

Brussels, trade.a.3.dir(2016)7548430

By registered letter with acknowledgment of receipt:

Subject: Your application for access to documents – Ref GestDem No 2016/1096

Dear Mr Harmsen,

We refer to your application of 4 March 2016 for access to documents under Regulation (EC) No $1049/2001^1$ ("Regulation 1049/2001"), registered on 7 March 2016 under the above mentioned reference number.

Please accept our apologies for the delay in providing you with this reply, which is mainly due to the high number of detailed and simultaneous requests for access to documents related to chemicals being dealt with by DG Trade. Moreover, we had to consult other services of the Commission on some of the documents identified that originate from them.

1. SCOPE OF YOUR REQUEST

You requested access to the following documents dated between January 2015 and 5 March 2016:

"all correspondence (including emails), agendas, minutes of meetings and any other reports of such meetings where the (science-based) criteria for endocrine disruptors (also spelled: disrupters) were discussed/mentioned between DG TRADE officials and officials/representatives of (one or more of) the following DGs/organisations: Secretariat-General; DG AGRI; DG SANTE; DG GROW; US EPA; US government; AmCham;

Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 20 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43.

CropLife; ACC; ECPA; Cefic; Burson-Marsteller; BASF; Bayer; Dow Chemicals; Monsanto; DuPont".

Further to your request, we have identified 31 documents which fall under the scope of your request. A list of these documents is enclosed in Annex 1. For each of the documents the list provides a description, and indicates whether parts are withheld and if so under which ground pursuant to Regulation 1049/2001.

2. ASSESSMENT AND CONCLUSIONS UNDER REGULATION 1049/2001

In accordance with settled case law, when an institution is asked to disclose a document, it must assess, in each individual case, whether that document falls within the exceptions to the right of public access to documents set out in Article 4 of Regulation 1049/2001. Such assessment is carried out in a multi-step approach: first, the institution must satisfy itself that the document relates to one of the exceptions, and if so, decide which parts of it are covered by that exception; second, it must examine whether disclosure of the parts of the document in question pose a "reasonably foreseeable and not purely hypothetical" risk of undermining the protection of the interest covered by the exception; third, if it takes the view that disclosure would undermine the protection of any of the interests defined under Articles 4.2 and 4.3 of Regulation 1049/2001, the institution is required "to ascertain whether there is any overriding public interest justifying disclosure".3

In view of the objectives pursued by Regulation 1049/2001, notably to give the public the widest possible right of access to documents, 4 "the exceptions to that right [...] must be interpreted and applied strictly".⁵

Having carefully examined the documents identified above in light of the applicable legal framework, I am pleased to release documents 1 to 22, 29 and the cover email in document **30**. Copies of these documents are enclosed.

Document 13, the part of document 11 which falls under the scope of your request, as well as the annexes to documents 1, 3, 4, 5, 8, 9, 12, 14 to 22 and 29, are fully released. As regards documents 6, 10, 19, the annex to document 2 and the cover emails in documents 3 to 5, 8, 9, 12, 14 to 18, 20 to 22, 29 and 30 only names and other personal data have been removed pursuant to Article 4.1(b) of Regulation 1049/2001 and in accordance with Regulation (EC) No 45/2001 ("Regulation 45/2001").6 Hence, the main content of these documents is accessible. In documents 1, 2, 7, in addition to personal data, other information was redacted pursuant to Article

Judgment in Sweden and Maurizio Turco v Council, Joined cases C-39/05 P and C-52/05 P. EU:C:2008:374, paragraph 35.

Id., paragraphs 37-43. See also judgment in Council v Sophie in 't Veld, C-350/12 P, EU:C:2014:2039, paragraphs 52 and 64.

See Regulation (EC) No 1049/2001, recital (4).

⁵ Judgment in Sweden v Commission, C-64/05 P, EU:C:2007:802, paragraph 66.

Regulation (EC) No 45/2001 of the European Parliament and the of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data, OJ L 8, 12.1.2001, p. 1.

4.1(a) third indent concerning the protection of the public interest as regards international relations.

Please note also that parts of documents 4, 7, 8, and 9 to 11, fall outside the scope of your request as they concern subject matters different from endocrine disruptors.

As regards <u>document 26</u>, we refer to the assessment of this document made by DG SANTE in the reply to your request for access to documents GestDem 2016/1133 (Ares(2016)2427348). Therefore, this document will not be part of the assessment contained in this letter.

I regret to inform you that documents 23, 24 25, 27, 28, 31 and the annexes to document 30 cannot be disclosed as they are entirely covered by the exceptions set out in Article 4.3 first subparagraph of Regulation 1049/2001. These documents contain also personal data protected under the exception of Article 4.1(b).

The reasons justifying the application of the exceptions are set out below in Sections 2.1, 2.2 and 2.3. Section 3 contains an assessment of whether there exists an overriding public interest in the disclosure.

2.1. Protection of the public interest as regards international relations

Article 4.1(a) third indent, of Regulation 1049/2001 provides that "[t]he institutions shall refuse access to a document where disclosure would undermine the protection of: the public interest as regards: [...] international relations."

The Court of Justice has acknowledged that the institutions enjoy "a wide discretion for the purpose of determining whether the disclosure of documents relating to the fields covered by [the] exceptions [under Article 4.1(a)] could undermine the public interest". More specifically, the General Court has stated that "it is possible that the disclosure of European Union positions in international negotiations could damage the protection of the public interest as regards international relations" and "have a negative effect on the negotiating position of the European Union. It added that "in the context of international negotiations, unilateral disclosure by one negotiating party of the negotiating position of one or more other parties [...] may be likely to seriously undermine, for the negotiating party whose position is made public and, moreover, for the other negotiating parties who are witnesses to that disclosure, the mutual trust essential to the effectiveness of those negotiations."

Document 1 is the internal report of a conference on endocrine disruptors which took place on 1 June 2015, to which staff of DG Trade participated. Part of a passage at page 2 of the report has been deleted as it contains an internal commentary on an issue which is not currently part of the TTIP negotiations. Putting in the public domain comments and speculations made by individual members of the Commission staff in earlier stages of the TTIP negotiations, would generate confusion and misunderstanding among our trading partners, including the US, regarding the position of the EU on specific topics. In particular, the redacted passage could give the wrong impression that the EU would be ready to discuss a matter in the context of

Judgment in Council v Sophie in't Veld, C-350/12 P, EU:C:2014:2039, paragraph 63.

⁸ Judgment in Sophie in't Veld v Commission, T-301/10, EU:T:2013:135, paragraphs 123-125.

⁹ *Id.*, paragraph 126.

ongoing or future trade negotiations on which in reality it is not willing to negotiate. This would weaken the credibility of the EU and may lead our negotiating partners to potential misleading conclusions. It would also undermine the balance achieved so far in the negotiations with the US and compromise the position of the EU in the context of upcoming negotiations with other major trading partners which have an interest on the subject-matter of chemicals.

Document 2 is the report of a meeting with the European Crop Protection Association (ECPA) on 28 April 2015. Three sentences in the last bullet point have been withheld as they contain opinions and views of individual staff members in relation to the objectives and results that the TTIP negotiations should achieve in their view, and information which indirectly reveals the position of certain relevant actors in the negotiations. The disclosure of personal views and positions on issues on which an official position of the Commission has not yet been adopted may weaken the credibility of the Commission in the negotiations as well as lead the EU's negotiating partners to potential misleading conclusions. Furthermore, the disclosure of the position of relevant counterparts in the negotiations would undermine in a reasonably foreseeable manner the climate of confidence and trust between the EU and its negotiating partners. Similarly, document 7 is the internal report of a meeting of the Committee on Sanitary and Phytosanitary (SPS) Measures in the World Trade Organisation (WTO). One sentence has been removed as it contains internal views and impressions of the author of the report concerning the position of the US within the Committee.

Disclosing these passages would jeopardise the mutual trust between the EU and US negotiators which is key to the success of any negotiation, particularly a politically sensitive one like the TTIP. Preserving a certain level of discretion and special care in handling documents that reflect the positions of our negotiating partners and internal views, impressions and characterisations of these positions is essential in order not to jeopardise the results achieved so far in the discussions. Negotiating partners need to be able to rely on each other's discretion and to trust that they can engage in open and frank exchanges of views without having to fear that that these views and positions may in the future be exposed. As the Court recognised in Case T-301/10 *in't Veld v Commission*, "[...] establishing and protecting a sphere of mutual trust in the context of international relations is a very delicate exercise." If the redacted information were to be disclosed, the US as well as other negotiating partners of the EU may fear that in the future their positions would be revealed and they may as a result refrain from engaging with the EU.

2.2. Protection of privacy and integrity of the individual

Article 4.1(b) of Regulation 1049/2001 provides that "[t]he institutions shall refuse access to a document where disclosure would undermine the protection of: [...] privacy and the integrity of the individual, in particular in accordance with Community legislation regarding the protection of personal data."

The Court of Justice has ruled that "where an application based on Regulation 1049/2001 seeks to obtain access to documents containing personal data" "the provisions of Regulation 45/2001,

Judgment in Sophie in't Veld v European Commission, T-301/10, EU:T:2013:135, paragraph 126.

of which Articles 8(b) and 18 constitute essential provisions, become applicable in their entirety". 11

Article 2(a) of Regulation 45/2001 provides that "personal data' shall mean any information relating to an identified or identifiable natural person [...]". The Court of Justice has confirmed that "there is no reason of principle to justify excluding activities of a professional [...] nature from the notion of 'private life'" and that "surnames and forenames may be regarded as personal data", 13 including names of the staff of the institutions. 14

According to Article 8(b) of this Regulation, personal data shall only be transferred to recipients if they establish "the necessity of having the data transferred" and additionally "if there is no reason to assume that the legitimate interests of the data subjects might be prejudiced". The Court of Justice has clarified that "it is for the person applying for access to establish the necessity of transferring that data". 15

Documents 1 to 10, 12, 14 to 25, and 27 to 31 all contain names and other personal information that allows the identification of natural persons.

I note that that you have not established the necessity of having these personal data transferred to you. Moreover, it cannot be assumed, on the basis of the information available, that disclosure of such personal data would not prejudice the legitimate interests of the persons concerned. Therefore, these personal data shall remain undisclosed in order to ensure the protection of the privacy and integrity of the individuals concerned.

However, names of senior managers of the Commission at Director level or above, and names of senior managers of private entities (e.g. Director, President, Vice-President) are disclosed.

2.3. Protection of the institution's decision-making process

Article 4.3 first subparagraph of Regulation 1049/2001 provides that "[a]ccess to a document, drawn up by an institution for internal use or received by an institution, which relates to a matter where the decision has not been taken by the institution, shall be refused if disclosure of the document would seriously undermine the institution's decision-making process, unless there is an overriding public interest in disclosure."

The decision-making process for the definition of the endocrine disruptors criteria is still ongoing despite the Commission having adopted and published on 15 June 2016: a Communication to the European Parliament and Council on endocrine disruptors, ¹⁶ an Impact

Judgment in *Guido Strack v Commission*, C-127/13 P, EU:C:2014:2250, paragraph 101; see also judgment in *Commission v Bavarian Lager*, C-28/08 P, EU:C:2010:378, paragraphs 63 and 64.

Judgment in *Rechnungshof v Rundfunk and Others*, Joined cases C-465/00, C-138/01 and C-139/01, EU:C:2003:294, paragraph 73.

Judgment in Commission v Bavarian Lager, C-28/08 P, EU:C:2010:378, paragraph 68.

¹⁴ Judgment in *Guido Strack v Commission*, C-127/13 P, EU:C:2014:2250, paragraph 111.

Judgment in C-127/13 P *Guido Strack v Commission*, EU:C:2014:2250, paragraph 107 and judgment in C-28/08 P *Commission v Bavarian Lager*, EU:C:2010:378, paragraph 77.

Communication from the Commission to the European Parliament and the Council on endocrine disruptors and the draft Commission acts setting out scientific criteria for their determination in the context of the EU

Assessment defining the criteria for identifying endocrine disruptors,¹⁷ and two draft acts relating to the implementation of, respectively, the plant protection and biocidal products regulations.¹⁸ These proposals and communications do not constitute autonomous decision-making processes ending with their publication, but are inextricably linked and are part of a larger decision making process which involves representatives of other EU institutions. The process of adoption of these acts, which will close the relevant decision-making processes, is fully ongoing as a final decision has not yet been adopted and discussions are still taking place between the Commission and the Member States.¹⁹

The internal discussions on the topic of endocrine disruptors have been characterised by a significant degree of difficulty and complexity both before and after the publication of the proposed draft acts. This is due to the social, economic and political implications of the Commission's proposals, the fact that there are still debates within the scientific community regarding the definition of endocrine disruptors, and the existence of different views and concerns within the Commission, other EU institutions and among the Member States.

At the same time, the Commission has been, and still is, the target of external pressure from conflicting interests of various stakeholders. These include the chemical industry both in Europe and abroad, civil society and the NGO community, consumer groups, Member States, members of the European Parliament and third countries. This external pressure is not hypothetical but is genuine and tangible. For instance, the Commission has been a target of criticism and concerns both by civil society²⁰ and the chemical industry.²¹ The Commission has also faced litigation before the General Court on the endocrine disruptors file,²² and there are indications that in the future the Commission may face further legal challenges before the EU Courts.²³ Considerable pressure originated also from the European Parliament.²⁴ Finally,

legislation on plant protection products and biocidal products, COM(2016) 350 final, available at http://ec.europa.eu/health/endocrine_disruptors/docs/com_2016_350_en.pdf.

Impact Assessment defining criteria for identifying endocrine disruptors, SWD(2016) 211 final, available at http://ec.europa.eu/health/endocrine_disruptors/docs/2016_impact_assessment_en.pdf.

See Draft Commission delegated Regulation setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012, C(2016) 3752 project, available at http://ec.europa.eu/health/endocrine_disruptors/docs/2016_bpcriteria_en.pdf; and draft Commission Regulation setting out scientific criteria for the determination of endocrine disrupting properties and amending Annex II to Regulation (EC) 1107/2009, C(2016) 3751 project, available at http://ec.europa.eu/health/endocrine_disruptors/docs/2016 pppcriteria en.pdf.

For more details about the process, and minutes of meetings between the Commission and the Member States representatives, see at http://ec.europa.eu/health/endocrine_disruptors/next_steps_en.

See *e.g.* https://corporateeurope.org/food-and-agriculture/2015/05/toxic-affair-how-chemical-lobby-blocked-action-hormone-disrupting; https://www.ciel.org/Publications/ToxicPartnership Mar2014.pdf; https://www.democracyforsale.eu/sites/lobbyawards/files/CEFIC-ACC%20nomination%20background.pdf.

See also *e.g.* http://www.euractiv.com/section/health-consumers/news/pesticide-industry-critical-of-endocrine-disruptors-criteria/.

Judgment of the General Court (Third Chamber) of 16 December 2016 in case *Sweden v Commission*, Case T-521/14, (ECLI: EU:T:2015:976).

In a presentation at a recent event in September 2016, Sweden openly criticised the Commission's proposals alleging that the criteria are not workable and not in line with the precautionary principle, and that the Commission has exceeded its implementing powers, thus suggesting that Sweden may in the future launch another Court action against the Commission. See the presentation at http://www.edc-eu-tour.info/sites/edc-eu-tour.info/files/field/event_documents/swedish_ministry_presentation.pdf. Other presentations made at

endocrine disruptors have been a controversial issue with trading partners and the topic of several discussions in the context of international trade fora.

<u>Documents 23 to 25, 27, 28, 31 and the annexes to document 30</u> must all be analysed and assessed against this background. These documents predate the adoption by the Commission of the package of proposals regarding the scientific criteria for the determination of endocrine disruptors. Their public disclosure would seriously undermine the above-mentioned ongoing decision-making process, as the draft measures proposed by the Commission have not yet been adopted.

In particular, documents 23, 25 and the first annex to document 31 contain draft minutes of Impact Assessment Steering Group (IASG) meetings on endocrine disruptors that took place on 19 March 2015 and 21 May 2015. These draft minutes reflect the discussions within the inter-service group in preparation of the draft impact assessment. In particular they contain detailed preliminary views, comments and suggestions expressed by individual Commission staff members. As such, the draft minutes set out how the thinking of Commission staff evolved in the run-up to the publication of the Commission's draft acts setting out the criteria for determination of endocrine disruptors.

Documents 24, 27 and 28, contain exchange of views, comments and opinions of individual staff members regarding draft Terms of Reference for a possible study on the impact of different options for setting endocrine disruptor criteria on various sectors. Eventually this study was not carried out by the Commission in view of time constraints and the lack of representative data. There exists a reasonably foreseeable and not purely hypothetical risk that if disclosed these draft documents and exchange of views would undermine the ongoing decision-making process on endocrine disruptors. In particular, divulging these preliminary drafts would lead to confusion and misunderstanding about the Commission's approach, and therefore seriously harm the decision-making process.

The annexes to document 30 and the second annex to document 31 contain preliminary drafts of a technical report on the "Screening methodology to identify endocrine disruptors for an impact assessment" and preparatory documents associated with it, as well as a draft report on the public consultation on endocrine disruptors. Final versions of these reports are publicly available on the website of DG SANTE.²⁵ However, their draft versions cannot be released as they contain preliminary views and options explored in the finalization of the documents, which if disclosed would impair the free exchange of views within the institution thus seriously undermining the ongoing decision-making process on endocrine disruptors.

the same event were also critical of the Commission's proposal (see http://www.edc-eutour.info/event/european-commission-proposal-criteria-endocrine-disruptors).

In the period from 2012 until 2016 the Commission received several parliamentary questions concerning the topic of chemicals and endocrine disruptors in particular. Parliamentary questions and replies of the Commission are available on the website of the European Parliament, at http://www.europarl.europa.eu/plenary/en/parliamentary-questions.html.

The final version of the report on the screening methodology is available at http://publications.jrc.ec.europa.eu/repository/bitstream/JRC101950/jrc%20screening%20methodology%20 for%20ed%20impact%20assessment%20%28online%29.pdf. The final report of the public consultation is available at http://ec.europa.eu/health/endocrine disruptors/docs/2015 public consultation report en.pdf.

In the exercise of its independent role as recognized by the EU Treaty, the Commission needs to be able to explore different options and proposals in the course of the decision making process. Moreover individual staff members need to be able to express their views freely at every stage of the decision-making process, especially in the early stages of the internal brainstorming, without having to fear that at the certain point of time they would have to defend or justify preliminary views which may have evolved and changed later on in the process. Therefore, disclosing preliminary documents on initiatives that were eventually not pursued or completed, or preliminary drafts of internal discussions and exchange of views between Commission officials, would effectively deprive the Commission from having frank, internal discussions at nonpolitical level prior to launching a formal proposal, as Commission staff would in practice be discouraged from discussing, in writing, any issues related to sensitive dossiers. In this respect, the jurisprudence of the EU Courts has recognized that the capacity of the Commission staff to express their opinions freely must be preserved²⁶, so as to avoid the risk that the disclosure would lead to future self-censorship. As the General Court put it, the result of such self-censorship "would be that the Commission could no longer benefit from the franklyexpressed and complete views required of its agents and officials and would be deprived of a constructive form of internal criticism, given free of all external constraints and pressures and designed to facilitate the taking of decisions (...)". 27

Moreover, in the dossier at hand, Member States, Member State experts, the Parliament and the Council and external entities wishing to legally challenge the draft delegated act, could draw on those preliminary views, expressed by Commission officials and reflected in the draft texts, to question the Commission's approach. For example, the presentation and reasoning of the policy options in support of a given policy choice might have changed – and it has to be possible for a Commission official to reflect this change in writing without the Commission having to defend this change in an ongoing decision-making procedure. This could seriously alter the institutional balance reflected in Articles 290 and 291 TFEU, undermining the position of the Commission *vis-à-vis* those of the Member States, the Parliament and the Council, and the Commission's ability to act in the general interest of the Union (Article 17(1) TEU).

It should also be noted that all the above-mentioned documents are covered by a general presumption of non-disclosure linked to the exception in the first subparagraph of Article 4(3) of Regulation 1049/2001. In particular, in joint cases T-424/15 and T-425/15, the General Court ruled that for "the purposes of applying the exception laid down in the first subparagraph of Article 4(3) of Regulation No 1049/2001, the Commission is entitled to presume, without carrying out a specific and individual examination of each of the documents drawn up in the context of preparing an impact assessment, that the disclosure of those documents would, in principle, seriously undermine its decision-making process for developing a policy proposal". Documents 23 to 25, 27, 28, 31 and the annexes to document 30 were all prepared in the context of the ongoing decision-making process for

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Judgment of the Court of First Instance (Seventh Chamber) of 18 December 2008 in case T-144/05, *Muñiz v Commission*, (ECLI: EU:T:2008:596), paragraph 89.

Judgment of the General Court (First Chamber) of 10 january 2013 in case T-403/05, *MyTravel v Commission*, (ECLI: EU:T:2008:316), paragraph 52.

Judgment of the General Court (Second Chamber) of 13 November 2015 in joint cases T-424/14 and T-425/14, ClientEarth v Commission, (ECLI:EU:T:2015:848), paragraph 97.

developing the Commission's draft acts setting out the criteria for determination of endocrine disruptors, and therefore are covered by the general presumption described above.²⁹

3. OVERRIDING PUBLIC INTEREST

The exception laid down in Article 4.3 of Regulation 1049/2001 must be waived if there is an overriding public interest in disclosure. Such an interest must, firstly, be public and, secondly, outweigh the harm caused by disclosure.

I note that the Commission has published a number of documents regarding the ongoing decision-making process for the definition of criteria for endocrine disruptors, including the impact assessment, and the draft proposals, the minutes of the ongoing discussions with the Member State expert group and standing committee, the criteria revised in light of these discussions, and has engaged in public consultations and dialogues with stakeholders³⁰. I consider that with these publications, the Commission has satisfied the interest of transparency relating to this file.

Therefore, while I recognise the importance of transparency in enabling citizens to participate in a democratic process, in particular in relation to the issue of endocrine disruptors which has indeed attracted the attention of several stakeholders, the public interest in obtaining access to the documents requested does not, in my view, outweigh the need to protect the above-mentioned decision-making process. Indeed, I consider that the proactive publications mentioned above have ensured the proper balance between the protection of the decision-making process and the interest of the public in being informed about this decision-making process. Consequently, I have to conclude that in this case and at this stage, there is no overriding public interest in full disclosure of documents 23, 24, 25, 27, 28, 31 and the annexes to document 30.

Pursuant to Article 4.6 of Regulation 1049/2001 "[i]f only parts of the requested document

4. PARTIAL ACCESS

are covered by any of the exceptions, the remaining parts of the document shall be released". Accordingly, we have also considered whether partial access can be granted to the attachments to documents 23, 24 25, 27, 28, 31 and the annexes to document 30. However, the requested documents are entirely covered under the exceptions described above as it is impossible to disclose any parts without undermining the protection the EU's ongoing decision making process. Documents 23, 24 25, 27, 28 and 31 also contain personal data protected under the exception set out in Article 4.1(b) of Regulation 1049/2001.

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That general presumption does not exclude the possibility of demonstrating that a given document, the disclosure of which has been requested, is not covered by that presumption (Judgment of the Court of Justice of 14 November 2013 in case C-514/11 P and C-605/11 P, *Liga para a Protecção da Natureza (LPN) and Republic of Finland v Commission* (ECLI:EU:C:2013:738), paragraph 66). In this specific case, indeed, final minutes of the IASG meetings were partially released to you by DG SANTE in reply to your request with GestDem reference 2016/1133 (see in particular, documents 25 and 42 containing the final minutes of the 6th and 7th IASG meetings). Accordingly, despite the above-mentioned presumption of non-disclosure, the Commission carried out in this case a concrete and specific examination of certain documents covered by your request for access.

All these documents are published on DG SANTE's portal dedicated to the topic of endocrine disruptors: http://ec.europa.eu/health/endocrine disruptors/policy/index en.htm.

In accordance with Article 7(2) of Regulation 1049/2001, you are entitled to make a confirmatory application requesting the Commission to review this position.

Such a confirmatory application should be addressed within 15 working days upon receipt of this letter to the Secretary-General of the Commission at the following address:

European Commission Secretary-General Transparency unit SG-B4 BERL 5/282 B-1049 Bruxelles

Yours sincerely,

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Jean-Luc DEMARTY

Encl.:

- List of documents
- Released documents