EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food chain: stakeholder and international relations
Science, stakeholders, enforcement

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By registered letter with acknowledgement of receipt

Ms Rachel Tansey
Corporate Europe Observatory (CEO)
26, rue d'Edimbourg
B-1050 Brussels

Advance copy by email:
ask+request-2800-445eeb54@asktheeu.org

Dear Ms Tansey,

Subject: Your application for access to documents – Ref GestDem No 2016/2151

We refer to your email dated 20.4.2016 in which you make a request for access to documents, registered on 22.4.2016 under the above mentioned reference number.

You request access to *"all communication, including emails, and documents (agenda, minutes, list of participants, etc) relating to: – the meeting of Marco Valletta with the European Risk Forum (ERF) on 17/03/2016, on the subject of 'precaution principle and EFSA'"*.

Your application concerns the following documents:

1. E-mail exchange on "European Risk Forum – Science-based Decision-Making Project" (17.2.2016; 9.11.2015; 5.11.2015);
2. Science-Based Decision-Making Monograph – Update;
3. Report of the meeting with ERF on 17.3.2016.

Documents 1 and 3 to which you have requested access contain personal data.

Pursuant to Article 4(1)(b) of Regulation (EC) No 1049/2001, access to a document has to be refused if its disclosure would undermine the protection of privacy and the integrity of the individual, in particular in accordance with EU legislation regarding the protection of personal data. The applicable legislation in this field is Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the EU institutions and bodies and on the free movement of such data[1].

[1] Official Journal L 8 of 12.1.2001, p. 1.

When access is requested to documents containing personal data, Regulation (EC) No 45/2001 becomes fully applicable[2].

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 to them and if there is no reason to assume that the legitimate rights of the persons concerned might be prejudiced.

We consider that, with the information available, the necessity of disclosing the aforementioned personal data to you has not been established and/or that it cannot be assumed that such disclosure would not prejudice the legitimate rights of the persons concerned. Therefore, we are disclosing the documents requested expunged from this personal data.

In case you would disagree with the assessment that the expunged data are personal data which can only be disclosed if such disclosure is legitimate under the rules of personal data protection, you are entitled, in accordance with Article 7(2) of Regulation (EC) No 1049/2001, 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-B-4
BERL 5/282
B-1049 Bruxelles

or by email to: sg-acc-doc@ec.europa.eu

Yours sincerely,

Lorenzo Terzi
Head of Unit

[2] Judgment of the Court of Justice of the EU of 29 June 2010 in case C-28/08 P, Commission/The Bavarian Lager Co. Ltd, ECR 2010 I-06055.

From: [mailto]
Sent: Wednesday, February 17, 2016 4:38 PM
To: VALLETTA Marco (CAB-ANDRIUKAITIS)
Subject: R: European Risk Forum - Science-Based Decision-Making Project

Ciao Marco,

Ti immagino molto occupato, ma spero di rubarti 45 secondi ora e possibilmente una mezz'oretta a metà marzo per una chiacchierata.

Ti avevo informato del progetto "Science-based Decision-making" dello ERF (v. sotto). Lo abbiamo lanciato e siamo in piena fase di incontri con esperti – academics, stakeholders, e regulators.

Mi chiedevo se potessi dedicarmi appunto una fetta di tempo per una chiacchierata? Apprezzeremmo molto poter approfittare della tua esperienza con il trinomio scienza-regolazione-policy e della tua conoscenza dei meccanismi della Commissione.

La discussione sarebbe confidenziale e informale, e potrebbe prendere spunto da alcuni dei temi inclusi nella nota allegata. Io sarò a Bruxelles nella settimana del 14 marzo prossimo – potremmo magari vederci davanti ad un caffè il mercoledì, giovedì o venerdì?

Grazie mille sin d'ora per l'interesse. Spero si possa combinare!
Un caro saluto

Da: Marco.VALLETTA@ec.europa.eu [mailto:Marco.VALLETTA@ec.europa.eu]
Inviato: 09 November 2015 11:46

A: [redacted]; [redacted]
Oggetto: RE: European Risk Forum - Science-Based Decision-Making Project

Caro [redacted]
Qui tutto bene, spero lo stesso per te
Quanto alla richiesta della ERF, mi vedo costretto a declinare per estrema mancanza di tempo

Cordiali saluti e spero a presto
Marco

From: [redacted] [mailto [redacted]]
Sent: Thursday, November 05, 2015 5:56 PM
To: VALLETTA Marco (CAB-ANDRIUKAITIS); [redacted]
Subject: European Risk Forum - Science-Based Decision-Making Project

Caro Marco,

Spero stiate tutti bene!

Ti scrivo per conto dello European Risk Forum (ERF, www.riskforum.eu), come ti ricorderai il think tank con cui collaboro e a cui hai parlato qualche tempo fa.

In 2005, the Risk Forum produced a major monograph, "Enhancing the role of science in the decision-making of the European Union". (A copy is attached.) This was a ground-breaking document. It set the policy agenda for a decade. Amongst other issues, it highlighted the need for a central advisory mechanism, specifically, a Chief Scientific Advisor, to oversee the process of scientific advice throughout the Commission. It identified the need for MEPs to gain access to the highest quality scientific evidence. It argued for the creation of a European Academy of Sciences. It explained the need for mandatory policies and guidelines covering the collection and use of scientific advice, risk assessments, communication with policy-makers, and the quality of scientific evidence.

After more than a decade, it is now appropriate to up-date this monograph. I attach a copy of the project plan.

As part of up-dating the document, we are setting up a steering committee. On behalf of [redacted] the Secretary-General of the European Risk Forum, we would like to invite you to **join the steering group as an observer.** We believe that the project would immensely benefit from direct insights from your understanding of science, consumer products and regulation, and of the operation of the EU's institutions.

The contributions by the members of the steering group, and the discussions there, will be strictly under the Chatham House Rule and of course commit the European Commission or you personally in no way. If you wish so, your involvement may also be considered on an anonymous basis / under the Chatham House Rule.

The group will meet three times, with the first meeting provisionally scheduled for 1 December 2015 (afternoon) in Brussels. Its role will be to oversee the work, to comment on intermediate outcomes, to provide expert insights, and to help the research team develop recommendations. Each meeting should last 2-3 hours.

Thank you for considering this proposal. I perfectly know you are very busy and solicited, but do hope that you will be able to join the Steering Group, even if you are unable to attend every meeting of the group. (In this modern age, we will make sure that all documents are circulated electronically, allowing members of the group to comment.)

Should you not be able to join, we would be grateful if you could recommend us other colleagues in various parts of the Commission whom you think could / would be interested in this initiative.

Look forward to hearing from you

Un caro saluto

[redacted]

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[redacted]
EUROPEAN RISK FORUM
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Email: [redacted]

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Science-Based Decision-Making Monograph – Update

Interview Discussion Guide – EU Officials

Topics for discussion with EU officials responsible for providing policy or legislative advice to decision-makers or for making regulatory decisions or for overseeing scientific advisory processes. The discussion will focus on the direct experience of the official and will be confidential.

- Principal uses made of scientific advice
  (Policy-making, legislative decisions, regulatory or substantive guidance decisions, review of legislative or policy decisions, crisis management)

- Sources of scientific advice for each principal use
  (Formal and informal sources, technical working groups, in-house, and external)

- Criteria and processes for selection of advisers
  (General or local mechanisms, policies, or practices; access to excellence; overcoming ideological bias)

- Briefing and utilisation of advisers
  (Frameworks, consultation with advisers and stakeholders, type of questions – value judgements)

- Mechanisms used for ensuring that advice obtained is relevant, unbiased, meets internationally-agreed standards of scientific excellence, and understandable for principal users i.e. "quality assurance"
  (General guidelines or processes or standards for scientific evidence and for scientific advisory groups; project-specific guidelines or processes; EU-wide or local policies; committee rules of procedure; access to excellent science; peer review mechanisms – findings of scientific advisers)

- Reporting of findings
  (Openness requirements; presentation guidelines; coverage of advice)

- Strengths and weaknesses of EU system of scientific advice
  (Overall, Policy-making, legislative decisions, regulatory decisions, substantive guidance, review of legislative or policy decisions, crisis management)

- Ideas for improvement

Report of the meeting with [redacted] on 17 March 2016

I met for approximately 25 minutes [redacted], who is working for the European Risk Forum.

[redacted] presented me the details of a project called "Science-based Decision making" by which the ERF is trying to collect views on how the scientific assessment is collected and used in view of risk management decisions.

Related to this we also discussed the following issues:

- Precautionary principle: whether the EU was reconsidering its policy on this issue; to which my reply was no
- Composition and function of the new Scientific Advisory Mechanism created by the Juncker Commission.