6 March 2017

Mr Geert Dancet
Executive Director
European Chemicals Agency (ECHA)
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Open letter on the independence and transparency of ECHA's Risk Assessment Committee

Dear Mr Dancet,

On 8 and 15 March, the European Chemicals Agency's Risk Assessment Committee (RAC) will discuss the hazard classification of Europe's most heavily used weedkiller, glyphosate. We are writing to express our concerns in relation to the independence and transparency of this Committee.

On its website, ECHA states that it is "*independent from all external interests and impartial in [its] decision making*". It also says it is "*open and transparent in [its] actions and decision-making*".

ECHA's Risk Assessment Committee is entrusted with the evaluation of health and environmental risks of chemical substances, such as glyphosate. Its opinions form the basis for regulatory decisions on the production, sale and use of such substances in the European Union (EU). Its members are selected by EU governments and appointed by ECHA.

Conflicts of interest
We are concerned that several members as well as the Chair of the Risk Assessment Committee appear to have a conflict of interest, according to ECHA's own criteria.

ECHA states that a conflict of interest arises "*where the impartiality and objectivity of a decision, opinion or recommendation of the Agency, including its bodies, is or might in the public perception be compromised by an interest held by, or entrusted to, an individual working for the Agency*".[1] Interests that could interfere with ECHA's work include employment by a "*business, consultancy, research institution or other enterprise whose funding is significantly derived from commercial sources*". ECHA's assessment of conflicts of interest explicitly takes into account current interests as well as *"those that existed during the last 5 years preceding the assessment*".[2]

[1] ECHA, March 2014, Decision of the Management Board on the prevention and management of conflicts of interest
[2] Ibid

By these standards, RAC members Slawomir Czerczak and Tiina Santonen appear to have conflicts of interest. Both are employed by public scientific institutes that also generate income from providing risk assessment consultancy services to the chemical industry (details included in the annex).

The responsibility to assess and mitigate RAC members' conflicts of interest rests largely with the Chair of the Committee. [3] However, the professional experience of the current Chair, Tim Bowmer, principally consists of risk assessment consultancy for the chemical industry (details included in the annex). He may not be best-placed to safeguard strict independence from industry interests.

Risk assessment performed for the industry, whilst respecting certain minimum standards, is likely to underestimate adverse health and environmental effects of chemical substances, in order to achieve the broadest possible authorisation for these substances. On the contrary, risk assessment performed for public authorities must fully document each potential safety issue so that policymakers can take informed decisions to protect people's health and the environment. The mindset of scientific institutes – whether public or private – and consultancies that compete to attract industry funding is incompatible with ECHA's mission to implement the EU's chemicals legislation "*for the benefit of human health and the environment as well as for innovation and competitiveness*".

Use of unpublished scientific evidence

We are also concerned that ECHA's Risk Assessment Committee relies on unpublished scientific evidence provided by the industry in formulating its opinions, in addition to published studies.[4]

Agencies such as ECHA, whose scientific opinions form the basis for regulatory action, should only consider scientific evidence that is publicly available so that any scientist can replicate the findings. Their work should be transparent and carried out by independent experts without conflicts of interest.

We respectfully ask you to enforce and improve ECHA's policies to safeguard its independence from industry, and transparency of its work.

Yours faithfully,

Jorgo Riss, Director, Greenpeace European Unit

Also on behalf of:

Avaaz
Corporate Europe Observatory
Friends of the Earth Europe
Health & Environment Alliance (HEAL)
Pesticide Action Network (PAN) Europe
WeMove.eu

Comité pour le développement durable en Santé, France
Ecologistas en Accion, Spain
Fundación Alborada, Spain
Générations futures, France
Genuk, Germany
Global 2000, Austria
GMWatch, UK
Initiativ Liewensufank, Luxembourg
PAN Italia
PAN UK
Réseau Environnement Santé, France
Testbiotech, Germany
Zéro - Associação Sistema Terrestre Sustentável, Portugal

[3] Ibid
[4] ECHA, July 2016, Letter to Avaaz

ANNEX

Chair of the Risk Assessment Committee (RAC)

Tim Bowmer, Chair of the RAC, worked in chemical industry consultancy in the areas of toxicology, analytical chemistry and risk assessment for more than 20 years. He was employed by two consultancies, TNO and TNO Triskelion. His contract with these organisations ended on 31 August 2012, the day before he started his employment as Chair of the RAC on 1 September 2012.

For 10 years, between 2002 and 2012, Dr. Bowmer acted as a Business Development Manager and Senior Account Manager, meaning that his role was to build and manage relationships with chemical companies and other clients. He also set up projects under the Long-Range Research Initiative of CEFIC, the European chemical industry lobby.[5]

TNO says it "*helps the chemical industry to innovate by enabling businesses to reduce costs and get new products to the market faster*",[6] whereas TNO Triskelion describes itself as "*a trusted service provider for over 75 years in the fields of chemical safety, risk assessment and registration*".[7]

Members of the Risk Assessment Committee

Sławomir Czerczak, RAC member for Poland, heads the Department of Chemical Safety of the Nofer Institute of Occupational Medicine.[8] His department provides consultancy services for chemical companies, among others. According to its website, the department "*assists manufacturers, importers and downstream users in evaluating and documenting that the risks arising from the use of substances they manufacture, import or use are adequately controlled*".[9] Services include toxicity and mutagenicity studies in compliance with Good Laboratory Practice.[10]

Tiina Santonen, RAC member for Finland, heads the Chemical Safety Team of the Finnish Institute of Occupational Health. Her institute also provides consultancy services to industry on the chemical safety assessment of various substances under the EU's chemicals regulations (REACH).[11] In 2010, it performed a scientific review on the toxicity of stainless steel for industry associations ISSF and EUROFER. [12] Dr. Santonen was involved in industry contracts until 2014.[13] In 2012, she also provided an expert opinion supporting the registration of a substance under REACH.[14] The European Commission has identified her as having a conflict of interest ('industry funding') in relation to particular subjects that the Scientific Committee on Occupational Exposure Limits (SCOEL) deals with.[15]

Furthermore, Prof. Czerczak and Dr. Santonen have both publicly defended industry positions. They signed a high profile letter in 2013 about the regulation of chemicals that interfere with the hormone system, termed endocrine disrupting chemicals (EDCs)[16]. The letter echoed the chemical industry's warnings against a "*no threshold approach*" towards these chemicals, asserting that "*a position stating*

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[5] Tim Bowmer, April 2015, ECHA Declaration of Interests
[6] TNO website
[7] TNO Triskelion website
[8] Slawomir Czerczak, January 2016, ECHA Declaration of Interests
[9] Nofer Institute of Occupational Medicine website (in Polish)
[10] Nofer Institute of Occupational Medicine website (in Polish)
[11] Tiina Santonen, February 2016, ECHA Declaration of Interests
[12] Tiina Santonen, May 2015, SCOEL Declaration of Interests
[13] Ibid.
[14] Tiina Santonen, February 2016, ECHA Declaration of Interests
[15] European Commission, DG Employment, Social Affairs and Inclusion, 2015, Minutes of the plenary meeting of the Scientific Committee on Occupational Exposure Limits (SCOEL)
[16] Dekant, W. et al, June 2013, Letter to Anne Glover on draft regulation of endocrine active chemicals

that it is impossible to define a safe limit or threshold for a substance with classified as endocrine disruptor … would ignore broadly developed and accepted scientific development and accepted knowledge regarding thresholds of adversity". However, experts on endocrine disruption agree that "*the existence of thresholds cannot be determined experimentally*" and that it is "*uncertain whether there are thresholds at all, at least for some endpoints*."[17] The Endocrine Society states that "*EDCs exhibit complex dose-response curves, and they can act at extremely low concentrations*". [18]

Prof. Czerczak and Dr. Santonen failed to declare the letter in their annual declaration of interests, which requires the declaration of public statements and positions during the past 5 years when they fall "*in the regulatory field of ECHA*" and are "*part of a regulatory, legislative or judicial process*". [19]

In 2016, ECHA's Management Board re-appointed both RAC members for a second three-year term. It stated that their declarations of interests raised "*no issues regarding their eligibility for membership*".[20,21]

[17] European Commission, Minutes of the expert meeting on endocrine disruptors, 24 October 2013
[18] Gore, A.C. et al, December 2015, The Endocrine Society's Second Scientific Statement on Endocrine-Disrupting Chemicals
[19] ECHA, March 2014, Guidance for filling in the Declaration of Interest
[20] ECHA Management Board meeting, September 2016, Appointment of Committee members
[21] ECHA Management Board meeting, December 2016, Appointment of Committee members

GREENPEACE

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Mr Geert Dancet
Executive Director
European Chemicals Agency (ECHA)

8 March 2017

Dear Mr Dancet,

Thank you for your prompt reply to our letter of 6 March. Unfortunately, your response of 7 March heightens rather than alleviates our concern that ECHA has failed to apply its own rules on conflicts of interest.

In particular, I would like to highlight four areas that your letter fails to address.

1. ECHA's conflicts of interest policy covers both interests that could interfere with ECHA's overall work and interests that could interfere with ECHA's work on a specific dossier, such as glyphosate. **Your letter explains how you manage specific conflicts of interest, but fails to address our concerns about conflicts of interest that can affect ECHA's overall work.**

2. ECHA's policy considers interests "that existed during the last 5 years preceding the assessment" as giving rise to potential conflicts of interest. Your statement that the RAC Chair "made a clean break with his previous employer" is far from reassuring. Allowing experts to move freely between the private sector and public authorities, so long as employment periods do not overlap, is the definition of revolving doors. **A transition from the private to the public sector cannot be considered a "clean break" without an appropriate cooling off period.**

3. ECHA's conflicts of interest policy considers consultancy services to be "private interests" that could interfere with ECHA's own mission. TNO, Triskelion B.V., the Nofer Institute of Occupational Medicine and the Finnish Institute of Occupational Health all provide such services. In particular, Triskelion B.V., the RAC Chair's former employer, is a company specialised in risk assessment services for the chemical industry. It focuses on the EU's chemicals legislation (REACH), and companies such as BASF have praised Triskelion B.V. for its support and professionalism, according to Chemical Watch's Global Service Providers Guide. **Conflicts of interest related to industry consultancy cannot simply be declared. They must be ruled out.**

4. ECHA's conflicts of interest policy requires that experts declare the "provision of an expert opinion or testimony in the regulatory field of activity of ECHA for a commercial entity or other organisation, as part of a regulatory, legislative or judicial process". The definition of scientific criteria for endocrine disruptors is the subject of an ongoing regulatory process. If an expert opinion in relation to this process can be omitted from the declaration of interests, the requirement to disclose such interests may as well be scrapped. **These rules only make sense if they are enforced.**

I would also like to reiterate our concern about ECHA's fundamental dependence on unpublished scientific evidence provided by industry. Whether or not this is "normal practice", we believe that it calls into question the independence of scientific assessments conducted by European agencies.

I look forward to your response on these points.

Yours sincerely,

[signed]

Jorgo Riss
Director, Greenpeace European Unit