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European Commission
Mr. Markos Kyprianou
DG Health and Consumer protection
B-1049 Brussels.

CABINET of A. VASSILIOU										
AV 890										
08-04-2008										
	AV	PB	DS	PP	ZS	EE	GG	ML	GZ	PT
A			X							
C	X									

Utrecht, 2 april 2008
our reference: HM/tgr/080402.01
contact: XXXXXXXXXX
subject: Concerning: Request for an internal review according to Regulation 1367/2006.

Dear Mr. Kyprianou,

Herewith we send you a request for an internal review (based on Regulation 1367/2006, art.10) concerning Commission Regulation 149/2008 of 29-1-2008 which was published in the Official Journal of 1-3-2008. Our opinion is that Regulation 149/2008, setting Maximum Residue Levels for food products, is fundamentally flawed on several grounds and should be reviewed. Below we will present our grounds for our request.

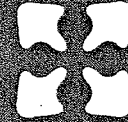
Procedural criteria:

Our organisation is entitled to make this request because we fulfil the criteria laid down in article 11 of Regulation 1367/2006. The Stichting Natuur en Milieu is an independent non-profit-making legal person in accordance with Dutch law (see Annex), founded in Promoting environmental protection is one of our central objectives which we are actively pursuing. The subject of the request is one of these objectives (see Annex).

Administrative Act:

At first site one might question whether Commission Regulation 149/2008 can be considered to be an administrative act meeting the criteria of art. 2(1)(g) of Regulation 1367/2006 concerning the 'individual scope'. However, interpreting this rather unclear article in the light of the Aarhus Convention, brings us to the conclusion that this Regulation does meet these criteria.

First of all Article 9(3) of the Aarhus Convention is not limited to acts of individual scope. It follows from settled case law that Community measures must as far as possible be interpreted in conformity with international agreements. Secondly, the notion of individual scope has been traditionally closely linked to the issue of individual concern and the application of the so called 'Plaumann' doctrine in individual standing. Since the internal review procedure has been devised in order to make this condition unnecessary under Article 230 EC, an equivalent barrier in the form of 'individual scope' would conflict with the aim of the Regulation. In line with this, close reading of Article 2(1)(g) leads to the conclusion that 'any measure of individual scope' is not strictly the same as 'administrative act of individual scope'. The words 'individual scope' might simply refer to the separating of legislative acts from administrative



acts.¹ Any other interpretation of this article would make the procedure rather meaningless as it would exclude practically all Community acts. For these reasons our conclusion is that Regulation 149/2008 can be considered as an administrative act subject to internal review, even when considered being not of an individual scope.

Furthermore, although the Regulation might have the form of a general measure, the contents of Regulation 149/2008 can be considered to be a compilation of decisions concerning the residues of all the individual products and substances. The contents therefore can be seen as individual decisions.

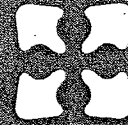
Grounds for internal review:

1. *No high level of consumer protection.*
 - o Regulation 396/2005 of 23-2-2005, amending Directive 91/414, provides for a "high level of consumer protection". Additionally this Regulation indicates that, according to Directive 91/414 "public health should be given priority over the interests of crop protection" and (for this reason) "MRLs should be set at the lowest achievable level consistent with good agricultural practice".
 - o Regulation 149/2008 does the opposite, it selects and regulates those MRL's from European member states which are the highest ones and to the highest level possible based on health standards (ADI/ARfD).
 - o The "Reasoned opinion on the potential chronic and acute risk to consumers' health arising from proposed temporary EU MRLs" (European Food Safety Authority, EFSA, 15-3-2007, Annex 1) states: "The European Union collected the national MRLs in place and identified for each pesticide/commodity combination the highest national MRLs or Codex MRLs, which are proposed as temporary EU MRLs.....".
 - o This means EU deliberately chose the highest MRL while lower MRLs were available. Choosing higher MRLs means the market can use more pesticides and/or use them in a later phase of production and it means enforcement is only done on very high residue levels. Therefore consumers will have a higher risk of being exposed to pesticide residues. EU therefore obstructs its own objective of creating a high level of consumer protection and violates Directive 91/414 provisions saying "the lowest achievable level" should be chosen. Additionally EU-regulation 396/2005 (23-2-2005) is clear in saying in Article 25: "Temporary MRLs shall be set at the lowest level that can be achieved in all Member States on the basis of good agricultural practice".
 - o Commission did not check good agricultural practices and didn't do an attempt to get MRLs at the lowest level. Why shouldn't available low MRLs based on good agricultural practices be acceptable for the EU as a whole? Commission didn't try to set the MRLs low but just started working with the highest available.
2. *No proper evaluation of the dossiers.*
 - o In the "Reasoned opinion....." (15-3-2007) EFSA, the Authority advising Commission, states that information they normally apply in the risk assessment (page 2 of 206) is not available:

¹ See on this matter: Pål Wennerås, 'The Enforcement of EC Environmental Law', Oxford Studies in European Law, Oxford University Press, New York 2007, p. 234-237.



- "information on the national authorisation of substances (including information on Good agricultural Practice)";
 - "the results of the supervised field trials supporting the national authorisation".
 - This means that it is not sure that national MRLs are based on Good Agricultural Practices and possibly environmental harmful practices by the basis of national MRLs. This also means that it is not sure that supervised fields trials are done according the rules and it is even not sure if they are performed at all. Lacking data could mean unnecessary high MRLs are set and the high level of consumer protection is not realised.
 - The reason for the so-called "temporary MRL-setting", the purpose of Regulation 149/2008, is the 'historical' situation on pesticides approval. This is not in accordance with regulation 396/2005 and Directive 91/414.
 - Part of the pesticides already on the market were not evaluated properly or possibly not evaluated at all. For decades pesticides were allowed on the market and MRLs set while incomplete or no dossiers were delivered by industry and in many EU-member states no specific rules were present for compiling a dossier and/or for the methods of evaluation and the evaluation process. So for many pesticides it can't be verified anymore how they entered the market and if member state evaluated a dossier. This means that it is necessary to check whether information at national level is available and, if so, what the quality of this information is.
 - EFSA didn't have the information and Commission took a decision on knowing the lack of information. As a result dossiers are not evaluated properly on the status of the national authorisation, on Good Agricultural practice and on field trials. We conclude that the decision of the Commission on MRLs has to be reviewed.
- 3 *Cumulative exposure of consumers not taken into account.*
- EFSA conducted in its "Reasoned opinion....." of 15-3-2007 an exposure assessment with the proposed temporary MRLs to see if health standards are exceeded. What EFSA didn't do is consider cumulative effects of for instance the large group of organophosphates (several dozens of these substances are on the market) and the group of substances having endocrine disrupting properties (EU listed many pesticide substances having these properties).
 - On 23-2-2005 EU- regulation 396/2005 was published. Article 14 provides for a cumulative (and synergistic) risk assessment: "Account shall be taken of b) the possible presence of pesticide residues arising from sources other than the current plant protection uses of active substances, and their known cumulative and synergistic effects, when the methods to assess such effects are available". So cumulative risk assessment has to be performed in the EU since 2005. EFSA had its Scientific Colloquium on cumulative risk assessment on 28/29-11-2006 (Annex 4) and discussed "six existing models (page 34 of the Colloquium report). Additionally it was stated that "the process of performing cumulative assessments should begin as soon as possible"(page 35).
 - For cumulative risk assessment of the group of organophosphates methods are available at least since 2002 (US-EPA, Annex 2). Already in 1996 USA changed the law (Food Quality Protection Act) to take cumulative risk into account, starting with the large group of organophosphates.
 - Dutch NGOs 'Consumentenbond' and 'Stichting Natuur en Milieu' also performed a cumulative risk assessment of organophosphates in Dutch



national diets already in 2001 ("Have we lost our heads", Annex 3) by Monte-Carlo simulation.

- o EFSA notes in its "Reasoned opinion..." (page 11 of 106) that metabolites of organophosphates contribute significantly to the overall toxicological burden and that several organophosphates (17 organophosphates, isofenphos, monocrotophos, prothiofos, tetrachlorfenvinphos, azinphos-methyl, ethoprophos, phosmet and others) are on the list for setting temporary MRLs. Raising all MRLs to just under the health danger-zone creates serious health risks since the individual toxicity should be added to a total toxicity in case of consumption of products containing multiple organophosphates.
 - o The fact that in Regulation 149/2008 still cumulative risk assessment is ignored now methods are available and consumer health is in danger is a direct violation of Directive 396/2005.
4. *Many (temporary) MRLs exceed health standards.*
- o In the "Reasoned opinion....." EFSA states that of a total of 236 substances, "of 92 substances, no consumer health risk was identified. Of the remaining substances, potential acute and/or chronic health risks could not be excluded for the MRLs under consideration".
 - o EFSA then points towards "refined calculations" after which the standards apparently are not exceeded anymore. This process of 'refinement' can only be performed by removing safety factors in the risk assessment and introducing other estimates lowering the exposure. This refinement process again is contrary to a precautionary approach and contrary to a high level of consumer protection. Removing safety factors and introducing uncertain estimates should not be used in the setting of MRLs.

Given all these serious flaws in decision-taking by the Commission we send you this request for a review of Regulation 149/208 and ask you to withdraw or suspend this Regulation in preventing harm to consumers.

Yours sincerely,
The Netherlands Society for Nature and Environment

Have we lost our heads?

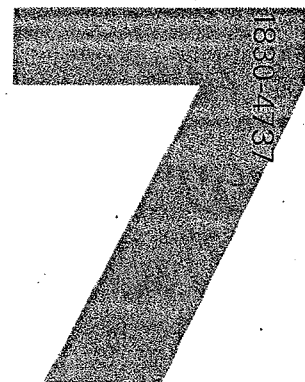
Neurotoxin residues harmful to the developing brains of our children

Consumentenbond



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Ronald Luijk and Sandra Schalk, ©Consumentenbond
Hans Muilerman, ©Stichting Natuur en Milieu
November 2000



**EFSA SCIENTIFIC COLLOQUIUM
SUMMARY REPORT**

**CUMULATIVE
RISK ASSESSMENT
OF PESTICIDES
TO HUMAN HEALTH:
THE WAY FORWARD**



European Food Safety Authority

28-29 November 2006 - Parma, Italy



**REASONED OPINION ON THE POTENTIAL CHRONIC AND ACUTE
RISK TO CONSUMERS' HEALTH ARISING FROM PROPOSED
TEMPORARY EU MRLs**

**ACCORDING TO REGULATION (EC) No 396/2005 ON MAXIMUM RESIDUE
LEVELS OF PESTICIDES IN FOOD AND FEED OF PLANT AND ANIMAL ORIGIN**

15 March 2007

SUMMARY

Active substances for which currently no EU Maximum Residue Levels (MRLs) exist and active substances covered by Directive 76/895/EEC¹ are subject to the setting of temporary EU MRLs (TMRLs) according to Regulation (EC) No 396/2005². The TMRLs shall be based on existing national MRLs established by the Member States and should respect the national agreements by which they were established, provided that they do not present an unacceptable risk to the consumers. The European Commission collected the national MRLs in place and identified for each pesticide/commodity combination the highest national MRLs or Codex CXLs, which are proposed as temporary EU MRLs to be included in Annex III of Regulation (EC) 396/2005.

In compliance with Article 24 of the abovementioned Regulation, EFSA has been requested by the European Commission to provide a reasoned opinion on potential chronic and acute risks to the consumers' health arising from the proposed TMRLs. The final dataset containing the proposed TMRLs to be evaluated was made available to EFSA in September 2006.

The European Commission compiled also a list of toxicological reference values (ADI-Acceptable Daily Intake and ARfD-Acute Reference Dose values) resulting from the evaluation of active substances under Directive 91/414/EEC³ and from JMPR evaluations. Missing toxicological reference values were provided by Member States derived from national evaluations of pesticides. If more than one ADI or ARfD value was reported, the Commission decided to propose the lowest value to be used for the risk assessment of the temporary MRLs.

It should be stressed that a specific MRL can be safe for a given Member State but would not necessarily be considered safe for another Member State due to different food consumption patterns. In order to ensure the safety of the proposed future EU MRLs, these limits have to be assessed with respect to the food consumption patterns of all European consumers. Therefore, EFSA developed a model for the risk assessment which is based on all the available European consumption data deemed suitable for the purpose of this exercise. The calculation

¹ OJ L 340, 9.12.1976, p. 16

² OJ L 70, 16.3.2005, p. 1

³ OJ L 230, 19.08.1991, p. 1



Organophosphorus Cumulative Risk Assessment – 2006 Update

August 2006

Appendices have been separated from the original PDF into individual PDF documents for viewing on-line.

This PDF contains the OP Cumulative Risk Assessment document without the appendices