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Reported by Alicia Isabel Saavedra Bazaga in the context of the TARN Conference on *Constitutionality, Powers and Legitimacy of EU Agencies or Agency-Like Bodies*, held in Florence

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EU Agencies and Transparency

Dominic Way began by providing an historical analysis of EFSA and EMA evolution in terms of “transparency” policies. Regarding EFSA, he noted that the agency embraced transparency since its inception providing operational transparency during its early years’ policies. From 2004 to 2009, EFSA had to face new challenges derived from the unpopularity of GM crops in Europe. Notwithstanding, EFSA made efforts to become more transparent, which was viewed positively by the European publics. After 2010, more process transparency was introduced in order to address concerns about conflicts of interest. Dominic also mentioned the new scientific data warehouse project, meant to contribute to scientific progress. However, professor Way noted that higher transparency may not always be considered a guarantee of trust in the Agency, but a tool often used by NGOs to help destroy public trust toward EFSA.

Regarding EMA, although the lack of transparency was not the reason for the creation of the agency, transparency was welcomed by the agency since its inception. The early transparency years were evaluated very positively by stakeholders and interested parties. After 2010 events, and Ombudsman recommendations, a lot of external pressure was put on the agency to become more transparent. EMA started then to act more strategically. Such calls for

transparency have resulted in an unprecedented level of access to EMA's information that benefits many sectors.

Thus, both agencies were committed to transparency since their inception and continued to introduce transparency enhancing policies. He noted that there are two types of transparency that co-exist: on the one hand, the idea of fishbowl transparency, which is cheap and quick policies to implement. On the other hand, transparency as information explained, that is reasoned transparency policies. In this context the presentation raised questions pertaining to conditions which can be held to satisfy the transparency requirement, type of regulations required and the impact on resources.

Regulatory decisions are made based on information submitted to EU regulatory agencies by the private sector and that information is made available to the wider public in order to comply with the requirements in EU legislation. However, the "ownership paradigm" may keep some information unavailable to the public if the agency finds that its disclosure might harm interests protected under EU legislation. What's the problem? The main argument presented by Dr. Korkea-aho was that the emerging ownership paradigm is inherently in tension with the EU's public access regime and the right of the general public to know the reasons behind EU policy-decisions. In this context further questions remain to be answered: what sort of protection the agencies' 'space to think' and internal decision-making require? Taking into account that the Regulation 1049/2011 says that third parties must be consulted before granting access to certain documents. What role should companies play in agencies information? Who should receive the benefit of access to information? Can the use of information in public debates be limited?

Most problematic part: do copyright rules matter? In relation to this question, Dr. Korkea-aho pointed to the notion of "shared ownership" of information to indicate that regulation has become a negotiation process where companies which legally own the copyright of the data have come to assume that they can exercise a veto over how "their" information is made publicly available. This opens up the questions of whether it is time for the EU legislature to consider access to information based on research purposes or specify the role of companies in evaluating commercial interest?

Consequently this opens up the questions of what is the "public interest" of agency action, where this notion remains understudied. Secondly, the function of "public access" is uncertain. Does it go beyond the legitimacy of EU agencies?

The presentation of professor Douma revolved around the question of how case law contributes to enhancing transparency. The CJEU has been decisive in underlining the rationale behind openness and transparency as well as in establishing the boundaries of the exceptions. In the light of interests such as protection of personal data, commercial interests and intellectual property rights, aspects of transparency and independence of EU agencies have been the focus of recent disputes. Has the CJEU struck a balance in its recent judgements that contributes to building trust in the scientific work by EU

agencies? One of his comments was that when it comes to transparency, EU agencies do not really comprehend the sense in which the institutions are looking for information.

Reference was made in the presentation to the Gyphosate Case T-545/11, on the process leading to the renewal of the licence for the named active substance by the European Commission. In questions regarding transparency and independence of the responsible agency and national bodies involved, the use of precautionary principle was suggested by critical experts due to the potential risks for human health of the substance. EFSA reached the conclusion that the substance posed no potential risks after having access to non-disclosed industry studies on the grounds of the original licence. The Commission provided such access because the General Court ordered it to do so, which, thus, indicates the reflex to withhold information from the public. The judgment has been appealed (by NGOs) and the judgment by the Court of Justice will be delivered on 23 November 2016 (case C-673/13 P). As professor Douma stated, we will see if there is still a narrow approach to access to info or not.