EUROPEAN PARLIAMENT 2009 - 2014

Committee on Civil Liberties, Justice and Home Affairs

1.4.2011

WORKING DOCUMENT

on the Annual Report on public access to documents (Rule 104(7) of the Rules of Procedure) for 2009-2010

Committee on Civil Liberties, Justice and Home Affairs

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C. Application of Regulation (EC) No 1049/2001 by agencies (case of EMA) and other institutions (case of EIB)

9. The unclear position after Lisbon, as **the current Regulation (EC) No 1049(2001) does not provide a proper framework, as it does not apply clearly to all the institutions, bodies, offices and agencies, as well as it does not make clear its relationship with other legal acts**, can be presented by the case 2493/2008/(BB)TS[1] against EMA (European Medicines Agency) regarding the denial of disclosure of adverse reaction reports. The case is also a good illustration how the involvement of the Ombudsman can cause a change in a wrong administrative practice. The Ombudsman clearly pointed that EU bodies should not act only in a passive way, but are bound by a proactive approach as well, meaning that they have to put the material into the public domain, whereby the two approaches are not alternatives but support each other. Regulation 726/2004[2] establishing EMA provides that Regulation 1049/2001 shall apply to documents held by the Agency (Article 73), while at the same time the agency has to make data on reports on adverse reactions publicly accessible under certain conditions (Article 26) and give the public appropriate levels of access to databases on adverse reactions (Article 57(1)(d)). The Agency understood the connection between the two legal acts in a way that Regulation 726/2004 derogated from the general principles of Regulation 1049/2001; it interpreted the term "documents" in such a way that data contained in an electronic storage system would be excluded; and raised the exemption of "unreasonable administrative burden". The Ombudsman refused such reasoning and explained that the specific regulation deals with the proactive approach, while at the same time the principles of Regulation 1049/2001 have to be fully applied. At the same time he refused the definition of document provided by the Agency stating that: *"82. The Ombudsman does not consider that the fact that the data stored in the EudraVigilance database may be made more secure through encryption... alters the fact that the contents of the database are 'documents' within the meaning of Article 3 of Regulation 1049/2001. The Ombudsman has consistently stated that 'content stored in electronic form' covers identified and re-identifiable sets of information contained in a database. Encrypted data will be 'a re-identifiable set of information' provided the agency can retrieve those data using the information technology tools at its disposal."*

10. Neither was the agency successful with its third claim regarding non-proportional administrative burden, whereby the Ombudsman stated: *"88. First of all, the Ombudsman recalls that Regulation 1049/2001 does not contain any exceptions, according to which the amount of administrative work would justify a refusal of access to documents... 90. ... The principle of proportionality cannot, on its own, stand as a reason to refuse a request for access to documents. The reasons for a refusal of access to documents must exclusively be based on the exceptions of Regulation 1049/2001. At most, if it were proven to apply, the principle of proportionality would only explain why justifications based on a concrete and individual examination of each of the documents could be replaced by justifications relating to a series of documents... 93. Regulation 1049/2001 contains, in any case, a procedural provision which can be applied to reconcile a situation where the administrative work caused to the institution would be disproportionate (namely, Article 6(3) of Regulation 1049/2001)."*[3]

[1] http://www.ombudsman.europa.eu/en/cases/draftrecommendation.faces/en/4810/html.bookmark

[2] OJ L 136, 30.4.2004, p. 1.

[3] A similar problem can be illustrated by a recent request by ChemSec regarding documents held by ECHA containing information on firms and quantities of substances on the SIN (Substitute It Now) list as foreseen by

Upon the Ombudsman's remarks in this case as well as in case 2560/2007/BEH[1] regarding clinical study reports and the protection of commercial interest EMA changed its policy in 2010.[2]

11. A more difficult question relates to the **proper relationship between the Treaty, Regulation (EC) No 1049/2001 and Regulation (EC) No 1367/2006 on the application of the Aarhus Convention** on Access to information, Public Participation and Decision-making and access to justice in Environmental Matters,[3] whereby the last one is stating that regarding commercial interest an overriding public interest in disclosure shall be deemed to exist where information requested relates to emissions into the environment (Article 6). In contravention with such a specific formulation in a recent case lodged by Bankwatch, regarding access to documents on carbon dioxide that it received in the framework of a project, the EIB stated that is not bound by Regulation (EC) No 1049/2001 as the matter did not concern its administrative tasks (as stated in Article 15(3) TFEU).[4] Here a clear definition of "administrative tasks" would be necessary, as well as an even more clear delimitation of grounds for refusal between the two mentioned regulations above.

D. Classified information - interinstitutional and individual aspects

12. Several **interinstitutional problems** on access to documents could be identified regarding access to **classified documents**, for example: the evaluation on the EU-China Rights Dialogue, the EU accession to the ECHR, accession to Schengen by Bulgaria and Rumania, etc. The issue raises on one hand the problem of interinstitutional cooperation, especially regarding the conclusion of international agreement for which after the entry into force of the Lisbon Treaty the Parliament has to give its consent. According to Article 218(10) TFEU the Parliament *"shall be immediately and fully informed at all stages of the procedure"*. On the other hand it raises the question of the access by the individual in the context of proper classification and possible over-classification, as such documents are not accessible to the general public. One of the main problems of the current system is the lack of a common definition of the term "*EU classified documents*" as well as their handling. In 2001 a widely criticised compromise was reached introducing Article 9 of Regulation 1049/2001 that serves as a kind of mutual recognition of different classifications. Such a situation is unacceptable as it presents **a grave breach of the rule of law** (Preamble of Charter, Articles 2 and 6 TEU) **and the principle of legal certainty** according to the theory of hierarchy of legal norms (constitution, law in accordance with the constitution and lower norms in accordance with legislation). At the moment we have a situation where we are operating at level 3 (each

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the REACH Regulation. Such a request (from 1 December 2010) has been refused (22 December 2010) whereby ECHA was reasoning that the disclosure would undermine the commercial interest of the companies. An unsuccessful confirmatory application was lodged on 21 January 2011 on which it was finally decided on 4 March 2011.

[1] http://www.ombudsman.europa.eu/cases/decision.faces/en/5459/html.bookmark
See also complaint 3106/2007/TS -
http://www.ombudsman.europa.eu/cases/draftrecommendation.faces/en/10071/html.bookmark#_ftnref14.

[2] http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/11/WC500099473.pdf

[3] OJ L 264, 25.9.2006, p. 13.

[4] Any possible inconsistence between the Treaties and the Aarhus convention would be much more difficult to solve, as the Aarhus convention is not above the Treaties.

institution has its own rules, or interinstitutional agreements are concluded), but **no common EU definition and categorisation of classified documents at the level of a law/proper legislation exists**. This means that between the primary level of the Treaties and the third level of internal and interinstitutional rules a proper legislative framework is missing in violation of Article 15(3), second subparagraph - a proper transparent legislative procedure on classification categories where the citizens would be democratically represented through their elected representatives has never been conducted. If the situation could be tolerated perhaps before, it is unacceptable under the new Lisbon Treaty introducing an obligatory Charter of Fundamental Rights, as well as much stricter and comprehensive provisions in the Treaties (importance of openness and the participation of citizens - Articles 9-12 TEU and the new provisions on access to documents and good governance - Articles 15 and 298 TFEU).

13. In that regard the new IIA between the Parliament and the Commission (see European Parliament decision of 20 October 2010 on the revision of the framework agreement on relations between the European Parliament and the European Commission (2010/2118(ACI), Annex 2)[1] can be welcomed as it provides extensively categories of classification, as well as procedures for handling of such information between the two institution. At the same time it does not apply to the Council. In that regard the negotiation mandate regarding **accession of the EU to the ECHR** provides a good illustration of the problems encountered by the Parliament. On 17 March 2010 the Commission submitted draft negotiating directives for the ECHR Accession Agreement, classifying those as "RESTRAINT EU". The documents were made available to the Members of the AFCO, LIBE and DROI Committees in the secure room of the Parliament. On 4 June 2010 the JHA Council adopted a Council decision authorising the negotiations, whereby the Annex providing the text of the negotiating directives was classified as "restraint" and not made public.[2] Upon request of the LIBE and AFCO Committees the Council agreed to make the document available but just to a limited number of Members and only in the premises of the Council, taking as precedence the 2002 IIA[3] between the Parliament and the Council, governing access by the Parliament to sensitive information of the Council in the field of security and defence policy. The same problem arose in the framework of the Schengen evaluation regarding Bulgaria and Romania, as well as in the framework of the EU-China Human Rights dialogue (SEC 1906.doc), whereby the 2002 IIA between the Council and the Parliament does not include the category "restraint".

12. Such practice by the Council is unacceptable in the framework of the Lisbon Treaty and the new prerogatives given to the Parliament, as well as from the perspective of democratic accountability. At the same time **the classification appears sometimes very questionable, particularly regarding documents referring to human rights**. The negotiating mandate for the ECHR appears to be a good example, where no strategic negotiations are at stake, but the whole procedure is meant to solve the problem of technical feasibility of the existing ECHR and EU judicial systems. Further, the rules regarding classification have **direct influence on access to documents by the public**. In that regard rules on access to classified documents (including interinstitutional rules) are supporting (flanking) measures for access to documents.

[1] OJ L 304, 20.11.2010, p. 47.
[2] It has been partly declassified in 2011:
http://register.consilium.europa.eu/pdf/en/10/st07/st07668-ex02.en10.pdf.
[3] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2002:298:0001:0003:EN:PDF.

Conclusions

Due to all mentioned in working documents 3 and 4 the following should be highlighted:

- a new common legislative framework on access to documents that is fully in compliance with the Treaties should be adopted;
- legislative transparency, especially in the framework of Council working groups, should be fully established;
- a detailed evaluation of the time-frames of handling applications for access to documents should be conducted, and strict consequences introduced in case of violating such time-frames;
- Regulation (EC) No 1049/2001 (as long as a new legislative framework is not agreed) should fully apply to all institutions, bodies, offices and agencies in accordance with the Treaties; any special procedures envisaged by the Treaties (for example, regarding the ECJ and EIB) should be interpreted strictly demanding clear definitions (for example, regarding "administrative task");
- a general legislative framework on classified documents should be established; interinstitutional cooperation should be based on such a general framework further developed by IIAs;
- the prerogatives of the Parliament should be fully respected (in the framework of legislation and international agreements).