequence of activities involving many people to a generalized result or a routine procedure. By aligning themselves with the expert rationality of medical discourse, the authors of the directive succeed in taking over some of its qualities, such as the presupposition of the possibility of total scientific control of the human biology, which can be construed out of the stylistic choices made in the first article.

Apart from medical terminology and stylistic conventions typical of scientific descriptions, Articles 1–5 are saturated with commercial jargon and include formulaic expressions typical of the contract genre. For example, the denotational scopes of such terms as "manufacturer," "authorized representative," "intended purpose," "placing on the market," "putting into service" are fixed and the circumstances under which the directive applies are specified here (Art. 1: 2f–7). Since the economic dimension of free trade is of paramount importance (as could be inferred already from the preamble), the first few articles are devoted to the way the implementation of homogenized rules for European trade should proceed through the transposition of national laws.

The directive positions Member States between the set of obligations and prohibitions that leave little room for choice. Thus, on the one hand "Member States shall take all necessary steps to ensure that devices may be placed on the market or put into service only if they comply with the requirements of the directive" (Art 2), and on the other "Member States shall not create any obstacles to the placing on the market or putting into service within their territory of the devices bearing the CE marking" (Art 4: 1). This indicates that pan-European regulations trump the sovereign decisions by Member States. The strong forms employed in the directive when putting states under EU obligation (e.g. "shall take all/the necessary steps/mesures" is used six times throughout the articles) contrast starkly with the weaker ways of suggesting how Member States could exercise their legitimate rights: "Member States *may* require the information to be supplied [...] in their official language" (Art. 4, emphasis mine).

Since articles 2–5 are addressed to Member States, they specify, at a fairly detailed level of description, their new duties, obligations, and prohibitions.

Unsurprisingly, this part of the directive is stylistically couched in deontic modality, with such expressions as "this involves the obligation of Member States to monitor the security and quality of such devices" (Art. 2), "devices must meet the essential requirements" (Art. 3), "Member States shall take into consideration the rule of proportionality" (Art. 4), "the common technical specifications shall be adopted" (Art. 5). This builds up a system of interconnected injunctions, even exhortations, to follow without challenging their ideological grounds. Cumulatively, this kind of style contributes to establishing of EU directivity as indisputable and inevitable for the perfected rationalistic version of the European future.

The idea that it is inescapably always up to the European Commission to make the final decision is corroborated in Article 8, where the safeguard procedure is discussed. Can Member States safeguard their markets/populations against devices that compromise health? In fact, they can only introduce "interim measures" (Art 8: 1) because they are obliged to immediately refer any cases of faulty devices to the EC, which "shall enter into consultations" (Art. 8: 2) with all the parties concerned and review the documentation before deciding if the "measures are justified" or not within the timespan of two months. It is only after the decision is announced that the Member State is entitled to taking "appropriate action against" the manufacturer (Art 8: 3).

The bulk of provisions in Articles 9–10 is designed to address manufacturers, and, not surprisingly, is also marked for its imperative style. The core of this part of the directive is a list of administrative (not technical) requirements a manufacturer needs to fulfill to be registered and certified to be able to put *in vitro* equipment on the EU market. The long list of things to prepare refers us often to various annexes in which the details of each procedure are stipulated. The style of the articles can be analyzed in terms of strong, unqualified expressions of "what must be done" (e.g. "the manufacturer must keep the declaration of conformity, the technical documentation referred to in Annexes III to VIII, as well as the decisions, reports and certificates, established by notified bodies, and make it available to the national authorities for inspection purposes for a period ending five years after the last product has been manufactured. Art. 9:7), as well as in terms of a peculiar circularity of exposition achieved through nominalizations, passivizations and repetitions (e.g. "where the conformity assessment procedure involves intervention of a notified body, the manufacturer, or authorised representative, may apply to

a body of his choice within the framework of tasks for which the body has been notified." Art. 9:8). This part of the directive is even more direct, formal, and unmitigated in the enumeration of requirements. The asymmetrical relationship between the all-powerful EC and the other agents is constructed and legitimized stylistically.

By contrast, the two articles (6–7) outlining the role of the EC monitoring body – Committee on Standards and Technical Regulations (CSTR) – are surprisingly short and enigmatic. The level of generality as regards information about the Committee's duties and procedures makes it impossible to conclude what particular tasks are assigned to it. In addition it is a self-regulating body that "shall adopt its own rules of procedure" (Art 6: 3). The difficulty to retrieve any specific information about the Committee increases with the legal bases for it buried in footnotes and in intertextual references to various Council Decisions laying down the rules for the exercise of powers conferred on the EC. It is also worth noting the fact that the directive is peppered with references to the CSTR's powers of oversight and control. For example, in Article 12: 3 reference is made to the "regulatory procedure referred to in Article 7(2), and in Article 13 it is said that "the urgency procedure [is] referred to in Article 7(4)." Meanwhile, Article 7 refers us further to Council Decision 1999/468/EC. As a result, it is impossible to know from *this* directive what the full powers of CSTR really are. In brief, it can be inferred that the main strategy of legitimization of the CSTR is through intertextual references to binding legal texts of a higher order, not through practical requirements of this directive.

Conclusion

This stylistic analysis of Directive 98/79/EC of 27 October 1998 on *in vitro* diagnostic medical devices has revealed certain linguistic patterns and discursive strategies that aim to legitimize EU directivity in the name of expert rationality. For example, the use of such lexico-grammatical resources as deontic modality, nominalization and passivization, or some terminology that belongs to medical, legal, and commercial jargon evidences the rationalization of directivity in terms of uses, effects, and requirements. Such textual arrangements as extensive listings, precise definitions, cross-referencing, and premise-conclusion argumentative schemas (e.g. in the preamble) testify

to the bureaucrats' efforts taken to project given solutions as justifiable. Interestingly, the level of detail with respect to requirements placed on Member States and manufacturers contrasts with the level of generality as regards the EC control and certification powers, which obscures starkly asymmetrical relations between the regulators at the European level and the addressees of the directive.

In terms of agency, while the European Commission and its bureaucratic subsidiaries (e.g. the Committee on Standards and Technical Regulations) have the capacity to "require," "direct," "certify," "verify," "monitor," and "issue final decisions"; Member States are to "implement," "take measures/steps," "transpose," "ensure" and "inform"; and manufacturers need to "apply," "register," and "comply." One implication of such a constellation of agents in the EU market is that it becomes more and more "evident" that more EU regulation and bureaucratic control is to be the only panacea for the chaotic, fragmented, unfair, exploitative, and unreliable forces of the market. Another implication is that European citizens, both individually and collectively, are largely projected as vulnerable and in need of protection by empowered institutions that need to "police" the market. This version of reality is additionally reinforced by expert authorization of the proposed solutions, justified by virtue of its recourse to stylistic trappings of technocratic discourses and legitimized as the only logical and rational "voice of consensuality."

This stylistic analysis has hopefully demonstrated that the well-coordinated discursive strategies of EU directivity, as employed in the main instrument of EC exercise power – the directive, construct, legitimize, and perpetuate its hegemony. Since EU hegemony consists in winning of the consent of the regulated by the regulators, one of the key aspects of EU governmentality is the embedding of its directivity in the discourse of expert rationality. Expert rationality is a technocratic order of discourse that legitimizes an ever-growing administration to implement, monitor, evaluate and, if necessary, enforce top-down political, economic, and social decisions. In this study, the properties of expert rationality have been presented in a historical perspective to show the "constructedness" of this discourse, as just one of the competing versions of governmentality. It has also been shown how it is possible to defamiliarize this discursive formation through attention to some textual and stylistic aspects of its verbal instantiations.

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The style of EU directives and the discourse of expert rationality

This article is devoted to the notion of expert rationality, understood as one of the central epistemic regimes of the discourse of the European Union. Expert rationality is instrumental to the legitimization of EU directivity and control of centrally designed political, economic, and social solutions for an integrating Europe. From a philological perspective, however, it is worth investigating how expert rationality tends to be textually realized. Therefore, this article discusses the stylistic properties of the genre of the directive based on Directive 98/79/EC of 27 October 27 1998 on *in vitro* diagnostic medical devices. The analysis focuses on the identification of such stylistic resources and the strategic applications that underpin the ideology of expert rationality.

Keywords: *European Union, political discourse, directive, expert rationality, governmentality*