

## ANNEX - RESPONSE TO THE RECOMMENDATIONS

Competent Authority response received 16 July 2007

Response by Greece to the recommendations of Mission report ref. DG (SANCO) 2007-7218 – in order to evaluate controls of pesticide residues in and on food of plant origin

<b>Recommendation</b>	<b>Action proposed by Competent Authority</b>
(1) The CAs should continue to establish a co-ordinated and comprehensive control plan for the marketing and use of plant protection products and assign sufficient staff to implement the controls, including follow-up, in accordance with Article 17 of Council Directive 91/414/EEC.	The Ministry of Rural Development and Food, via the Directorate for Plant Production Protection, is planning and is applying a coordinated control programme for the marketing and use of plant protection products, including follow-up, in accordance with Article 17 of Directive 91/414/EEC. Updated control guidelines are being finalized and are scheduled to be issued by December 2007 at the latest.  The number of staff involved in controls is set to increase after completion of the training programme in late 2008.
(2) The CAs should ensure that the annual report to the Commission, under Article 17 of Council Directive 91/414/EEC, is complete.	The annual report to the European Commission pursuant to Article 17 of Directive 901/414/EEC includes findings from most of the country's nomi, but covering all the basic agricultural regions in Greece where crops are grown, i.e. where plant protection products are used.  Results from all nomi will be requested and are expected to be incorporated into the 2009 annual report to the Commission for control results from 2008.

<b>Recommendation</b>	<b>Action proposed by Competent Authority</b>
<p>(3) The CAs should transpose amendments to Directives 76/895/EEC, 86/362/EEC and 90/642/EEC on pesticide MRLs within the required timelines</p>	<p>As it says in section 5.1 of the mission report, all legislation has to date been transposed into national law. All harmonizing amendments to the directives on pesticide residues are listed in the annex to the pre-mission questionnaire and were made within the requisite timelines.</p> <p>The exceptions are Directives 88/298/EEC and 89/186/EEC, which have not indeed been transposed into national law. The MRLs given in Directive 89/186/EEC have been amended by subsequent directives that have been transposed into national law. To be more precise, some of the MRLs in Directive 88/298/EEC are still in force, but since these two directives date from 1988 and 1989 respectively, the process of harmonizing them will be applied once the subject has been examined by lawyers from the Ministry. We would also point out that the MRLs in Directive 88/298/EEC that are still in force will be added to the annexes to Regulation 396/2005, which has immediate effect without the need to harmonise Member State legislation.</p> <p>It is clear from the above that recommendation number 3 with its general wording is at odds with point 5.1 of the mission report, which is in fact correctly worded.</p>
<p>(4) The CAs should implement audit systems as required by Article 4 (6) of Regulation (EC) No 882/2004.</p>	<p>The procedure for setting up an internal audit system in the Ministry of Rural Development and Food for pesticide residue controls is currently being looked into.</p> <p>As has already been pointed out in connection with Article 22 of JMD 15523/06, GG 1187/B/31-8-06, "Requisite supplementary measures for implementing Regulations (EC) 178/2002, 852/2004, 853/2004, 854/2004 and 882/2004 of the European Parliament and of the Council and harmonisation of Directive 2004/41/EC of the European Parliament and of the Council", the plan is to issue national implementing measures for the procedures governing the internal and external audit of the bodies which have been commissioned by the EFET to carry out the official audit to ensure that the operational criteria of Regulation 882/04 are met. In legislative terms, this action will end with the amendment of Presidential Decree 223/01, GG 223/A/ 06-09-00, "Organisation of the Hellenic Food Safety Authority [EFET]", which is currently being worked on.</p>

<b>Recommendation</b>	<b>Action proposed by Competent Authority</b>
<p>(5) The CAs should ensure there is efficient and effective co-ordination between all competent authorities carrying out official controls in accordance with Article 4 (3) of Regulation (EC) No 882/2004.</p>	<p>As stated in section 6.2(3) of the mission report, vertical communication within the Ministry of Regional Development and Food is working well. This creates a sound basis for pesticide residue controls on agricultural products of plant origin.</p> <p>The deficiencies referred to in the report concerning communications between the Ministry of Rural Development and Food and the EFET are, we think, of minor significance and do not affect control activities. Furthermore, experience acquired on a practical, day-to-day basis, shows that communications are improving. This is largely attributable to the holding of meetings and visits by representatives from the EFET and the Ministry of Rural Development and Food. These representatives work, by sector of competence, on the preparation, compilation, implementation and evaluation of the findings of the official programme of pesticide controls.</p> <p>In the event of an emergency, representatives of the two bodies contact each other immediately to exchange information and work together.</p>
<p>(6) The CAs should consider including instructions for carrying out a risk assessment and criteria for the notification of pesticide residue findings as specified by the "Draft guidance document on notification criteria for pesticide residue findings to the Rapid Alert System for Food and Feed system" (SANCO/3346/2001, rev. 7) into EFET's written procedures for the operation of the RASFF system.</p>	<p>An assessment of the level of dietary risk posed by pesticide residues (dietary risk assessment) is carried out by pesticide residue experts from the Directorate for Plant Protection at the Ministry of Rural Development and Food. Depending on the assessment results, and on the basis of document SANCO/3346/2001 rev. 7, the Directorate for Plant Protection takes a decision about whether or not to make a notification to RASFF, this being done via the EFET.</p> <p>Guidelines on RASFF notifications were issued by the EFET in circular 6975 of 13 April 2006, which also covers the sector of pesticides, and by means of the commissioned implementation of an Annual Audit Programme in EFET circular 6976 of 13 April 2007). More detailed guidelines pursuant to document SANCO/3346/2001 rev. 7 are scheduled to be sent to the competent authorities in 2008.</p>
<p>(7) The CAs should ensure that they take account of the reliability of food business operators' own checks when carrying out official controls as stipulated in Article 3 (1) (c) of Regulation (EC) No 882/2004.</p>	<p>The provisions of the article in question are already applied as a criterion when implementing the control programme. This is confirmed by the "follow up" checks which are carried out regularly, as was ascertained and as referred to in the mission report.</p>

<b>Recommendation</b>	<b>Action proposed by Competent Authority</b>
<p>(8) The CAs should ensure that feed and food business operators can obtain sufficient numbers of samples for a supplementary expert opinion as required by Article 11 (7) of Regulation (EC) No 882/2004.</p>	<p>In point of fact, Article 11(6) of Regulation 882/2004 states that "[the competent bodies] ...shall ensure that feed and food business operators can obtain sufficient numbers of samples for a supplementary expert opinion, unless impossible in case of highly perishable products or very low quantity of available substrate".</p> <p>This being the case, it should be explained that, in this specific instance, the samples of fruit, vegetables and cereals obtained for the checking of pesticide residues constitutes a particularly perishable assortment (tissue/probable residues), particularly if the goods in question are not handled as they should be, as this will lead to a rapid reduction in the levels of residues in the substrate. The way an official sample is handled cannot be guaranteed once it is handed over to the auditee. This, to our mind, is why the words "unless impossible in case of highly perishable products" was added to Article 11 of Regulation 882.</p> <p>Furthermore, not a single auditee has to date submitted a request to the sampling experts from the Regional Centres for Plant Protection and Quality Control and from the Directorates for Rural Development for such a sample.</p> <p>In accordance with the law (Article 3 of JMD 332622, GG B 115), the plan is to re-examine the sample at the request of the interested party (objection). The re-examination will be done on a laboratory sample kept in the laboratory from the original sample.</p> <p>The EFET, in accordance with the requirements of Article 11(7) of Regulation (EC) 882/2004, applies the provisions of the Food and Drinks Code. Specifically, a business whose food is subject to a laboratory check concerning a chemical risk or parameter may, if the food is deemed not to comply with the relevant legislation, lodge an appeal. To allow this right to be exercised, two samples (A and B) are always taken, sample B (for the appeal under investigation) being kept secure at the Official Audit Laboratory.</p>

<b>Recommendation</b>	<b>Action proposed by Competent Authority</b>
<p>(9) The CAs should ensure that the national reference laboratories work closely together, so as to ensure efficient coordination between them, with other national laboratories and the Community reference laboratories in accordance with Article 33 (5) of Regulation (EC) 882/2004.</p>	<p>In accordance with JMD 15523/06, the EFET is the Central Competent Authority and, as such, is responsible for determining the National Reference Laboratories. When exercising its competences, it invites the National Reference Laboratories to discussions at least once a year in order to facilitate coordination.</p> <p>The following bodies have been designated national reference laboratories for different categories for pesticide residues in food of plant origin: the Residue Laboratories of the Benaki Phytopathological Institute (pesticide residues on fruit, vegetables and cereals, plus analysis methods) and the General State Chemical Laboratory (pesticide residues on cereals, analysis methods).</p> <p>The Director of the Residues Laboratory at the Benaki Phytopathological Institute has been designated the EU laboratories contact for all categories (pesticide residues in fruit, vegetables and cereals, plus analysis methods). He is responsible for communications with Community Reference Laboratories in the field of pesticide residues in food of plant origin. Also, and in conjunction with the competent authorities, he ensures effective coordination and keeps other laboratories informed about technical and laboratory-related matters.</p>

<b>Recommendation</b>	<b>Action proposed by Competent Authority</b>
<p>(10) The CAs should ensure that all designated laboratories comply with Article 12 of Regulation (EC) No 882/2004, or come under the derogation provided for in Article 18 of Commission Regulation (EC) No 2076/2005. The laboratories could put in place the SANCO guidelines for 'Quality Control Procedures for Pesticide Residue Analysis' (Document No SANCO/10232/2006) which also foresees regular participation in relevant proficiency tests.</p>	<p>The Residue Laboratories of the Benaki Phytopathological Institute and of the State Chemical Laboratory, which have been designated national reference laboratories for various categories of pesticide residues, comply fully with the requirements of Article 12 of Regulation (EC) 882/04.</p> <p>The residue laboratories of the Regional Centres for Crop Protection and Quality Control at the Ministry for Rural Development and Food, which have been taking part in official checks for a number of years now, were recently supplied with additional state-of-the-art analytical equipment, which opens up the way for further development at analytical level. These laboratories are at the pre-evaluation stage for the completion of accreditation, which is expected to be completed by the end of 2007.</p> <p>The control laboratories regularly take part in the EU proficiency tests, with good results, and they already follow the guidelines on "Quality Control Procedures for Pesticide Residue Analysis" (Document No SANCO/10232/2006).</p>

<b>Recommendation</b>	<b>Action proposed by Competent Authority</b>
<p>(11) The CAs should consider substantially increasing the range of analytes including metabolites covered by their analytical methods for pesticide residues in food of plant origin, so as to better reflect the substances that are marketed and used and to ensure implementation of Directive 76/895/EEC, Directive 86/362/EEC and Directive 2006/125/EC. They should ensure that analytical methods used comply with Article 11 of Regulation (EC) No 882/2004 and for the analysis of baby food with Article 7.2 of Directive 2006/125/EC.</p>	<p>Recently the control laboratories were provided with additional high-tech analytical equipment (LC/MS and the like). The Residues Laboratory of the Benaki Phytopathological Laboratory is thus validating methods for 70 more active substances and metabolites. Validation is expected to be completed within two months, bringing the number of substances controlled up to 180, compared with the 135 average number of substances controlled by control laboratories in the EU. Similar procedures mean that this number is set to increase still further.</p> <p>The residues laboratory of the State Chemical Laboratory has developed an analytical method that includes around 90 active substances and metabolites in processed foods of plant origin. The method will also be validated for baby food, including substances from the Annexes to Directives 2003/13/EC and 2003/14/EC, with low limits of analytical determination.</p> <p>The residue laboratories of the Regional Centres for Crop Protection and Quality Control, by using the new analytical facilities, are expected to continue the gradual increase in the number of active substances and metabolites analysed by 20% per year, as has been the case over the last few years.</p>