

## MAURICI Daniela

*Project*

**From:** MAURICI Daniela  
**Sent:** 28 July 2008 19:01  
**To:** Team Risk Assessment; 'a.hardy@csl.gov.uk'; 'a.chesson@abdn.ac.uk'; a.flynn@ucc.ie; harry.kuiper@wur.nl; 'Schans, dr.ir. J. (Jan)'; 'JCL@food.dtu.dk'; John Collins; josef.schlatter@bag.admin.ch; 'kd.jany@t-online.de'; 'VANNIER Philippe'  
**Cc:** KOETER Herman; Vittorio SILANO; Team SCA; 'Sue Barlow'  
**Subject:** Mandate on Threshold of Toxicological Concern - request for nomination of experts for SC WG to be established  
**Attachments:** SC\_717rev2\_TTC draft mandate\_final no track.doc

Dear Colleagues,

please find attached the draft mandate on the Threshold of Toxicological Concern approach (TTC) discussed and adopted at the last plenary of the Scientific Committee on the 15th July.  
Sue Barlow has kindly accepted to chair the working group that needs to be soon established. In this view, I would like to kindly ask you to propose names of experts you think could be interested of being part of this working group. In order to be able to contact them in due time, could you please send back to me the proposed name of experts **by the 10th September?** We are planning to have the first working group meeting between middle of October/beginning of November.

Thanks a lot for your cooperation.

My best regards

Daniela

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**From:** Sue Barlow [suebarlow@mistral.co.uk]  
**Sent:** 29 July 2008 17:21  
**To:** MAURICI Daniela  
**Subject:** Re: Mandate on Threshold of Toxicological Concern - request for nomination of experts for SC WG to be established

Dear Daniela

It is unfortunate that we were not aware in the SC about the PPR mandate - at the meetings Tony tells us about a lot of things but I do not recall him ever mentioning TTC and pesticide metabolites. Having looked at the Art.36 call for the work required, the first 2 bullets (see below) under the call cover some aspects that the SC WG will also likely want to cover.

- Provide an up-to-date (or state-of-the-art) review of the scientific literature on the basis, strengths, weaknesses and validation of the TTC concept in relation to the toxicological end points assessed in the evaluation of the toxicological properties of chemicals (genotoxicity, short and long term toxicity, carcinogenicity, neurotoxicity, reproductive toxicity).
- Review how the TTC concept is currently used by European regulatory bodies and international organizations in food safety.

The remaining 3 bullets of the call are specific to pesticide residues and metabolites but will be very relevant to what the SC might say about the applicability of the TTC concept to each sector of EFSA's work. As the PPR call will close this week and the resulting report from the contractor might be available around a year from now, I hope the SC will be able to utilise some of the outcome. One possibility would be to invite the contractor to be a member or observer in the SC WG.

**Concerning WG membership:**

1. Staffan Skerving has already volunteered.
2. To have Josef involved would also be very good and I agree with Josef's 2 suggestions
3. Andy Renwick ([A.G.Renwick@soton.ac.uk](mailto:A.G.Renwick@soton.ac.uk)) who together with Ian Munro has led the JECFA work on this (excellent if he would come, but he may not as he is trying to reduce his commitments overseas), and
4. Corrado Galli ([Corrado.Galli@unmi.it](mailto:Corrado.Galli@unmi.it)) (who was involved with the ILSI Europe initiative on TTC and is good in meetings so long as you do not ask him to draft much).
5. Another possibility is the carcinogenicity specialist Giovanni Zapponi ([giovanni.zapponi@iss.it](mailto:giovanni.zapponi@iss.it)) from the ISS, Rome. He was very helpful when the SCF looked at the possibility to use the TTC by analogy with the US Threshold of Regulation for food contact materials.
6. Someone from Professor Gundert-Remy's group at the BfR would be good. They have published on using the TTC approach to deal with zero tolerances in food and feed and on use of TTC with respect to decisions on reprotox testing under reach (e.g. see "Zero tolerances in food and animal feed - are there any scientific alternatives. in Toxicol Lett 175, pp118-135, 2007 by Heberer et al. And "Exposure-triggered reproductive toxicity testing under the REACH legislation: a proposal to define significant/relevant exposure" in Toxicol Lett 176, pp68-76, 2008 by Bernauer et al.. All these authors are from the Federal Institute for Risk Assessment, Thielallee 88-92, D-14195 Berlin, Germany.
7. It would be good to have volunteers from FEEDAP and the new ANS and CEF Panels, especially the latter as TTC is already used for flavourings. Jean-Claude Lhuguenot, now on CEF and also the new chair of its Food Contact Materials WG, was also a co-author on some of the ILSI Europe papers by Kroes et al.
8. I agree we need someone from the DG SANCO Committees joint WG on TTC.
9. We may need someone with endocrine disrupter expertise, though I can cover that if necessary.
10. The mandate asks us to consider nanoparticles (Staffan can cover that), micro-organisms (but this - according to Dan - is a non-starter as even one or two micro-organisms can multiply up to millions under the right conditions) plant pests and GMOs. So we might need to include, at least at some point in the work, people with expertise in those areas.

There are also publications on use of TTC for minor genotoxic components in pharmaceuticals and for ingredients in personal care and household consumer products but all the authors are from the relevant industries.

I would suggest a maximum of 12 persons on the WG.

Best wishes  
Sue

----- Original Message -----

**From:** MAURICI Daniela

**To:** Sue Barlow

**Sent:** Tuesday, July 29, 2008 10:50 AM

**Subject:** FW: Mandate on Threshold of Toxicological Concern - request for nomination of experts for SC WG to be established

Dear Sue,  
the e-mail below for your information.

As also mentioned in the e-mail of Josef, how many people would you suggest to have on board for this WG? I think it would be good may be to include someone that is also following the mandate of the PPR panel for the TTC in order to be aware of all the developments within EFSA. Do you agree? I'm going to have a short meeting with Luc on Thursday.

Regards

Daniela

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**From:** MOHIMONT Luc

**Sent:** 29 July 2008 10:12

**To:** MAURICI Daniela

**Cc:** SEBESTYEN Istvan; DUNIER-THOMANN Muriel

**Subject:** FW: Mandate on Threshold of Toxicological Concern - request for nomination of experts for SC WG to be established

Ciao Daniela,

The PPR Panel is going to adopt a new mandate on the toxicological relevance of pesticide metabolites in food commodities.

Within this mandate, the Panel will explore the applicability of the TTC approach in the pesticide residues area.

I have informed Djien about this and recently we launched a call on the TTC concept:

[http://www.efsa.eu.int/EFSA/efsa\\_locale-1178620753812\\_1178712444487.htm](http://www.efsa.eu.int/EFSA/efsa_locale-1178620753812_1178712444487.htm)

The deadline for submission of offers is the end of this month.

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In order to cooperate, could you keep us (Istvan and myself) aware of the activities of the SC on this ? Is it possible to circulate the draft mandate of the SC to the PPR panel?

Is it possible to meet one of these days (Thursday or Friday) ?

Thanks a lot.

Luc

PS: could you send me the EC document (reference 15 of the SC mandate) ?

MAURICI Daniela

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From: TIRAMANI Manuela  
Sent: 01 September 2008 11:57  
To: MAURICI Daniela  
Subject: RE: Mandate on Threshold of Toxicological Concern - request for nomination of experts for SC WG to be established

Dear Daniela  
As for the experts that could be part of the working group, I would like to suggest 2 professors of the University of Milano, that are also members of 2 Panels in EFSA. I do not know whether this might create problems. However, they both are very good toxicologists known at international level and have worked on the TTC issue in their career. They are

Prof. Corrado Galli (Contam Panel, he did not submit any proposal for the PPR Panel call on TTC)  
University of Milan  
b. Toxicology - Department of Pharmacological Sciences  
Milan Italy  
Tel +39 (0)2 503 18315  
Fax +39 (0)2 503 18260  
[corrado.galli@unimi.it](mailto:corrado.galli@unimi.it)

Prof. Angelo Moretto (PPR Panel, he did not submit any proposal for the PPR Panel call on TTC; he also has "exposure" knowledge and background)  
Piazzale S. Stefano 1  
Pedale e Polo Universitario Luigi Sacco,  
D. International Centre for Pesticides and Health Risk Prevention (ICPS), Milano, Italy  
Tel. +39 02 35686650  
Fax +39 02 38203163  
[angelo.moretto@icps.it](mailto:angelo.moretto@icps.it); [angelo.moretto@unimi.it](mailto:angelo.moretto@unimi.it)

I hope it helps  
Kind regards  
Manuela

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From: MAURICI Daniela  
Sent: lunedì 1 settembre 2008 9.44  
Subject: Team Risk Assessment

**MAURICI Daniela**

*covered*

**From:** HEPPNER Claudia  
**Sent:** 01 September 2008 12:37  
**To:** MAURICI Daniela  
**Subject:** RE: Mandate on Threshold of Toxicological Concern - request for nomination of experts for SC WG to be established

Dear Daniela

Ups. I just sent after I got your reminder an email to the CONTAM panel as I didn't distribute your request in July and I was not aware that Josef already volunteered for this WG. We will shortly discuss then at the panel meeting (as I have sent the request to the panel) and say that CONTAM is sufficiently covered. I don't know how many other nominations you got, could you also take two (or even more) experts from CONTAM? (I also would have suggested Corrado Galli).

Cheers  
Claudia

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**From:** MAURICI Daniela  
**Sent:** 01 September 2008 11:59  
**To:** HEPPNER Claudia  
**Subject:** FW: Mandate on Threshold of Toxicological Concern - request for nomination of experts for SC WG to be established

Dear Claudia,

as you can see from the e-mail below, Josef has already expressed the interest of being part of the WG and he also suggested some names. I have included these names in the document I am preparing to be discussed at the next SC plenary. May be you can discuss with Josef during your plenary if you would like to propose some other experts to be included in the "proposal" document. Otherwise I would consider the expertise for your panel already covered by these names.

Thanks again for your prompt reply.

Regards

Daniela

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**From:** josef.schlatter@bag.admin.ch [mailto:josef.schlatter@bag.admin.ch]  
**Sent:** 29 July 2008 08:44  
**To:** MAURICI Daniela  
**Cc:** suebarlow@mistral.co.uk  
**Subject:** AW: Mandate on Threshold of Toxicological Concern - request for nomination of experts for SC WG to be established

Dear Daniela,

I strongly suggest asking Andy Renwick to join this working group and I assume that some members of the CEF and ANS panel will be nominated by their respective chairs.

As I was involved for quite some time in the further development of the TTC concept (decision tree) I am personally interested in this WG and would be willing to join. If an other member of the CONTAM panel would be needed, I am willing to ask in the next plenary (early September) or Claudia Heppner could send out an e-mail. Otherwise I suggest Corrado Gally ([corrado.galli@unimi.it](mailto:corrado.galli@unimi.it)) who was also involved in the development of the TTC. A further suggestion would be Marja Pronk from rivm.

I do not know how big the WG should be but a member of the TTC-WG of the Commission might also be considered (propose Jim Bridges [J.Bridges@surrey.ac.uk](mailto:J.Bridges@surrey.ac.uk))

Best regards

Josef

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Emeritus Professor School of Medicine  
University of Southampton, Medical and Biological Sciences Bldg  
Bassett Crescent East  
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**Dr. Josef Schlatter**

Head of the Nutritional and Toxicological Risks Section

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**Von:** MAURICI Daniela [<mailto:Daniela.MAURICI@efsa.europa.eu>]

**Gesendet:** Montag, 28. Juli 2008 19:01

**An:** Team Risk Assessment; [a.hardy@csl.gov.uk](mailto:a.hardy@csl.gov.uk); [a.chesson@abdn.ac.uk](mailto:a.chesson@abdn.ac.uk); [a.flynn@ucc.ie](mailto:a.flynn@ucc.ie); [harry.kuiper@wur.nl](mailto:harry.kuiper@wur.nl); Schans, dr.ir. J. (Jan); [JCL@food.dtu.dk](mailto:JCL@food.dtu.dk); John Collins; Schlatter Josef BAG; [kd.jany@t-online.de](mailto:kd.jany@t-online.de); VANNIER Philippe

**Cc:** KOETER Herman; Vittorio SILANO; Team SCA; Sue Barlow

**Betreff:** Mandate on Threshold of Toxicological Concern - request for nomination of experts for SC WG to be established

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