John Dalli
Member of the European Commission

Brussels, 16. 10. 2012

Dear Ms De Rijk,
Dear Mr Muilerman,

I am responding to the letters of Stichting Natuur en Milieu and of PAN-Europe dated respectively 2 and 10 April 2008 and addressed to the Health Commissioner requesting the Commission to carry out an internal review of Regulation (EC) No 149/2008[1].

The European Court of Justice in its judgement of 14 June 2012 in case T-338/08 has annulled the decisions of the Commission of 1 July 2008 rejecting the requests made by Stichting Natuur en Milieu and PAN-Europe.

As you are aware, the Commission has launched a formal appeal against the General Court's judgement of 14 June 2012 in case T-338/08. Pending this appeal and because the appeal is not suspensory the Commission has undertaken an internal review of Regulation (EC) No 149/2008, taking into account the letter of 25 June 2012 of Mr Phon van den Biesen on behalf of Stichting Natuur en Milieu and PAN-Europe and the discussion that took place on 3 September 2012 between Commission officials, Mr Phon van den Biesen and PAN-Europe representatives.

Both the arguments advanced in the letters of 2 and 10 April 2008 and the discussion on 3 September 2012 established that the review request was directed at the setting of temporary EU maximum residue levels (MRLs) taking into account existing national MRLs. Accordingly, our review was limited to Annex III of Regulation (EC) No 149/2008.

By way of introduction, we believe it is useful to recall the general approach taken in laying down Annex III, before addressing the separate grounds advanced in support of the review request.

General approach for establishing temporary EU MRLs taking into account existing national MRLs as prescribed by Regulation (EC) No 396/2005

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[1] OJ L 58, 1.3.2008, p 1-398.

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Regulation (EC) No 396/2005 aims to move from a situation in which MRLs are set by the Member States to a situation in which MRLs are fixed at EU level instead, based on uses throughout the EU Member States and in the rest of the world, safe for the different groups of EU consumers and directly applicable (see recitals 2 and 3 of Regulation (EC) No 396/2005). In order to allow for a transition from the national systems to a harmonised system, and because the precise determination of MRLs requires lengthy technical assessment (see recital 19 of Regulation (EC) No 396/2005) a special procedure was foreseen for the first establishment of temporary MRLs.

The provisions for the first setting of temporary MRLs are laid down in Chapter IV of Regulation (EC) No 396/2005. The first setting of temporary MRLs was to be based on non-harmonised existing national MRLs provided that they did not present an unacceptable risk to consumers.

Recitals 30 and 31 of Regulation (EC) No 396/2005) explain why and how such a procedure should be followed:

(30) It is good administrative practice and technically desirable to coordinate the timing of decisions on MRLs for active substances with decisions taken for those substances under Directive 91/414/EEC. For many substances for which Community MRLs have not yet been set, decisions are not due to be taken under that Directive before the date of entry into force of this Regulation.

(31) It is therefore necessary to adopt separate rules providing for temporary but mandatory harmonised MRLs, with a view to setting MRLs progressively as decisions are taken on individual active substances as part of the evaluations under Directive 91/414/EEC. Such temporary harmonised MRLs should be based, in particular, on existing national MRLs established by the Member States and should respect the national arrangements by which they were established, provided that the MRLs do not present an unacceptable risk to consumers.

These first temporary MRLs were thus not based on a complete dossier followed by an assessment according to Article 10 which is normally required for the setting of an MRL under Chapter II of Regulation (EC) No 396/2005.

Nevertheless, as required by the Regulation, the temporary MRLs were to be established at levels presenting no unacceptable risks to consumers. These temporary MRLs were to be used at EU level until the full evaluation under Directive 91/414/EEC and Regulation (EC) No 1107/2009 and the subsequent review of existing uses had taken place, as explained in recital 32 of Regulation (EC) No 396/2005:

(32) Following the inclusion of existing active substances in Annex I to Directive 91/414/EEC, Member States are to re-evaluate each plant protection product containing those active substances within four years of the date of inclusion. The MRLs concerned should be retained for a period of up to four years to provide for continuity of authorisations and, on completion of re-evaluation, should be made definitive if they are supported by dossiers which satisfy Annex III to Directive 91/414/EEC, or be set to a default level if they are not so supported.

The procedure to establish Annex III containing temporary MRLs as specified in Chapter IV (Articles 22 to 25) of the Regulation was strictly followed.

Article 22 required that for all active substances not yet included in Annex I to Directive 91/414/EEC (except those for which EU MRLs had already been set, and for substances in Annex IV), temporary MRLs shall be established taking into account the information from the Member States about their national MRLs and, where relevant, a reasoned opinion by EFSA. Annex III had to be established within 12 months after the entry into force of the Regulation. This period of time was very short and did not allow for lengthy technical assessments.

Under Article 23 Member States were required to notify their national MRLs according to a format provided by the Commission and upon request by the Commission, also the good agricultural practice (GAP), which specifies the use authorised by the Member States. For the Member State which notified the use leading to the highest MRL, this Member State had to provide also, when available, information on the residue trials and monitoring data.

According to 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 (GAP)*". This meant in practice that the MRL in the Member State with the GAP leading to the highest MRL should be selected as draft EU temporary MRL, provided that it did not present an unacceptable risk to consumers. This requirement was introduced to allow Member States to keep their authorisations for plant protection products in place, pending the finalisation of the review programme under Directive 91/414/EEC, as well as the review of existing MRLs, as laid down in Article 12 of Regulation (EC) No 396/2005.

The Commission developed a database and provided Member States with a spread sheet for notifying their national MRLs and by August 2005 the Commission finalised a database with all MRLs notified by Member States, indicating the critical (highest) MRL for each pesticide/crop combination, and the Member State in which this level was authorised. The Commission made the list available on the Directorate General Health and Consumers (DG SANCO) public website and asked the European Food Safety Authority (EFSA) to provide a reasoned opinion on the potential risks to consumer health of all these draft temporary MRLs.

In accordance with Article 23(c), the Commission also collected from the Member States all toxicological endpoints (Acceptable Daily Intake values (ADI) and Acute Reference Dose values (ARfDs)) used in their national evaluations. The Commission then selected the lowest of them to be used by EFSA.

EFSA collected all available national dietary exposure models used by Member States for their national evaluations, including those for vulnerable consumer groups such as children.

EFSA provided a reasoned opinion on an updated list of draft temporary MRLs on 15 March 2007[2]. EFSA indicated that the opinion was a screening of the national MRLs, based on worst case assumptions. In the first place it was assumed that consumers only eat food with residue levels as high as the maximum residue level over their entire lifetime. EU annual reports show, however, that the actual residue levels are much lower than the MRL and that about 60% of food contains no measurable residues[3]. Secondly it was assumed that due to variability of residues certain individual food items (e.g. an apple or pepper) contain up to 7 times more residues than the MRL. Recent scientific studies show that the actual variability of

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[2] http://www.efsa.europa.eu/en/efsajournal/pub/32r.htm

[3] For reports from 1996 to 2006 see: http://ec.europa.eu/food/fvo/specialreports/pesticides_index_en.htm Later reports also confirm this observation (see: http://www.efsa.europa.eu/en/pesticides/mrls.htm).

residues is not 7, but rather in the order of 3 times the residue level measured in composite samples (samples for analysis contain 10 apples).

MRLs regarding 92 of the 236 substances were assessed to be safe under the worst case conditions. As a consequence for those, no further evaluations were necessary because when the MRLs are already safe at worst case conditions, they will also be safe at realistic conditions. This stepwise approach is developed and recommended by the World Health Organisation (WHO[4]).

For the substances for which an unacceptable consumer risk could not be excluded, the Commission organised meetings between EFSA and those Member States whose MRLs needed refined risk assessment. These Member States were invited to provide precise levels of residues in the edible portion of the crop and any other information that were used in the refinement of the risk assessment when they fixed the national MRLs.

Based on this information the intake assessments were adapted. If an MRL was identified as safe for all EU consumer groups, it was proposed as temporary MRL. In case the refinements did not lead to a safe temporary MRL, lower national MRLs were considered from other Member States or if no safe national MRL was identified, the temporary MRL was proposed at the lowest limit of analytical determination (LOD). This was the case for one or more MRLs of about 96 active substances. For those substances Member States had therefore to withdraw the corresponding national authorisations. The list of proposed temporary MRLs was published on the DG SANCO website and notified to the World Trade Organisation (WTO) member countries according to the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).

On 1 March 2008 the temporary MRLs were published in Regulation (EC) No 149/2008, entering into force on 1 September 2008. From that moment onwards the Commission, the Member States and EFSA started to work on the review of these temporary MRLs as part of the review process provided for in Article 12 of Regulation (EC) No 396/2005. This review consists of thorough evaluation of all existing MRLs including the temporary ones, based on the EFSA peer reviewed toxicological endpoints after their approval or non-approval under Directive 91/414/EEC or Regulation (EC) No 1107/2009. This work is currently on-going.

Grounds invoked for the internal review

1. No high level of consumer protection

You argue that Regulation (EC) No 149/2008 does not set the MRLs at "the lowest achievable level consistent with GAP" because not the lowest but the highest national MRL was selected as draft temporary MRL.

However, according to Article 25 of Regulation (EC) No 396/2005 *"temporary MRLs shall be set at the lowest level that can be achieved in **all** Member States on the basis of good agricultural practice"*.

The addition "that can be achieved in all Member States" means in fact that each temporary MRL should be established at the highest MRL applicable in any of the Member States (provided that this MRL is based on GAP).

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[4] http://www.who.int/foodsafety/publications/chem/pesticides/en/index.html

As you correctly mention the Commission did not check all GAPs to see if lower levels were possible because the Commission was not required to verify whether Member States can achieve lower levels. On the contrary, the provisions of Regulation (EC) No 396/2005 required the Commission during this exercise to respect the national MRLs provided that consumer safety was ensured, as explained in Recital 31

"Such temporary harmonised MRLs should be based, in particular, on existing national MRLs established by the Member States and should respect the national arrangements by which they were established, provided that the MRLs do not present an unacceptable risk to consumers."

The reason why the legislator did not require the Commission to check whether lower levels were achievable in Member States is that this could not be achieved at the first establishment of harmonised MRLs. This kind of verification would have required a much longer period of time. Moreover it was foreseen that all uses and MRLs would be reviewed in a second phase after the complete substance evaluation under Directive 91/414/EEC.

Of course the Commission sees the merit in comparing GAPs between Member States for similar pest control situations as such, but in the frame of Chapter IV of Regulation (EC) No 396/2005 this was neither foreseen nor possible in the time frame imposed by the legislator. I would like to draw your attention to the work done in the framework of Directive 2009/128/EC on the sustainable use of pesticides, where such actions are planned.

It should be noted that even after the review of the existing MRLs under Article 12 of Regulation (EC) No 396/2005 and after the introduction of sustainable use practices, differences between Member States in authorisations of GAPs will remain because of geographic and climatic differences (e.g. some insect pests are present during a longer period in the season in southern Member States than in northern Member States and thus the GAP is also different).

You claim that "Regulation (EC) No 149/2008 [..] selects and regulates those MRLs from EU Member States which are the highest ones and to the highest level possible based on health standards (ADI/ARfD)".

That is not correct. MRLs were not set just below the ADI or ARfD. They were based on GAP. In some cases the GAP level correspond to less than 1 % of the ADI, in some cases up to 99%. In most cases the predicted/estimated exposure represents a value in between these values.

In conclusion the temporary MRLs first established by Regulation (EC) No 149/2008 comply with a high level of consumer protection as they do not lead to an exceedence of the ADI or ARfD for any of the EU consumer groups, including the most vulnerable ones.

The methodology for the first setting of temporary MRLs in Annex III complied with the provisions of Articles 22 to 25 of Regulation (EC) No 396/2005.

2. No proper evaluation of the dossiers

You argue that data which should normally be reviewed in the course of a risk assessment was not available and therefore not reviewed. You indicate that the Commission took a decision on temporary MRLs disregarding the fact that information was lacking.

I need to point out, however, that Articles 22 to 25 of Regulation (EC) No 396/2005 do not set up a procedure for a full evaluation of a complete dossier in the process for first setting temporary MRLs.

For the first setting of temporary MRLs it was necessary to evaluate whether MRLs presented unacceptable risks to consumers. EFSA indeed stated that its opinion was not based on all information normally available for MRL evaluations, but also explained how it bridged the data gaps. As follows from the above discussion, during this exercise EFSA's task was not to check whether the Member States fixed the national MRLs according to the data requirements set under Directive 91/414/EEC, but to verify whether these national MRLs did not present an unacceptable risk for consumers in the EU. As explained earlier, Regulation (EC) No 396/2005 requires that the arrangements under which these national MRLs were set in the past were respected. It has to be kept in mind that procedures in the Member States in the past varied considerably. It is expected that Member States verified whether their MRLs were established at levels safe for their own consumers. However national MRL are not per se safe for all EU consumers. Therefore the national MRLs could not be taken over automatically, but had to be checked for safety for all EU consumer groups.

After the inclusion of a substance in Annex I to Directive 91/414/EEC Member States have 4 years to ensure the full compliance with all data requirements and evaluation criteria for all uses and thus for all MRLs. In parallel with this process, the review of all MRLs including temporary MRLs is on-going under Article 12 of Regulation (EC) No 396/2005. The submission of a full dossier under Directive 91/414/EEC, now replaced by Regulation (EC) No 1107/2009, is the prerequisite to the review of MRLs under this provision. In other terms the review under Article 12 could not start before the full dossiers were required by law.

3. Cumulative exposure of consumers not taken into account

You claim that EFSA did not consider the cumulative effect of residues of plant protection products and you provide as an example the group of substances called "organophosphates".

According to Article 14(2)(b) of Regulation (EC) No 396/2005, when deciding on an application concerning MRLs, the Commission shall take into account "*the possible presence of pesticide residues arising from sources other than current plant protection uses of active substances, and their known cumulative and synergistic effects, when the methods to assess such effects are available* ".

Cumulative exposure assessment was not applied when temporary MRLs were adopted because the methods to perform such assessment were not yet available and had still to be developed.

As reflected in recital 6 that these methods should be developed in consultation with EFSA:

(6) It is also important to carry out further work to develop a methodology to take into account cumulative and synergistic effects. In view of human exposure to combinations of active substances and their cumulative and possible aggregate and synergistic effects on human health, MRLs should be set after consultation of the European Food Safety Authority[...]

In 2006, EFSA started to develop a methodology for cumulative risk assessment. The first results of this exercise, e.g. the cumulative evaluation of the triazoles, have been published on the EFSA website. EFSA has been confronted with many methodological problems which

caused a substantial delay of the project. In particular the lack of data on cumulative exposure and the classification of common assessment groups are problems that EFSA is currently solving. In addition, at the request of the Commission, EFSA is developing a model for taking into account the cumulative risk when deciding about individual MRL applications. EFSA has indicated that it will publish general guidelines for the application of cumulative risk assessment in the course of 2013. It is true that cumulative evaluation methods are also under development in other parts of the world and that results of pilot studies have been published elsewhere also. However, these methods are not immediately applicable to the EU situation because of different consumption patterns.

For the first setting of temporary MRLs in Annex III of Regulation (EC) No 396/2005, EFSA performed some combined exposure assessments when possible (e.g. for the phosphides), but could not do this for all groups of substances (e.g. the organophosphates). When the methods are developed and finalised by EFSA, the Commission will require that they are used for the setting of new MRLs and for the review of MRLs under Article 12.

From your letter I understand that you are particularly concerned about the 17 organophosphates for which temporary MRLs are set. I can reassure you in this respect, because meanwhile all but two of these have been withdrawn or are being phased out from the European market, most of them even worldwide. Only ethoprophos and phosmet may still be used in the EU albeit under very strict conditions (e.g. ethoprophos only for soil treatment against nematodes). The most recent European Union Report on Pesticide Residues in Food for 2009 showed that fewer organophosphates occur in the samples and that multiple residues only contain one or two plant protection products containing organophosphates.

4. Many (temporary) MRLs exceed health standards

You express concern about the process of refinements of the risk assessments.

As explained earlier in this letter, the procedure for assessing the national MRLs was stepwise. The first step was a screening by EFSA which showed that already for 92 substances no risk was identified under worse case assumptions. Of the remaining 144 EFSA could not exclude potential risks unless more data were available about consumer exposure under more realistic assumptions. Refinement does not mean the removal of safety factors, but consists of the substitution of exaggerated values by precise data from scientific studies when available.

Refinement of the risk assessment took place between September 2007 and January 2008, involving Commission representatives, experts from EFSA and experts from those Member States who had set MRLs with potential risks for consumers.

The experts examined the studies submitted at the time that these national MRLs were laid down. Criteria for acceptance of refinements had been agreed by them in advance. Refinements allowed were about the precise level of residues in the edible portion: field studies on residues immediately after harvest, peel pulp distribution, processing (juice making, oil pressing, winemaking, cereals to bread, beets to sugar etc.) and residues variability studies. It was agreed that monitoring data and data on the percentage crop treated were not accepted in the assessment, because these could change from one year to the next and may seriously underestimate the exposure. In case no reliable information was available the worst case exposure was assumed. For many pending active substances new EFSA toxicological endpoints were used to replace national toxicology studies. In their absence the lowest ADI and ARfD were taken.

For substances that did not pass the EFSA screening for the chronic (life time exposure) exposure assessments the first step in the refinement was to assume a lifetime exposure of food with residues of half the MRL values. This step (only to be used for this temporary MRL exercise, agreed by all Member States) was based on the fact that the real exposure is always less than one third of the MRL over lifetime. For substances that still exceeded the ADI, further refinements were carried out using supervised field trial data, processing studies, corrections for peel/pulp distribution and edible portions. When the ADI was still exceeded, decisions were made about which uses had to be withdrawn, in most cases the 3 to 4 largest contributors to the intake.

The exercise resulted in withdrawal of one or more MRLs for 96 of the remaining 144 substances evaluated by EFSA.

In conclusion, based on the rigorous approach as well as the thorough reviews described above, the Commission is of the view that there are no temporary MRLs included in Regulation (EC) No 149/2008 which are set at a level presenting an unacceptable risk for consumers.

Conclusion

For the above reasons, the internal review of Regulation (EC) No 149/2008 leads to the conclusion that the Commission could not replace the approach it applied in that Regulation with the approach that you suggest in your request for a number of legal and practical constraints. At the same time, the review has confirmed that in adopting Regulation (EC) No 149/2008, the Commission complied fully with the requirements of Regulation (EC) No 396/2005. The comments put forward in your request for internal review, as well as your request to withdraw or suspend Regulation (EC) No 149/2008, thus have to be dismissed as unfounded.

Yours sincerely,