Response of the Competent Authorities of Portugal to the recommendations of Report ref. DG(SANCO)/2012-6298-MR of an audit carried

out from 20 to 27 November 2012 in order to evaluate controls of pesticides

N°	Recommendation	Action Proposed by the Competent Authority	
1	Ensure that the provisions of Directive 2009/128/EC are transposed into the national legislation, as required by Article 23 of the same Directive.	The Law 26/2013, of 11 April, transposes into the national legislation the Directive 2009/128/EC, as required.	
2	Ensure that appropriate training covering issues related to PPPs and pesticide residues, is provided to ASAE inspectors to keep them up-to-date in their competencies, as required by Article 6 of Regulation (EC) No 882/2004.	The National Action Plan (NAP) establishes the training of the inspectors from all the inspection authorities. As soon as the NAP is approved, there will be contacts with ASAE to develop a training plan. ASAE gives training to its inspectors covering the different areas of expertise, and there has been a reduction / change on the staff that leads to the need to renew the training courses for new inspectors, two actions are usually performed annually in the most important areas.	
3	Ensure that regular and in-depth official controls on the marketing of PPPs are carried out in order to provide guarantees that PPPs placed on the market comply with the requirements of Regulation (EC) No 1107/2009, in particular Article 28 of this Regulation.	The NAP establishes the increasing of inspections along the years of duration of the Plan. Also the training referred above will contribute to the possibility of the development of an annual plan of control. There is a strengthening of cooperation between the two authorities of ASAE and DGAV, achieving that relevant information is made available to the inspectors in time where an action is scheduled planned, ASAE counting now with the collaboration of phytosanitary inspectors to monitor the situations identified	
4	Ensure that formulation analysis is performed as part of the official controls to guarantee that PPPs placed on the market meet the requirements laid down in Article 29(1)(a), (c), (d) and (h) of Regulation (EC) No 1107/2009.	The NAP establishes the implementation of an annual plan of control that analyses a sample of 5% of the products in the market.	

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5	Ensure that the official laboratory designated for formulation analysis of PPPs is assessed and accredited in accordance with the European standards, as required by Article 12(2) of Regulation (EC) No 882/2004.	The Laboratory of Formulation Analysis is already being assessed and reactivated, and the accreditation request is foreseen for last trimester of 2013.
6	Ensure that all professional users of PPPs are subject to official controls to ensure that PPPs are applied in accordance with the conditions specified on the labels as required by Article 55 of Regulation (EC) No 1107/2009 and to provide guarantees that pesticide residues do not exceed the EU MRLs as provided for in Article 18 of Regulation (EC) No 396/2005.	The control of the use of PPPs is addressed in the NAP, foreseeing its extension beyond the inspections related with cross-compliance. Regarding the control of application of PPPs according the conditions of the label, it will be one of the indicators to be verified in the context of the additional control.  The Madeira will adapt it to the specificities of agriculture practiced, the methodology that will be established at national level to ensure the official control of the substances involved.  DRAPC - We will try to comply, at regional level, as defined in the National Action Plan and additional control in this matter mentioned there, prepared by the various entities involved.
7	Ensure that a National Action Plan is adopted for setting up quantitative objectives, targets, measures and timetables to reduce the risks and impacts of pesticide use to human health and environment as laid down in Article 4(1) of Directive 2009/128/EC.	The Project of the National Action Plan (NAP) was completed by the working group and is now, since the 20 <sup>th</sup> March until the 30 <sup>th</sup> April, in public consultation, as required by Article 4 of Directive 2009/128/EC.
8	Ensure that all official laboratories designated for pesticide	LRVSA-Madeira performs its activity trying to follow the guidelines of

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	residues implement Document SANCO/12495/2011 "Method Validation and Quality Control Procedures for pesticide residues analysis in food and feed", in conjunction with Article 28 of Regulation (EC) No 396/2005.	the Document SANCO/12495/2011 and the Article 28 of Regulation (EC) No 396/2005.  LRVSA-Madeira expects the audit team to specify the guideline aspects that are not followed.  The DRAPN- Laboratory follows the Document SANCO/12495/2011.  The L-DRAPN was audited in 17e18-04-2013, IPAC Assessment for extension of scope of accreditation (multiresidues method - EN12393-2 method P) - 24 pesticides.  The LRP (INIAV) follows the Document SANCO/12495/2011 in its daily analytical activity, so the internal procedures of MQ are in accordance with this document and for that reason we do not understand the statement where it is said that we do not fully apply the Document SANCO/12495/2011.  The LRP quality control procedures, both internal and external are in compliance with the Document SANCO/12495/2011.  In what regards the external quality control, the LRP has always taken part in the EU Proficiency Tests, and it was only in 2012 that the participation was reduced due to financial difficulties.		
9	Ensure that all designated laboratories for pesticide residues have LC-MS/MS and GC-MS/MS or arrange for available analytical resources to be allocated and used appropriately so as to guarantee that official controls of pesticide residues are effective and efficient as required by Article 4(2)(c) and 4(2)(d) of Regulation (EC) No 882/2004.	LRVSA-Madeira is equipped with an LC-MS/MS, a GC-TOF/MS and several GC's as GC-ECD, GC-NPD or GC-FPD. LRVSA-Madeira agrees that GC-MS/MS is, nowadays, the state-of-art equipment for screening analysis, which permits to achieve appropriate sensitivity and can substitute several GC's with selective detectors. On the other hand, GC-TOF/MS cannot be judged as an obsolete equipment since it is more		

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		multipurpose than GC-MS/MS. It also permits to achieve the necessary sensitivity for many pesticides and a degree of confidence in qualitative analysis higher than GC-MS/MS.  The LRP (INIAV) has got a GC-TOF/MS and a GC/MSN; as to LC-MS/MS Equipment, efforts are being made for its acquisition, as early as possible.
10	Ensure that a sufficient number of samples is taken for pesticide residue analysis in order to allow for a representative assessment of the consumer exposure and compliance with the EU legislation in force, as laid down in Article 30(1) of Regulation (EC) No 396/2005.	The number of samples taken for pesticide residue analysis is decided in an annual basis, according to the EU Implementing Regulations concerning the multiannual control plan and the agricultural products that have particular national or regional interest and / or an historical past of non-compliances.  The NAP also establishes the progressive increase of the number of samples and products.
11	Ensure that the NRL fulfils the tasks set out in Article 33(2) of Regulation (EC) No 882/2004.	The technicians of the official laboratories have received training and technical support given by the LNR (LRP-INIAV) since its foundation, particularly for its installation and beginning of activity. Some certificates of these training were presented during the audit.  The technical support that the LNR gives to the official laboratories is varied, covering new methods of analysis, quality control procedures regarding Accreditation and support in daily routine activities.  In fact, training and workshops have not been lately organized; neither have comparative tests between official laboratories, due to difficulties felt by the LNR, which were caused by internal restructuring and

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		financial problems. Nevertheless, the support is given to official laboratories, whenever it is necessary and requested. It is the LNR intention, as soon as the conditions allow it, to promote new training/workshops and proficiency tests between official laboratories.		
	Ensure that official controls on the marketing of PPPs are performed regularly, on a risk basis and with appropriate frequency as laid down in Article 3(1) of Regulation (EC) No 882/2004.	Please see the answer given at recommendation 3		
	Ensure that, in the case of irregularities identified, the inspection report includes measures to be undertaken by the business operators concerned and a copy of the inspection report is provided to the operator as required by Article 9(2) and 9(3) of Regulation (EC) No 882/2004.	ASAE always raises a process of CO, and is made known to the trader of any irregularities found and the respective economic sanctions by the notification under art. 50. a RGCO. Through the analysis of results of inspetives actions traders found illegally will be targets to regularly monitor, within the availability achieved between the planned operations. According to the regulations established, this information is transmitted to the competent authority (DGAV) responsible for marketing authorization, which is responsible for preparing a report communicating the corrective measures to implement, being responsible also to follow these situations		
	Ensure that annual reports on the scope of and results from official controls under Regulation (EC) No 1107/2009 are transmitted to the Commission within the deadlines indicated in Article 68 of the Regulation.	The NAP establishes that the entities that perform the controls shall send to DGAV the report of the actions of control during the first trimester of the following year, which will allow DGAV to make its report within the required deadlines.		
15	Ensure that efficient and effective coordination between CAs	The common actions and the training that are established in the NAP		

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	involved in official controls takes place as laid down in Article 4(3) of Regulation (EC) No 882/2004.	will force the increasing in the coordination that is recommended.  (1) Already answered in 3: there is a strengthening of cooperation between the two authorities, and it was agreed the collaboration of phytosanitary inspectors working in DGAV for monitoring of situations of violations identified in the inspective actions of the ASAE  (2) In matters in question in the Autonomous Region of Madeira intervene only two distinct entities, the Regional Directorate of Agriculture and Rural Development, through its various directions services based on pre-established procedures, and the Regional Inspection of Economic Activities. The link between these two bodies is governed by a protocol established between both parties. Within their areas of competence they communicate directly with the respective national authorities.		
16	Ensure that appropriate actions are taken in the case of non-compliances identified so as to provide guarantees that the operator remedies the situation as required by Article 54 of Regulation (EC) No 882/2004.	The fact that it has been assigned to the General Inspector of the ASAE decision-making power over the processes raised of CO, in the short-term will allow the rapid conclusion of them and permitting to sanction offenders in due time. This circumstance leads to the consequent correction and by extension the prevention of non-conformities detected, simultaneously with the enhanced performance of phytosanitary inspectors working in DGAV for monitoring of situations of violations identified  The Plan for Food Security of the Autonomous Region of Madeira, which articulates with the National Plan for Control of Pesticide		

Action Plan received from the Competent Authority, 30 April 2013

# ANNEX

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N°.	Recommendation	Action Proposed by the Competent Authority
		Residues in respect to samples of vegetable production site has proper traceability thereof. Whenever one is detected nonconformity with applicable legal requirements, the services of the Regional Directorate of Agriculture and Rural Development with expertise in the area of technical assistance to farmers, are informed by Alert, under which carry out a direct contact with the offender, evaluate the cause of the occurrence and issue technical recommendations considered important to the adoption of appropriate phytosanitary practices.
17	controls on the use of PPPs and appropriate measures are taken in the light of their results as provided for in Article 4(6) of Regulation (EC) No 882/2004.	IGAMAOT is carrying out an external audit covering both official controls of pesticide residues and official controls on the use of PPPs that will be concluded on the 1st semester 2013.  During the next cycle of our MANCP (2014-2018)  Internal or external audits will be performed based on an approach of risk evaluation.