

# Teaching Global Administrative Law

## *A New Domain for Administrative Law?*

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### 1 Introduction

The international landscape has radically changed in the last 40 years. Many public functions, traditionally exercised by national authorities, are now governed at the international (and supranational) level. Above and beyond the EU Institutions, a variety of bodies and organizations have been created globally: they are often different from the traditional International Organizations (IOs) because of their memberships, their mission, their regulatory powers, and their tools. Every single area of life, from sport to the environment, from health to trade, from food to culture, from labor to transportation, has new global regulatory regimes which produce norms, enact decisions, manage procedures, and settle disputes. These developments are the natural product of economic globalization and of the consequent need to take care of public interests at the international level.

Many of these regulatory regimes overlap. Furthermore, they live in an environment which lacks a Constitution and a Parliament. They are not always the result of multilateral agreements among member States, but have different origins.<sup>1</sup> ICANN, for example, is a private US company, but its decisions spread all over the world. Again, global regulatory regimes can be of a private or public nature and can use a variety of tools and instruments, such as standards, guidelines, private regulation, infra-institutional rules, and soft law. It is the case of the World Bank's operational policies; of the International Labor

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1 Sabino Cassese, *'Lo spazio giuridico globale'*, Roma-Bari, Laterza, 2003; Sabino Cassese, *'Il diritto globale. Giustizia e democrazia oltre lo Stato'*, Torino, Einaudi, 2009; Lorenzo Casini, *'Potere globale. Regole e decisioni oltre lo Stato'*, Bologna, Il Mulino, 2018; Eyal Benvenisti, *'The Law of Global Governance'*, Hague Academy of International Law 2014; Benedict Kingsbury, Nico Krisch, Richard B. Stewart, *'The emergence of Global Administrative Law'*, Law and Contemporary problems, 2005, 68, 15; Benedict Kingsbury, *'The Concept of Law in Global Administrative Law'*, Eur. J. Intern. L., 2009, vol. 20, 29; Maria Rosaria Ferrarese, *'Prima lezione di diritto globale'*, Roma-Bari, Laterza, 2012.

Organization's (ILO) standards; of the WADA's antidoping code, and so on. Sometimes they even have their own dispute settlement system, other times no Courts or Tribunals are instituted inside them. Their decisions affect not only national States, but also civil society, NGOs, national administrative authorities, and private corporations.

Their variety explains why, when we are confronted with this reality, it is necessary to use a different lens. The international law lens continues to be necessary and important: it can explain the relationships between a global regulatory regime and the national States or clarify whether we are before a public classic international organization or something different, or if a dispute settlement system is of a dyadic or triadic nature. But for a more comprehensive look at these new regulatory bodies, we also need other lens: the administrative law lens, for example, can help us understand how they adopt their decisions, how these public powers can be made accountable, how they enforce their decisions, how to force them to open their procedure to participation, and how to demand transparency in their actions.

The more lenses we have, the more we can understand the complexity of this new landscape and its implications in terms of justice: a constitutional law approach, in this discourse, is useful too, because global constitutionalism addresses the foundations and limitations of the principles of political order in the global context, which is essential for discussing democracy and fundamental rights before global powers and institutions. But also sociological and economic analyses are important in understanding the causes of their institution, comprehend effects and consequences on civil society and States' legal orders and adjust or modify them. As Lorenzo Casini says, "indeed, GAL scholarship owes several insights to political science and sociological studies on globalization, as well to works in economics, history, and anthropology, that have been crucial in enabling GAL to understand complex concepts such as regulatory regimes, accountability, legitimacy, and governance more generally".<sup>2</sup>

## 2 Why the Global Order Is Complex and Why It Could Become a Global Disorder

The creation of numerous global bodies and Institutions taking care of different public interests above and beyond the national level generates many

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<sup>2</sup> Lorenzo Casini, 'Global Administrative Law', in Jeffrey L. Dunoff, Mark A. Pollack (eds), *'International Legal Theory: Foundations and Frontiers'*, Cambridge University Press, 2019.

problems, which concern their democratic legitimacy, their mutual relations, the need to build judicial protection mechanisms and remedies, and the necessity to limit abuse of powers.

One of the problems is related to their plural, varied and composite nature: the fact that many different actors have arisen beyond the State for environment, trade, food safety, health, and work regulations means there is a risk that the rules produced by a specific sectoral regime, for example by the World Trade Organization, conflict with those of other sectoral regimes or international regional organizations carrying out the same public functions and taking care of the same interests. The fragmentation of this myriad of regulatory bodies, in fact, generates overlaps and requires rules that can ensure their cohabitation.<sup>3</sup>

These rules of coexistence are not easy to identify and an important role in determining when and to what extent a norm or a decision produced in a given regulatory regime can penetrate a different sectoral regime, or impose itself and prevail over it, is often played by Courts, which are called upon to build the stepping stones between the different regulations.

A significant case is the well-known Kadi decision, in which a Court of an international regional system (the European Union Court of Justice) checked a decision made by an international organization (the United Nation Security Council) to safeguard fundamental rights and founding values recognized at the European level, denying access to its system to UNSC decisions.

The fact that Courts act as guardians of the different regulatory systems, however, can highlight another problem: in particular, if international Courts adopt the choices on the cohabitation of the different regulatory regimes and decide how to balance the many interests at stake, it is necessary to question who the global judges are and what funds their legitimacy for making these choices.

It is the case of Art. XX of the GATT agreements: it establishes that restrictive measures for international trade can be justified to ensure human, animal and plant life and health. When a State imposes a restriction on the trade of a product using this standard, the Dispute Settlement System of the World Trade Organization can establish, applying a proportionality test – in a similar way to those used by administrative Courts in reviewing administrative decisions – what should be the correct balance between trade interests and health interests. In the well-known *Thai Cigarettes* case of 1990, for instance,

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3 Sabino Cassese, *I Tribunali di Babele. I giudici alla ricerca di un nuovo ordine globale*, Donzelli editore, 2009.

the Appellate Body (AB) of the WTO decided that the value at stake, health, could be protected with a less incisive measure on the freedom of trade of cigarettes, concluding that the restrictive measures imposed by the State were illegal and unjustified.

The WTO dispute settlement system, composed of first instance bodies and a Court of Appeal (the panels and the Appellate Body), is considered an advanced judicial system after the juridification process following the Uruguay Round. But, if we look at the procedural rules governing its functioning, we might wonder whether it really is a judicial system in the traditional meaning of the word. If one examines its fundamental features, one may have some doubts: the negotiating-diplomatic component remains significant in the composition and functioning of its adjudication bodies, the procedures are still partially secret, and non-governmental organizations (NGOs) have limited access to procedure. We should ask, therefore, which is the source of its legitimacy and why its decisions – that affect not only States but also civil society, commercial corporations and private citizens – should be accepted and considered legally binding.

More generally, we should consider that different global courts could have different problems of legitimacy depending on their legal regime and source, and that should make their decisions more or less acceptable or binding.

Global Courts are an extremely heterogeneous category:<sup>4</sup> it is necessary not only to distinguish between inter-state Tribunals, as instances for resolving conflicts between States, and supranational Tribunals, as instances for the protection of citizens against the States, but also to recognize that the different judges could have varying degrees of independence regarding the governmental bodies, different compositions, diverse evolution layers, diplomatic or legal traits in defining the dispute, different legal training of their judges and so on.<sup>5</sup>

Some identify three characteristics that international Courts must possess in order to be considered democratically accountable: they should base their decisions on legal arguments (in particular articles 31 and 32 of the Vienna Convention on the Law of Treaties); they should be independent and impartial judges; they should decide through procedures possibly open to third-party participation. At the international level, these traits are often lacking in dispute

4 Laurence R. Helfer – Anne-Marie Slaughter, 'Why States Create International Tribunals: A Response to Professors Posner and Yoo', Calif. L.R., 2005, vol. 93, 3.

5 Joseph H.H. Weiler, 'The geology of International Law – governance, democracy and legitimacy', J. Int. Law, 64, 2004, 547. On supranational and International Courts see also Edoardo Chiti, Bernardo G. Mattarella (eds.), 'Global Administrative Law and EU Administrative Law', Relationships, Legal Issues, and Comparison, Springer, 2011.

settlement bodies. Diplomatic thinking often prevails over the legal one, and independence is not firmly guaranteed, due to both the systems of appointment and the proximity to the interests of the executives; the procedures are often secret, in order to favor negotiation practices and resolutions based on agreements between the parties.<sup>6</sup>

Another factor of complexity – and potential disorder – derives from the variety of the constitutive and organizational structures of the global regimes. Their genesis can be very different, as well as their memberships, with important consequences on the accountability deficit.

Furthermore, they are also heterogeneous from the point of view of their public or private nature and their consequent course of action. Beyond the common drive that generated them – namely economic globalization – regulation beyond the state did not follow a unitary constitutive model, giving birth to public international organizations or private bodies, using tools of the public sphere or exclusively private modules, giving rise to binding or soft law measures.<sup>7</sup>

With regard to their organizational features, for example, we find not only classical international organizations but also transnational bodies made up of administrations (governmental networks), mixed public-private bodies and private institutions. Each global entity corresponds to different accountability regimes and sometimes different forms of action, not necessarily corresponding and symmetrical to the public or private nature of the bodies using them.

Furthermore, they can have different relations with the States, with civil society, with the sectoral national administrations, and with NGOs.

That raises further problems: it is necessary to ensure that a national administration, which is a member of a mixed global network that produces standards or guidelines regulating a specific sector, can be held responsible and accountable for its choices; or again it implies the need to find accountability mechanisms suitable for the action of a private body whose technical rules have legal effects on States, national administrations, and civil society. And it is necessary to understand whether or not the way in which a rule is generated can influence its ability to enter into other legal regimes.

The transnational “networks”, which constitute one of the best suited institutional solutions for coordinating the global action of national administrations,

6 Armin Von Bogdandy – Ingo Venzke, ‘On the democratic legitimation of International Judicial Lawmaking’, German, Law Journal, 2011, vol. 12.

7 Benedict Kingsbury, ‘The Concept of Law in Global Administrative Law’, (n 1), 29; Sabino Cassese, ‘Oltre lo Stato’, Roma-Bari, Laterza, 2007; Lorenzo Casini, ‘Potere globale. Regole e decisioni oltre lo Stato’, (n 1).

are based not on top-of-the-line logic but on the horizontality of relations and can be of both a public and mixed nature. In the first case, the nodes of the network are made up of representatives of national governments or administrations who agree – often through soft law – on the policies and actions which will then be implemented, through binding legal acts, at the national level. The regulation that is produced through the network therefore enters and influences the national systems, and determines the contents of the national law.

For this type of network, accountability mechanisms must be guaranteed, but it is not clear how. If we consider the action produced by a national administration, as it is known, legitimacy can be assured through participatory mechanisms that allow the representation of stakeholders' interests in decision-making procedures; furthermore, a judicial review of the administrative decisions constitutes another important remedy for people who are affected in their legal interests.

On the contrary, when the same national administration participates in a transnational network, the stakeholders have little or no ability to influence the results of the global decision-making process and, usually, there are no remedies available for challenging the final network's action before a judge. The circumstance, therefore, that the position of the national administration is expressed in the network determines a decrease in the power of stakeholders, to the point that some legal systems, such as the United States, impose on their own authority (this is the case, for example, of the Federal Drug Administration in the context of its participation in the International Conference of Harmonization) to open a national participatory procedure in which interested parties can represent their interests and influence the public authority position in the global network.

The problems are even more delicate when the transnational network is mixed public/private. Again, the International Conference on Harmonization (ICH), set up to develop the technical standards for the registration of medicinal products, allows the participation, in addition to some governmental agencies, also of some associations that bring together the main multinational pharmaceutical products. Thus constituted, however, these networks can generate various problems, ranging from the exclusion of subjects representing categories or countries on which their action nevertheless falls, to the capture of regulators by those being regulated, to conflict of interest, to the impossibility of effective control over their action.

Then, again, there is another flaw related to the effectiveness of global powers: it concerns the enforcement of their decisions. The enforcement mechanisms for standards and decisions adopted at a global level continue to be anchored to a negotiation-diplomatic logic, which refers to the bargaining

power of States. Even though the juridification process has led to the institution of Courts and dispute resolution systems, as was the case in the World Trade Organization with the creation of the Dispute Settlement System,<sup>8</sup> the sovereignty of States is still an obstacle to effective global justice, because it imposes a largely power-based logic. Therefore, also in this aspect, it is necessary to recognize the limits of juridification: in other words, if it is true that “the creation of adjudication procedures entrusts the assessment of violations to third parties, and sometimes also recognizes to civil society and individuals a role of promoters of monitoring compliance”, however, “the Contracting States reaffirm the principle of sovereign immunity and the right of equality during the enforcement phase, which remains dominated by the rule of consensus and by horizontal logic”.<sup>9</sup>

With respect to the accountability and enforcement problems generated by global bodies, Global Administrative Law scholars are trying, with some success, to transfer to the action of global powers the typical guarantees and principles existing at the national level in order to increase the democratic legitimacy of the Institutions, to make decision-making procedures more fair and just, to strengthen rationality, proportionality and publicity of final decisions,<sup>10</sup> and to build administrative and judicial review mechanisms.

Obviously, the contribution from administrative law still remains insufficient if we look at the substantial data, since it does not solve the problem of the starting inequality of the parties, particularly evident in the functioning of some regulatory regimes, but it constitutes, together with the instruments of private law, international law and constitutional law, an important key for understanding, rationalizing, and legalizing the global legal space.

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8 R.E. Hudec, ‘*The Role of GATT Secretariat in the Evolution of WTO Dispute Settlement Procedure*’, in AAVV, ‘*The Uruguay Round and Beyond: Essays in Honor of Arthur Dunkel, J. Bhagwati and M. Hirsch, Berlin*’, 1998, 109; Barbara Marchetti, ‘*The WTO Dispute Settlement System: Administration, Court or Tertium Genus?*’, Suffolk Transnational L.R., 2009, vol. XXXII, 3, 567.

9 Barbara Marchetti, ‘*The enforcement of global decisions*’, Sabino Cassese (ed.), ‘*Research Handbook on Global Administrative Law*’, Edward Elgar, 2016; Thomas Nagel, ‘*The problem of global justice*’, Philosophy and Public Affairs, 2005, 33, 113; Joseph H.H. Weiler, ‘*The geology of International Law – governance, democracy and legitimacy*’, (n 5), 547.

10 Sabino Cassese, ‘*Chi governa il mondo?*’, Bologna, Il Mulino, 2012; Carol Harlow, ‘*Global Administrative Law: the Quest for Principles and Values*’, Eur. Journal Int. Law, 2006, vol. 17, 1, 187.

### 3 How to Study a Fragmentated Global Order

As we have already said, in the global order we have a lot of fragmentation and variations in actors, procedures, decisions, relations with State and civil society, accountability mechanisms, and review mechanisms (Courts, dispute settlement system, arbitration). In regulating this institutional scenario, the role of Global Administrative law can be to limit powers.

If we examine the different national administrative law traditions, from civil law to common law countries, there is a common denominator that brings them together: it is the core of rules and principles which governs and limits powers and procedures of the administrative authorities, when they are called upon to ensure the multiple responsibilities of the Modern State. In any administrative law system, there are limits placed on administrative power, which are bound both substantially and procedurally, and there are tools and remedies given to citizens to enforce these rules and to protect their interests.

This nucleus is also fundamental in the newborn global administrative law. In particular, GAL tries to develop procedural guarantees and review mechanisms to ensure legal accountability of international administrations, particularly because these bodies and Institutions exist in a legal space in which – as we highlighted before – neither a Parliament nor a Constitution can effectively limit them.

If global powers cannot be limited through the traditional channel of representative democracy, participatory democracy can partially assure some degree of accountability. The aim is to build decision-making procedures to make them transparent, reasonable, accountable, and open to participation. More specifically, guarantees and principles of administrative law, like the notice and comment procedure, the right to be heard, the duty to give reasons, the impartiality principle, the proportionality principle, the right to access documents, and the transparency principle can counterbalance the lack of representative democracy, contributing to decrease the accountability deficit that characterizes many of these global bodies.

From a methodological point of view, that means, first of all, to go into a deep analysis of different global regulatory regimes, to recognize their features, and to apply mechanisms and general principles to make them accountable and just. But also trying to find common guarantees and rules applicable to all the global administrations to assure a minimum standard of rule of law and global justice.

#### 4 How to Teach GAL?

For many reasons, teaching Global Administrative Law is not an easy task. When we teach national administrative law, or comparative administrative law, we start from an idea of public administration, we examine the public authorities which carry out public functions in a given national system, then we explain the rules and principles that govern their organization and actions, we analyze them from a structural and functional point of view; again, we study the legal regime of administrative decisions, the grounds for their review before the Courts, their contractual activity, their civil liability and, at least broadly, their administrative justice. All these elements differ from State to State, but they are generally supported by a tendentially stable and certain ground: there may be border issues, in identifying what “public authority” is or is not, but the dividing line between administrative function, on the one hand, and judicial and legislative functions, on the other, is quite clear; as well defined is, in its essential core, the object to be investigated.

A stable and certain background is lacking, on the contrary, when we study and teach global administrative law. First of all, it is not easy to draw the same dividing line between the executive function, on the one hand, and the judicial and legislative functions, on the other; secondly, it is not clear, in the global context, “who makes what”, identifying offices and competences.

Furthermore, among the various bodies and Institutions existing beyond the State, we must distinguish between formal treaty-based international or intergovernmental organizations (such as the WTO, the Security Council, the World Bank), transnational networks of domestic regulatory officials (such as the Basel Committee on Banking Supervision), hybrid public/private regulatory bodies (such as the ICH, the World Anti-Doping Agency, ICANN, the Global Fund to Fight Aids, Tuberculosis and Malaria – Global Fund) and private regulatory bodies (such as International Sport Federations, the Society for Worldwide Interbank Financial Telecommunications) to understand to what extent principles and guarantees of Global Administrative Law can be applied.

Teaching global administrative law therefore means, first of all, to analyze and distinguish between the different global regulators, to know how to trace their origins and constitutive powers, to examine their public or private traits, to discover their tools and instruments of action, to understand their relationships with States or national regulators, and to know their sources of law and procedural rules.

It also means to verify how the fundamental principles of administrative law – the duty to give reasons, the principle of transparency and publicity, the

right to be heard, and proportionality and reasonableness principles – can help to make bodies not democratically elected more accountable.

In this perspective, many global administrative law courses have been instituted around the world, not only at the New York University (Institute for International Law and Justice), where this discipline was born (and taught for the first time), but in several Italian Universities like Tor Vergata in Rome, Bocconi in Milan, La Tuscia in Viterbo, Palermo and Trento.

Teaching Global Administrative Law means, conclusively, to analyze the global rule of law and its implications for global powers, through the analysis of the different regulatory regimes and their features. The International Organization for Standardization (ISO), the Codex Alimentarius Commission and the International Conference on Harmonization (ICH) can be considered three useful and paradigmatic case studies for our discussion.

## 5 The International Organization for Standardization (ISO) and the Codex Alimentarius Commission as Global Standard-Setting Bodies

The ISO is probably the most important standard-setting organization operating in the global space. It is an independent non-governmental Institution which adopts non-binding standards which are subsequently transposed in national binding norms because of the World Trade Organization TBT (Technical Barriers to Trade) Agreement. Because this agreement strongly encourages Member States to base their regulations and measures on international standards (mostly from ISO) as a means to facilitate trade, these standards become *de facto* binding. ISO has 164 national members and three membership categories: the member bodies, which are considered the most representative standard body in each country and the only members that have voting rights; correspondent members, which do not participate in standards promulgation but are informed of the work of ISO, even if they do not have their own standard organization; and subscriber members, which are countries with small economies which can only follow the development of standards.

The National standards bodies can be private or public: in western industrial countries they are generally private (like the American National Standards Institute), but consist of members from both the private sector (such as businesses, professional societies, and trade associations) and federal agencies, while in most other countries they are governmental, especially in developing countries. Because of this mixed membership, ISO is a hybrid public-private

organization whose publicness has become more and more pronounced.<sup>11</sup> This increase in the dimension of public law has required more accountability mechanisms, open decision-making procedures, and cooperation with other standardization bodies and institutions like the ILO.

In particular, the study of ISO confirms that much in international standardization involves a balancing of interests. These can be interests of the same kind, like commercial interests of different manufacturers or industries, or interests of different stakeholder groups (such as consumers, environmentalists, or governments). But if standards setting has public policy implications, the way in which these standards are established is crucial; particularly, it becomes fundamental to wonder if all the relevant actors are sitting at the negotiating table, if there is a way to assure reasonable and proportionate decisions and to make the decision-making process transparent; if there is some possibility of reviewing the outcome of the standard-setting procedure by people affected by ISO decisions, and so on.

The same problem can arise with the Codex Alimentarius Commission (CAC). This institution was established in 1963 by FAO and the World Health Organization to establish food standards, guidelines and codes of practice to promote fair practice in food trade and to protect consumer health. These standards constitute a formally non-binding law, but their importance has grown enormously due to the express reference in the international agreements on phytosanitary measures adopted within the WTO. Since these standards constitute for developing countries a condition for trading their products (which otherwise could be rejected for health protection reasons), they are *de facto* binding.

In the formulation of these standards, the participation of numerous stakeholders is established and encouraged, in order to make decisions open, participatory, and accountable.

But, for many reasons, while the industries of rich and developed countries actively participate in the formulation of standards, consumers and environmental protection associations have limited ability to influence the Codex Alimentarius Commission's decision-making procedure. In particular, environmental and consumer associations in poor and developing countries do not have the economic resources or skills needed to exercise effectively their

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11 Eran Shamir Borer, 'Legitimacy without Authority in Global Standardization Governance: the Case of the International Organization for Standardization (ISO)', in Sabino Cassese, Bruno Carotti, Lorenzo Casini, Eleonora Cavalieri, Euan MacDonald (eds.), 'Global Administrative Law: the Casebook', 3rd ed., IRPA, Institute for International Law and Justice, NYU School of Law, 2012, 162.

participation rights. Trivially, these actors cannot afford to pay travel expenses to attend Commission meetings, nor are they able to compete in terms of the expertise necessary to effectively exert some influence on the decision-making process.

An attempt to face this initial imbalance was made by setting up a Fund (the Codex Trust Fund) to encourage the participation of developing countries, but this reform is still not enough to guarantee the effectiveness of participation rights. Furthermore, the tendentially irreversible nature of these standards (once approved according to the consensus principle) makes subsequent changes difficult, even if future greater participation of developing countries had been guaranteed.

Establishing participatory rights and due process can therefore result in an empty and formal exercise of guarantees if the starting position of the Member States (or of the interested parties) is so unequal that it does not allow an effective possibility of influencing the decision-making process. From this point of view, therefore, the traditional guarantees and principles of administrative law, while producing some results, prove to be insufficient and require further efforts to reduce the substantial inequality between rich and poor countries.

## 6 The International Conference on Harmonization (ICH)

The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) was set up in 1991 and was initially composed of three drug regulation authorities (from the US, the EU, and Japan) and R&D pharmaceutical industry associations from the same regions. The purpose of the ICH is to harmonize the technical requirements of drug registration rules concerning the quality, efficacy, and safety of drugs: it has issued more than 50 guidelines so far, which have become *de facto* global standards, adopted not only by its members, but by many companies and countries beyond the ICH regions.

This public-private harmonization network has grown in the last 20 years: its membership consists now of 50 different entities as founding members, regulating members, and observers. Among them, regulating members are now the regulatory authorities of Canada, Switzerland, China, Brazil, Singapore, South Korea, and Turkey.

In adopting its guidelines, the ICH conducts a five-step procedure. In the first step, the expert working group develops a draft guideline, which is released for consultation. Consultations have to take place in each of the regions, according to the rules established for any regulatory authority, but comments may

also be submitted directly to the ICH Secretariat. After all comments have been transferred to the working group, a consensus-building process takes place. If a consensus is reached, the guideline will be submitted to the regulatory members of the Assembly, who have to reach a sufficient consensus. After that, the harmonized guideline moves immediately to the final step of the process, which is regulatory implementation. They are legally non-binding, but they all have to be implemented domestically by the member regulatory authorities.

In her research on ICH, Berman highlights three different critical aspects in ICH functioning. The first issue is related to the (in)adequacy of the guideline development procedure: even though the (regional) consultation procedures can assure participatory rights, and hence some accountability, nothing is established about how input can influence output, in the absence of any duty to give reasons for the acceptance or rejection of comments, and with the lack of appeal mechanisms at the transnational level.

A second issue concerns the inclusion of the pharmaceutical industry in the harmonization process: while its inclusion can create advantages for the effectiveness of the process, also because of expertise brought by these private actors, on the other hand, it can also raise concerns around regulatory capture: Berman observes that “while public interest stakeholders, such as patients organizations, may comment on drafts, they are not at the table with the pharmaceutical industry and the regulators when these drafts are being developed in the working group sessions. Indeed, according to some accounts, ICH guidelines promote faster and cheaper drug development that benefits the industry, but do so at the expense of patient security. This raises the question of whether NGOs representing patients (or other public interests) should be allowed at the table”.

A third issue is related to the global effects produced by ICH guidelines. They do not affect only the ICH countries, but have become *de facto* global standards that are adopted or relied on by non-ICH members. Their impact goes beyond the ICH membership and their content reflects the interests of developed and rich countries (and of their industries) without taking into account the interests of poor and developing countries. More specifically, as Berman stresses, “the problem manifests itself when local industries in non-ICH countries follow these guidelines that were never tailored to their needs” because “the guidelines often reflect a standard that is unattainable or unaffordable, while their high or complicated requirements are not necessarily justified from a public health perspective”.<sup>12</sup>

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12 Ayelet Berman, ‘Public-private Harmonization Networks: the Case of the International Conference on Harmonization (ICH)’, Sabino Cassese, Bruno Carotti, Lorenzo Casini,

Addressing this problem of “regulatory capture” and participatory rights of non-ICH countries and stakeholders means to find new solutions in relation to governance mechanisms and guideline development procedure: in doing this, global administrative law principles and guarantees can offer some help to make global powers more just and legitimate. But it is not enough.

As Nagel observed in *The problem of global justice*, “If we look at the historical development of conceptions of justice and legitimacy for the nation-state, it appears that sovereignty usually precedes legitimacy. First there is the concentration of power; then, gradually, there grows a demand for consideration of the interests of the governed, and for giving them a greater voice in the exercise of power. It is the existence of concentrated sovereign power that prompts the demand, and makes legitimacy an issue”.<sup>13</sup>

## 7 Global Powers, Juridification Process and Rule of Law

From what has been said above, it can be concluded that the composition and identity of the decision-maker tell us a lot about the global institution, its functioning and its logic dynamics: they reflect, in other words, the forces at play and the technical or political nature of the regulator. Of course, the question of its independence is also fundamental, looking at the independence from both the Member States and the regulated parties.

Even the appointment mechanisms and the background – diplomatic or legal – of officials sitting in the Boards or panels shows the degree of juridification of the international organization or, on the contrary, the prevalence of diplomatic logic:<sup>14</sup> if the dispute settlement mechanism, for example, has a dyadic structure and operates on a diplomatic basis, the final decision escapes the sphere of legal dimension and remains anchored to negotiation between the parties, privileging the contractual powers of the conflicting parties.

If, on the contrary, the settlement of the dispute between the contracting parties is entrusted to third parties (triadic model), the latter will tend to be impartial and will seek the right and just solution according to law.

The constant demand for predictability and certainty in international relations, especially in trade, has strengthened and incremented – as is well

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Eleonora Cavalieri, Euan MacDonald (eds.), *Global Administrative Law: the Casebook*, 3rd ed., IRPA, Institute for International Law and Justice, NYU School of Law, 2012, 228.

13 Thomas Nagel, *The problem of global justice*, (n 8), 113.

14 Joseph H.H. Weiler, *The geology of International Law – governance, democracy and legitimacy*, (n 5), 547.

known – the juridification and judicialization of the global space, producing in sectoral regulatory regimes a division of tasks between those who make decisions (with the rule of consensus or according to more informal procedures) and those who review these decisions, whether with the more developed features of a real Court or with those of a compliance committee.

Equally important in understanding the nature of the global institution or organization is the presence or absence of rules governing the decision-making procedure: however, it remains difficult, at the international level, to obtain information on what is about to be decided, to guarantee transparency for the stakeholders, to ensure that interested parties have a right to be heard, and to have adequate investigations before the final decision. On the one hand, it is difficult because many procedures are de-formalized and do not lead to formal and individual decisions, as the regulatory authorities use much more frequent informal negotiation and diplomatic agreements.

On the other hand, transparency and publicity of decision-making processes and judicial control are lacking in a context of extreme technical complexity.

Consider once again the International Conference on Harmonization: even though private citizens and NGOs have the standing to do so, it is clear what difficulties these subjects would face in controlling information or making effective participation within the standard-setting procedure of the transnational network. Or in influencing the outcome of the procedure approved by the Basel Committee for setting financial or commercial standards with highly specialized content.

Looking at these global regulators, an effort is needed to adapt the traditional rules and principles of administrative law to a reality which, due to its complexity, cannot be read according only to traditional categories or a specific legal discipline. This is why the Global Administrative law approach cannot be – as we already said at the beginning of this article – exclusive but has to be inclusive.<sup>15</sup> Through the GAL lens, global regulators have first of all to be described and analyzed, and then form the ground for a more general theory. But such approach has to be combined with analysis conducted also through the lens of international and private law, together with historical, economic and sociological perspectives.

As Lorenzo Casini highlights, “GAL and its scholarship may continue to fruitfully face challenges launched by globalization if they remain inclusive and consistent with its origins, and do not claim to offer solutions or responses,

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15 L. Casini, ‘Global Administrative Law’, (n 2).

but rather frame problems and raise questions that are able to illustrate and unpack such ambiguities”.<sup>16</sup>

Teaching GAL means, first of all, moving from this methodological premise.

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