28.2.2014

NOTICE TO MEMBERS

Subject: Petition 1268/2010 by Cristóbal Aguado Laza (Spanish), on behalf of the ASAJA Valencian Farmers' Association, concerning plant protection products, pests and plant diseases

1. Summary of petition

The petitioners call for the reinstatement of plant health products withdrawn from the market by the EU prior to the imminent entry into force of the more stringent plant health regulation, arguin that they play an important part in containing the new pests emerging within the EU. At the same time, they call for stricter rules governing plant products from third countries and the non-application of the principle of import tolerance (contained in Regulation 396/2005). They also urge that those operating in the commercial coproduction sectors throughout the EU be subject to the same rules and that plant products be subject to the same residue and pesticide limit values independently of their origin.

2. Admissibility

Declared admissible on 21 January 2011. Information requested from Commission under Rule 202(6).

3. **Commission reply**, received on 18 July 2011

The petition is addressing three different issues, each of them governed by specific sets of EU legislation or common practices. As a consequence, the Commission proposes to deal with each of them separately.

a) Extension of accelerated procedure to authorise active plant protection substances

The petitioner refers to active substances contained in plant protection products which as a result of a Commission decision have not been included in Annex I of Directive 91/414/EEC. Those active substances were part of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC and which was set up to review according to EU standards the active substances present on the market of Member States in July 1993. As a result of that review programme more than 300 active substances have been included in Annex I to Directive 91/414/EEC. According to this Directive the approval of active substances and authorisations of plant protection products containing those substances must ensure a high standard of protection. Therefore these active substances have been evaluated according to the requirements in Annex II and Annex III to Directive 91/414/EEC and approved based upon the risk assessment according to the criteria in Annex VI to Directive 91/414/EEC. Their use in plant protection products can be considered as safe for humans, animals and the environment. An aspect of the decision making process is also to guarantee –whenever possible- the availability of a broad spectrum of different active substances e.g. from the point of resistance management.

Following the progress report presented by the Commission under Directive 91/414/EEC, the European Parliament by its Resolution of 30 May 2002 and the Council in its Conclusions of 12 December 2001 asked the Commission to review Directive 91/414/EEC and identified a number of issues for the Commission to address. The Directive will now be repealed and replaced by Regulation (EC) No 1107/2009 which will be applicable in all Member States from 14 June 2011. This Regulation takes into account the conclusions of the European Parliament, the experience gained from the application of Directive 91/414/EEC and recent scientific and technical developments.

In order to ensure that diversification of agriculture and horticulture is not jeopardised by the lack of availability of plant protection products, the Regulation establishes specific rules for minor uses. In that context, according to Article 51(9) the Commission has to present by 14 December 2011 a report to the European Parliament and the Council on the establishment of a European fund for minor uses, accompanied, if appropriate, by a legislative proposal. In this respect 'minor use' means use of a plant protection product on crops which are (i) not widely grown in that Member State or (ii) which are widely grown, to meet an exceptional plant protection need.

Petitioners ask for the "immediate extension of the accelerated procedure to all reclassified active substances, i.e. those withdrawn by Community decision and for which a new application for inclusion is now being submitted."

The scope and conditions for the application of the accelerated procedure are clearly described in Commission Regulation (EC) No 33/2008 and read as follows:
"Where a second, third or fourth stage substance has been the subject of a non-inclusion Decision in accordance with Article 6(1) of Directive 91/414/EEC, and a draft assessment report has been prepared, any person who had participated as notifier in the procedure leading up to that decision or any person who in agreement with the original notifier replaced him for the purposes of this Regulation, may submit an application in accordance with the accelerated procedure provided for in Articles 14 to 19 of this Regulation. Such an application must be submitted within six months from the date of publication of the non-inclusion decision as regards third and fourth stage substances, or, within six months from the date of entry into

force of this Regulation as regards second stage substances."

74 active substances are covered by this accelerated procedure. This procedure applies to 10 active substances not included in the framework of the second stage of the review programme and to 64 active substances voluntarily withdrawn during the third stage of the review programme (49 substances; all listed in Commission Decision 2008/934/EC) and during the fourth stage of the review programme (15 substances; all listed in Commission Decision 2008/941/EC). An overview of those active substances can be found in Document SANCO 01896/2008, Rev of 21 January 2011[1] (Resubmission of Applications for Inclusion of Active Substances not Included in Annex I to Directive 91/414/EEC).

The accelerated procedure is designed to allow the Commission to take a decision on the basis of an updated dossier before the date at which Member States, as required by the non-inclusion decisions, have to withdraw the national authorisations for plant protection products containing those active substances.

In order to allow the examination of those substances to be completed, the period for Member States to withdraw authorisations in respect of those substances was extended from 31 December 2010 to 31 December 2011 by Regulation (EU) No 741/2010.

Conclusion

When evaluating active substances, a high level of protection of human and animal health and the environment needs to be ensured while at the same time guaranteeing -whenever possible- the availability of a broad spectrum of different active substances. All active substances which were part of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC have therefore been evaluated according to the EU requirements and criteria. The accelerated procedure was applicable to a limited group of substances meeting the criteria as set out in Regulation (EC) No 33/2008. However to speed up the approval of active substances, strict deadlines have been established for the different procedural steps in Regulation (EC) No 1107/2009 which has been adopted after extensive discussions with all parties involved. The EU is not indifferent to the problems faced by farmers. Therefore, the Regulation contains specific provisions for minor uses to ensure that diversification of agriculture and horticulture is not jeopardised by the lack of availability of plant protection products. In this respect the authorisation holder, official or scientific bodies involved in agricultural activities, professional agricultural organisations or professional users may ask for the authorisation of a plant protection product already authorised in the Member State concerned to be extended to minor uses not yet covered by that authorisation. Under these provisions, the Commission also has to present a report to the European Parliament and the Council on the establishment of a European fund for minor uses by 14 December 2011.

[1] http://ec.europa.eu/food/plant/protection/evaluation/resubmission_table_rev08062009.pdf.

b) Increase in plant health control in the European Union of pests and diseases from third countries

The Union's plant health regime (CPHR), including plant health (phytosanitary) import requirements, is based on Council Directive 2000/29/EC. In 2008, the Commission decided, given the numerous challenging factors (e.g. globalisation of trade, changes in trade patterns and emergence of new trades) that the CPHR needed to be evaluated. The evaluation took place in 2009-2010 and led to a decision to review and update the EU plant health legislation. Stakeholders have been largely involved in the ongoing process. One of the elements that are to be reviewed is the import regime with a particular attention to be paid to high-risk trades (in particular: trade in plants for planting / propagating material and new trades). The reviewed CPHR should *inter alia* more effectively prevent the introduction of plant pests from third countries, through e.g. faster response to emerging risks. The legal proposals from the Commission are scheduled for 2012. The Petitioners are invited to consult extensive information on the CPHR review on the Commission's website at http://ec.europa.eu/food/plant/strategy/index_en.htm .

Conclusion

The Commission is in the process to review and update the EU plant health legislation, including the import regime. The legal proposals from the Commission are scheduled for 2012. The Petitioners are invited to participate in this process. The Commission considers consultation of stakeholders of the plant health regime a key element of the review and the impact assessment.

c) Elimination in the European Union of the concept of 'import tolerances' of plant protection residues from third countries

The use of the concept of "import tolerances" (i.e. Maximum Residue Level (MRL) for imported products) is necessitated by international trade rules. The EU has international obligations which do not allow the EU to block imports of commodities treated with pesticides, unless there is a good reason such as if the level of residues still present on the commodity is unsafe for EU consumers. This obligation is irrespective of whether the same pesticide is also used in the EU or not. Therefore there is no reason for EU to refuse the setting of a maximum residue level for pesticides that may have been used on imported goods. Such an MRL can only be set based on a submission of a comprehensive file which is evaluated based on solid science. In case that this evaluation has a positive outcome, the EU decides then on a level for which the use of pesticides is safe for the consumers. Being similarly applied also by EU trading partners, the use of the concept enables export of agricultural products from the EU to all third countries as long as this is safe for the consumers in these countries. Likewise, it enables import of agricultural products from third countries into the EU as long as this is safe for consumers in the EU. If such a concept would not be used by the EU and its trading partners, Spanish wine producers, for example, would no longer be allowed to export wine to countries like the USA and Japan, where some pesticides legally used in Spain are not authorised.

It is true that several pesticides used in third countries are not authorised in the EU. In many cases this is not for reasons of consumer safety. The marketing may not be economically

profitable so that the manufacturer is not willing to pay the price for registration in the EU. In other cases, different pesticides are required for controlling pests that do not occur in the EU or on crops that are not grown in the EU. In such cases it is possible to import treated products into the EU when an import tolerance is established. An import tolerance is only set when a dossier is submitted and evaluated by the European Food Safety Authority (EFSA) showing that the residues do not present a consumer risk. In the case that these residues are not safe for any of the EU consumer groups, no import tolerance is granted.

Conclusion

Elimination of the concept of "import tolerances" is neither in the interest of EU farmers nor does it appear feasible because of our international obligations. Therefore the Commission dissuades actions to depart from the concept of "import tolerances".

4. Commission reply, received on 28 August 2013

Further to the latest information received, the Commission can provide an update as regards the second issue of the petition (Increase in plant health control in the European Union of pests and diseases from third countries).

Concerning the two other elements of the petition, namely the authorisation of active plant protection substances (part I) and reciprocity (part III), the response provided by the Commission in writing on 18 July 2011 and during the meeting of the Committee on Petitions on 8 May 2012 can still be regarded as comprehensive and up-to-date.

Following the evaluation (2009-2010) and review (2010-2011) by the Commission of the EU plant health regime, a legislative proposal was developed for a Regulation on protective measures against pests of plants, which was adopted on 6 May 2013 (COM(2013) 267 final).

The proposed Regulation should provide new tools for increased protection against new pests of plants reaching the Union with plants and plant products from third countries, combined with new measures to ensure early detection and immediate eradication of outbreaks of such new pests. To this end, mandatory surveys would be required from the Member States on their territories for outbreaks of regulated pests and clear rules set out as regards pest eradication. Union financial support would be provided to the Member States for carrying out those surveys and to the operators concerned for the lost value of plant material destroyed for outbreak eradication purposes.

The regime would also be modernised as regards movements of plants and plant products inside the Union, resulting in the reduction of administrative burden and costs for operators.

The Petitioners are invited to consult extensive information on the legal proposal and the accompanying impact assessment on the Commission's website at http://ec.europa.eu/food/plant/plant_health_biosafety/rules/index_en.htm.

5. Commission reply, received on 28 February 2014

Further to the information previously provided on this petition, an update is offered as regards issues on plant protection products which were raised in the Petitions committee meeting of 5th December 2013 that pertain to Regulation (EC) No 1107/2009 concerning the placing on the market of plant protection products and to Regulation (EC) No 396/2005 on the setting of pesticide residues maximum residue levels (MRLs).

Part I ***: P*lant protection products**

Minor uses:

According to Article 51(9) of Regulation (EC) No 1107/2009[1] on plant protection products, the Commission is required to submit a report to the European Parliament and the Council on the possible establishment of a minor uses fund.

The report was due by December 2011, but due to lengthy consultations with other Commission services, and to other more recent overriding priorities, it was ultimately postponed. Now the Commission expects to adopt the report on minor uses in February 2014.

The report on minor uses foresees in the creation of an independent coordination facility ("Technical Secretariat") on minor uses which is co-funded by the Commission. Main objectives of this coordination facility are information sharing and coordination of minor use work between Member States and stakeholders, and stimulation of harmonisation.

In addition to the proposed coordination facility on minor uses the Commission will support an ERANET on Integrated Pest Management with specific reference to minor uses (IPM ERANET). ERANETs are research coordination instruments whereby Member States can coordinate their National research activities and ultimately fund joint projects. Some of the relevant expected outputs are the mapping of on-going research activities and to ensure coordination and reduce overlapping between national and EU funding.

Coordination between the IPM ERANET and the proposed coordination facility will be imperative and ultimately beneficial to resolving future minor use crop issues.

Availability of active substances:

It should be emphasized that currently there are around 450 approved active substances and that since the petition was introduced the Commission has caught up with the backlog of applications for approval and as a consequence many new active substances have been approved.

To better coordinate and monitor the use of emergency authorisations according to Article 53 of Regulation (EC) No 1107/2009 the Commission has prepared a Working Document on Emergency Situations (SANCO/10087/2013). This document lays down the procedure for Member States when granting such an authorisation under Article 53 and introduces the use of a notification form that provides the necessary transparency and clarification.

The introduction of this Working Document has increased the harmonisation between

[1] OJ L 309, 24.11.2009

Member States in granting emergency authorisations and also resulted in a better reporting to the Commission. On a regular basis the Commission makes the notifications of emergency authorisations received from Member States publically available.

However, it is important that Member States uphold the integrity of the authorisation system. In particular, emergency authorisations should not be granted as a routine alternative to extensions of use or other forms of standard authorisation.

As stated above the Commission is working on solutions regarding the availability of active substances especially for minor uses. In this respect the Commission is aware that a lack of plant protection solutions can carry potential negative effects on human health and the environment, due to possible illegal use of plant protection products, and that EU agriculture should remain competitive.

Part II : Plant health

Import of plant products:

Concerning the element of the petition on phytosanitary import requirements and the implementation of a limitation of market access for third country products in a similar way as third countries apply to EU products, *[The reference to part III and reciprocity seems to be a mistake. In the relevant part (part II), the petition does not seem to request reciprocity with third countries as regards the requirements for import but to apply rules similar to those of some third countries as regards the number of entry points, inspections and registration of plots, etc.]* , it needs to be indicated that phytosanitary import restrictions can only be based on identified risks, in line with the WTO-SPS Agreement.. The Commission follows up the evolution of import interceptions and can put import restrictions in place when justified. This was the case recently for the import of citrus fruit from South-Africa: after numerous interceptions, Commission Decision 2013/754/EU introduced some additional requirements.

Part III : **Pesticide residues**

Import of plant products:

Concerning the element of the petition on reciprocity (part III), the response provided by the Commission in writing on 18 July 2011 and during the meeting of the Committee on Petitions on 8 May 2012 can still be regarded as comprehensive and up-to-date.