PRESS RELEASE
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OPEN LETTER TO CATHERINE GESLAIN-LANÉELLE, EXECUTIVE DIRECTOR OF THE EUROPEAN FOOD SAFETY AUTHORITY

Catherine Geslain-Lanéelle
Executive Director
European Food Safety Authority
Largo N. Palli 5/A
I-43100 Parma
Italy

3 February 2009

Dear Ms Geslain-Lanéelle

RE TRANSPARENT SCIENTIFIC DISCUSSION ABOUT EFSA'S OPINION ON THE USE OF SODIUM MONOFLUOROPHOSPHATE IN FOOD SUPPLEMENTS

We are writing this as an open letter to help ensure that interested parties and stakeholders are kept informed over EFSA's crucial work on risk assessment. We were stimulated to write to you in response to your organisation's reaction, as published by Nutraingredients.com on 29 January, to our critique of EFSA's risk assessment methodologies on the use of sodium monofluorophosphate in food supplements. Two days earlier, we had issued a press release publicising our own critique, and another by Professor Vyvyan Howard. Your organisation's response, given by an unnamed spokesperson, was dismissive and failed to deal with any of the substantive scientific or legal issues raised.

Your spokesperson stressed to Nutraingredients that EFSA values both its transparency and its independence. In this light, we make this public and formal request, given that we have yet to have any response from EFSA on substantive issues raised by the ANH in past consultations.

We make this request on behalf of a wide range of interested parties including consumers, health professionals, retailers and manufacturers of natural products. We ask specifically that EFSA provides to us its considered response to the substantive points made in our critique, which can be found at the following link: http://www.anhcampaign.org/files/090126_ANH_EFSA-sodium-monofluorophosphate-opinion.pdf. We also ask that you respond to the independent commentary by Professor Vyvyan Howard, which can be found at: http://www.anhcampaign.org/files/090123-Commentary-Prof-Vyvyan-Howard-EFSA-SMP-opinion.pdf.

To facilitate this, we believe the most pertinent issues requiring EFSA's attention are as follows:

1. Why is EFSA providing an opinion for an ingredient for which the apparent intended use is clearly medicinal, i.e., for reducing the risk of dental caries? If

the intention is not medicinal, what is the nutritional and non-medicinal purpose of sodium monofluorophosphate's proposed inclusion in food supplements?

2. The ANH critique identifies four papers that suggest that the highest no observable adverse effect level (NOAEL) for children is likely to be in the region of 0.9 mg fluoride/day. The UK's Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT), as cited in the EFSA opinion, determined that an intake of 0.05 mg/kg bw/day could be considered as a no observable adverse effect level (NOAEL) for moderate dental fluorosis (i.e., 0.6 mg/day for a 12 kg child). Using the same methodologies used by EFSA for other risk analyses on essential vitamins and minerals, an uncertainty factor should then be applied to this figure to derive the UL, leading to a figure substantially less than 0.6 mg/day. However, the Tolerable Upper Intake used by EFSA for 1 to 3-year-olds is actually substantially greater than this, i.e., 1.5 mg/day. Why such a discrepancy?

3. EFSA appears to have failed to consider adequately the implications of combined fluoride exposure from public drinking water (in fluoridated regions), natural mineral water, toothpaste and other dental products, and foodstuffs. Why does EFSA not take these combined potential intakes into account when evaluating the risk posed by the dosages proposed by the petitioners?

4. If EFSA is to accept the NOAEL proposed by the UK's COT, why does EFSA not reject the majority of supplemental dosages being requested by the petitioners given that most already exceed this NOAEL?

5. Given that the EFSA opinion states that intakes above the tolerable intake level (TIL) might occur in the case of most children, why is the general tone of the opinion a positive one, rather than a negative one?

6. Your spokesperson, in his/her comment to Nutraingredients on 29 January, said, *"The opinion to which you refer was an evaluation of the safety of sodium monofluorophosphate added for nutritional purposes as a source of fluoride in food supplements and on bioavailability of fluoride from this source. The safety of fluoride itself was outside the remit of the Panel."* We therefore ask, given that the intended use of sodium monofluorophosphate is as a source of fluoride, rather than of sodium or phosphorus (the other mineral elements within the molecule), how can the "safety of fluoride itself" be ignored in EFSA's evaluation?
[Is this because the safety of fluoride has previously been evaluated by EFSA's predecessor, the Scientific Committee on Food (SCF) (in 1996; http://ec.europa.eu/food/fs/sc/oldcomm7/out09_en.html)? And if so, why

does the present opinion not adequately take into account the adverse effects considered by the SCF in its 1996 opinion?]

We would also like to draw your attention to Article 30 of Regulation 178/2002, the very regulation that established EFSA in 2002 and the one that dictates general food law across the EU. This Article, concerning "diverging scientific opinions", calls for EFSA to identify where divergence might be taking place, and if so identified, to dialogue with other authorities "with a view to either resolving the divergence or preparing a joint document clarifying the contentious scientific issues." Given most Member States, with the obvious exception of Ireland and the UK, have rejected fluoridation of the public drinking water supplies primarily on the basis of safety concerns, could you please provide us with a list of EU Member States and also non-European food safety authorities that have endorsed the use of sodium monofluorophosphate as a food (or dietary) supplement?

We hope that such transparent debate of the science will contribute to improving many people's confidence in the risk analyses being carried out at present by EFSA. Our view is that EFSA's methodologies do not adequately reflect the known science and so are sometimes unnecessarily cautious. In other cases, such as in the case of the sodium monofluorophosphate opinion, EFSA appears to have gone the other way, giving a positive opinion by using different methodologies that could expose some population groups, notably children, to significant risks.

Transparent debate will, we believe, ultimately benefit all parties, including EFSA itself. However, even more importantly, it will ensure that consumers are not exposed to unnecessary risks, whilst also ensuring that there is a lesser risk of unjustified restriction of their freedom to choose safe and efficacious products.

We look forward to receiving your answers to these important questions at your earliest convenience.

Signed:

Dr Robert Verkerk, Executive & Scientific Director
Dr Damien Downing, Medical Director

Note: EFSA's written response should be mailed to the above at:
Alliance for Natural Health, Curtis Road, Dorking, Surrey RH4 1XA, UK and/or emailed to info@anhcampaign.org.

FOR FURTHER INFORMATION, PLEASE CONTACT:

Liz Davies, ANH Campaign Administrator, Tel: +44 (0)1306 646 600,
Email: info@anhcampaign.org

NOTES TO THE EDITOR

Nutraingredients article on release by ANH critiques of EFSA's opinion on sodium monofluorophosphate in food supplements
http://www.nutraingredients.com/Regulation/ANH-questions-EFSA-scientific-approach

Response by EFSA reported by Nutraingredients
http://www.nutraingredients.com/Regulation/EFSA-defends-independence-against-toxic-toothpaste-attack

Commentary by the ANH on EFSA opinion on sodium monofluorophosphate
http://www.anhcampaign.org/files/090126_ANH_EFSA-sodium-monofluorophosphate-opinion.pdf

Commentary by Professor Vyvyan Howard on EFSA opinion on sodium monofluorophosphate
http://www.anhcampaign.org/files/090123-Commentary-Prof-Vyvyan-Howard-EFSA-SMP-opinion.pdf

Commentary by the ANH on EFSA opinion on calcium fluoride ("EFSA-Are You Trying to Poison Us?")
http://www.anhcampaign.org/news/efsa—are-you-trying-to-poison-us

About the Alliance for Natural Health
www.anhcampaign.org

The Alliance for Natural Health (ANH) is an international, non-governmental organisation, based in the UK. It was founded in 2002, and works on behalf of consumers, medical doctors, complementary health practitioners and health-product suppliers worldwide, to protect and promote natural healthcare, using the principles of good science and good law.