Competent Authority response to the report recommendation received 27 February 2018

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Response of the Control Body to the recommendations of report ref. DG(SANTE)/2017-6068-MR of the audit carried out from 22 November 2017 to 01 December 2017 in order to evaluate the implementation of the organic production standards and control measures applied by a recognised Control Body operating in Turkey

N°	*Recommendation*	*Action Proposed by the competent authority*
1	Ensure that any changes in the measures applied by the CB are notified to the Commission thereof, as required by Article 12(1)(a) of Regulation (EC) No 1235/2008 and that accurate information on the control activities is submitted to the Commission in the annual report referred to in Article 12(1)(b) of the same Regulation. This recommendation **is based upon conclusion No 4** Associated finding No 2 and 15	**Root-cause-analysis:** Up until now we have followed the procedure as defined in Article 33 (3) of regulation EC 834/2007, respectively provided the information in the course of submitting our annual report with the technical content as required by Article 11 3. of 1235/2008 and were therefore not aware that any change of our standard, besides notifying it to and getting it approved by our AB, must also be submitted to the commission upon occurrence. **Corrective actions/Modifications:** We will from now on adapt pour procedure and any revision/change of our equivalent standard, after being approved by the AB, will be notified without delay to the EU commission. We have changed out work instruction 09-04-10 accordingly. **Date of implementation:** From now on.
2	Ensure that the management of the information on the activities carried out worldwide allows for the CB to guarantee that: All planned controls are carried out, as required by Articles 65(1) and 65(4) of Regulation (EC) No 889/2008; All information necessary for the preparation of the audits is received before a date decided by the CB, including the information referred to in Article 71 of Regulation (EC) No 889/2008 as well in Article 63(1) of the same Regulation. This recommendation **is based upon conclusion No 26**	**Root-cause-analysis:** * *Please note that it has been necessary to delete this text in order to respect the provisions of Article 339 of the Lisbon treaty as regards confidentiality* does. deduced from our database, provide an inspection planning schedule to each of our satellite office and on a regular basis does request updates to the satellite offices with regards to the status of implementation of audits. After an audit is carried out it will be uploaded into our system, but this may, occasionally, be done with delay. However, within 4 hours * is

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N°	*Recommendation*	*Action Proposed by the competent authority*
	Associated findings No 7, 14, 17, 18 and 51	able to get up to date data from any satellite office in the world. But it is correct that not any audit may be registered in our database on a daily bases. This is also due to the fact that audits may be physically conducted prior to be registered in our database but just based on the planning provided. And also due to the fact that some satellite office do not have direct access to the current database. **Corrective actions/Modifications:** We are in the implementing phase to change to a new database and change our IT structure accordingly. With the new database, any audit prior to be even planned and consequently conducted, must be registered in the system and therefore can be supervised and controlled on day to day bases by the HQ of *. Likewise we will better be able to intervene in any ongoing processes or redirect processes in case we discover lack of compliance with the regulation. **Date of implementation:** End of March 2018 go live of new database in HQ national department. End of June 2018: go live of new database in HQ international department. And starting from them consecutively train and connect satellite offices to the new database. By end of 2018 respectively beginning of 2019 have all satellite offices connected to the system.
3	Ensure that the risk assessment implemented by the CB serves as a good basis for determining the intensity of the announced and unannounced	AL 21-02-2018 **Root-cause-analysis:**

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N°	*Recommendation*	*Action Proposed by the competent authority*
	inspections, as required by Article 92c(2)(a) of Regulation (EC) No 889/2008, and in particular that all compulsory criteria referred to in Article 65(4) of the same Regulation are taken into account for the risk assessment. This recommendation is **based upon conclusion No 27** Associated finding No 20	In our procedure (B09-04) and instruction (C09-04-02) we did already consider these criteria. Nevertheless the risk-assessment-template did not fully reflect these criteria. **Corrective actions/Modifications:** D-DE_08-450 D-DE_09-450 Table "#1_risk-assessment" We will change our priorization for the identification and selection of operators to be inspected additionally. Operators of the highest risk-category will be selected first to comply with the requirement of 10% additional inspections. Table "ref-proposals_hidden_f(1+2)" We will include additional indicators as follows: • Indicator "output/quantity" for risk-parameter "1- Intensity of production/activity" • Indicator "residue-case" for risk-parameter "2- Contamination / commingling / interchanging" • Indicator "combination of several scopes " for risk-parameter "3- Company's structure / complexity" • Indicator "pending or repetitive non-conformities or ineffective implementation of corrective measures" for all risk-parameters Staff will be instructed accordingly.

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N°	*Recommendation*	*Action Proposed by the competent authority*
		Date of implementation: By the end of April 2018
4	Ensure that: additional control visits carried out in accordance with Article 65(4) of Regulation (EC) No 889/2008 of at least 10 % of operators under contract in accordance with the risk category are performed, as required by Article 92c(2)(b) of the same Regulation; the selection of operators to be submitted to unannounced inspections and visits is determined on the basis of the risk analysis and that these are planned according to the level of risk, as required by Article 92c(2)(d) of the same Regulation. This recommendation **is based upon conclusion No 27** Associated findings No 21 and 22	**Root-cause-analysis:** Our interpretation and approach was to weight the risk-categories by giving the highest risk-category the biggest weight in order to allocate more attention to them than to the lower risk-categories. Our approach did consider all risk-categories. From now on we will follow your clarification by starting with the highest risk-category to comply with the required percentage of additional measures. **Corrective actions/Modifications:** We will adapt our risk-assessment, refer to no 3 above. Furthermore will specify our instruction "C-EN_09-04-02_Inspection, #4.5.1, afterwards staff will be instructed accordingly. **Date of implementation:** By the end of April 2018"
5	Ensure that derogations are only granted to operators in line with documented procedures and only after all necessary information has been verified by the CB, to ensure the fulfilment of all conditions by operators. This recommendation is **based upon conclusion No 37** Associated findings No 34 and 36	**Root-cause-analysis:** Our accredited procedure up until now has been based upon defining and informing the operator what kind of information must be presented in order to be granted derogation. Before a certification decision concerning the derogation was taken that information was revised and only if considered to be in line with the criteria defined the derogation was granted. However, there

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N°	*Recommendation*	*Action Proposed by the competent authority*
		was no defined procedure for application by operators to be granted a derogation. **Corrective actions/Modifications:** - We will elaborate and integrate in our QM an application format for operators to apply for and to be granted a derogation - We will integrate the application phase for derogation in our Equivalence standard - We will define a evaluation procedure for reviewing the application - We will define a procedure to inform operators about approval or denial of derogations **Date of implementation:** 1. During March 2018 elaborate detailed procedures and related document 2. During April 2018 conduct trainings and raise awareness at our staff with regards to the upcoming new procedure. 3. End of April 2018 inform operators in writing about the new procedure for applying for derogation. 4. From end of April, transitional phase between old and new procedure until end of June 2018 and from then on all derogations must be applied to * by the new procedure.
6	Ensure that the planning of samples includes taking samples during unannounced controls as appropriate, according to the risk profile of	**Root-cause-analysis:** In case of Turkey usually announced inspections are carried out as

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N°	*Recommendation*	*Action Proposed by the competent authority*
	operators, in order to comply with Article 65(2) of Regulation (EC) No 889/2008. This recommendation **is based upon conclusion No 44** Associated finding No 42	well during periods critical to the production of the crop (threats by pests and diseases). That means that announced inspections are in many cases conducted during e.g. critical spraying periods before harvest to have the most means to verify compliance. Additional risk based inspections focus on certain aspects according to the risk profile of the operator and may therefore not necessarily include the need for sampling. However, we do recognize that in case of Turkey most samples are pulled during announced inspections whereas in other countries this is not generally the case according to our internal statistics. **Corrective actions/Modifications:** C-EN_09-04-03_Sampling and Analysis B-EN_09-04_Inspection, sampling (as Evaluation) + Review We will specify our instruction and procedure in order to reduce the perception for the operators to be targeted on samples; afterwards staff will be instructed accordingly. **Date of implementation:** By the end of April 2018
7	Ensure that the list of operators contains the information required in Article 11(3) of Regulation (EC) No 1235/2008, in particular that only operators under contract are listed. This recommendation **is based upon conclusion No 47** Associated finding No 46	AL – 21.02.2018 **Root-cause-analysis:** Our list of operators is updated once a week! Our list did not show operators cancelled but it includes operators suspended, too. Suspension means that operator is still subject to the control system, therefore they are listed in the operators' list

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N°	*Recommendation*	*Action Proposed by the competent authority*
		(During suspension period of certification the Agreement remains in force and any obligations under the Agreement remain valid. Apparently we have a misinterpretation from our side. This is why long-term suspended operators may be still published in the operators' list without considering or distinguishing between the ones who are really suspended (willing and capable to implement measures) and the others who are long-term suspended (not willing or not capable to implement measures anymore) The contractual relationship of the latter is indeed like "cancelled". Article 11 (3e) of EU 1235/2008 does not require to publish the status of the operator. According to this article the result is to publish only operators subject to the control system. Nevertheless our operators' list indicates a contact-point at * homepage where information is readily available on their certification status, the product categories concerned, as well as suspended and decertified operators and products. By verifying our operators' list we have detected an error concerning the hyperlink to the "contact-point". **Corrective actions/Modifications:** 1) We will update immediately the hyperlink in the operators' list linked with contact-point (search-engine). **Date of implementation:** By the end of week no 8/2018

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N°	*Recommendation*	*Action Proposed by the competent authority*
		2) Additionally, we will specify our instruction "C-EN_09-05-02_Certificates_Issuance, Validity, Withdrawal, Suspension" by stating maximum period of suspension (e.g. 1 year) to identify and to change status of long-term suspended clients whose certification will be withdrawn. From the date of withdrawal of certification the contractual relationship is terminated unless * and the Client agree otherwise. After revision staff will be instructed accordingly **Date of implementation:** By the end of April 2018
8	Ensure that inspections are effective and cover all requirements of the CB standards, and in particular that Inspectors record the results of assessment of the precautionary measures applied by the operators in line with Section 2.2. of D-EN_001 of the CB standards; Inspectors verify records on the reason for use of fertilizers and PPPs, in line with Article 72 of Regulation (EC) No 889/2008; Inspections cover the handling of non-organic products by operators, as required by Sections 2.2. and 2.3 of D-EN_004 of the CB standards. This recommendation **is based upon conclusion No 57 ? 58 ?** Associated findings No 50, 51 and 52	**Root-cause-analysis:** In case or production the estimation of harvest quantities as well as the guideline to verify all product flow in case of processors is defined in working instructions and standard control programs the quality manual. However, a systematic documentation of such activities in order to assure a homogenous approach by all inspectors is not fully implemented. With regards to recommendation No. 52 we would like to clarify that the processing plant did not handle any non-organic product but all product entering the processing plant was from certified plots which is why no separated mass balance calculation for non-organic product was done. However, product from in conversion

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N°	*Recommendation*	*Action Proposed by the competent authority*
		fields had entered the processing plant and was sold as organic which was no verified based on records. **Corrective actions/Modifications:** - Organic System Plan (D-EN_09-201) has been modified to require the operator to document the reason/need for treatment with plant protection products). Likewise the OSP has been modified to include detailed description of the precautionary measures applied by the operator in order to prevent e.g. from drift from adjoining non organic land use presenting a risk of contamination for the organic crop. - The plot/field list (D-EN_09-224) has been modified to include estimation of harvest amounts from buffer zones - Inspection report for production (D-EN_09-310_IR_Agr_revised) has been modified to include detailed documentation of harvest yield estimation and harvested amounts including amounts harvested from buffer zones. - Inspection report for processing has been modified to include specific questions addressing the verification of sales of non-organic or respectively in transition product **Date of implementation:** Documents were modified and first trainings with reviewers and certifiers were done to collect their feedback with regards to practicability of the new requirements.

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N°	*Recommendation*	*Action Proposed by the competent authority*
		During March 2018 the final version of the respective documents will be elaborated and included in our QM, followed in April 2018 by trainings provided to inspectors. Documents will be in use for new certification processes from May 2018 onwards.
9	Ensure verification of the labels applied by operators on the final product **for export**, to guarantee that only labels complaining with Article 24 of Regulation (EC) are used by operators. This recommendation is **based upon conclusion No 59** Associated finding No 55	**Root-cause-analysis:** We approve a system of labelling and verify if it is capable of assuring compliant labelling. During inspections labels are checked if correct and if in compliance. However, this is may not be done for each and every label used in case of exporting products labelled as organic with the EU organic logo. **Corrective actions/Modifications:** The inspection report has been further amended to include more specific question related to the use of the EU organic label and require samples to be attached to the inspection report. Likewise the procedure for issuing of CoIs was amended to include guidance that the operator should submit – if product is labelled as organic with the EU organic logo – prove of final label to * together with other related documents for exports. **Date of implementation:** Modified QM documennst have been elaborated and will be included in the QM during the month of march 2018. During April 2018 the relevant staff members will be trained on evaluation of

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N°	*Recommendation*	*Action Proposed by the competent authority*
		compliant labelling and starting from May 2018 the new procedure will be effectively in place.
10	Ensure that documented risk assessment is implemented to decide on the physical checks carried out to the consignments for export to the EU, as required by Article 13 (4) of Regulation (EC) No 1235/2008. This recommendation **is based upon conclusion No 66** Associated finding 63, 64 and 65	**Root-cause-analysis:** Export consignments are only occasionally checked in case of high risk but no systematic approach on risk evaluation performed. **Corrective actions/Modifications:** We have identified already several indicators to identify a potential need for physical check These indicators up until now are designed to include amongst others, previous severe non compliances, positive residue detections of the past, suspicions arising from previous inspections, etc Based on these criteria we will document the result whether < to prescind from conducting physical checks or < to conduct an additional inspection as physical check or < to conduct a sampling as physical check. We will amend our procedures to include work instruction that if the risk analysis reveals a severe risk or threat to the organic integrity of the product the responsible staff members have to conduct a physical check of the consignment. The check may either consist in revision of documentation or sample taking, as determined appropriate. **Date of implementation:** Currently the criteria for the risk analysis are being defined and

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N°	*Recommendation*	*Action Proposed by the competent authority*
		revised by the technical staff members. Likewise the procedure for conducting physical checks is being defined and the work instructions are being elaborated. After finalizing the respective documents we will have to do an internal consulting for practicability and work flow By the end of April 2018 we expect all procedures to be finalized and integrated in the QM. During May 2018 we will have a pilot/transitional phase so that staring from June 2018 the procedure shall be implemented on all consignments exported to the EU.

* *Please note that it has been necessary to delete this text in order to respect the provisions of Article 339 of the Lisbon treaty as regards confidentiality .*

EUROPÄISCHE KOMMISSION
GENERALDIREKTION GESUNDHEIT UND LEBENSMITTELSICHERHEIT

Gesundheits- und Lebensmittelaudits und Analysen

DG(SANTE)/2017-6068 – RS

AUSZUG AUS DEM BERICHT DER GD GESUNDHEIT UND LEBENSMITTELSICHERHEIT ÜBER EIN AUDIT IN KONTROLLSTELLEN 22. NOVEMBER – 1. DEZEMBER 2017

BEWERTUNG DER VON EINER ANERKANNTEN KONTROLLSTELLE IN DER TÜRKEI ANGEWANDTEN STANDARDS UND KONTROLLMASSNAHMEN FÜR DIE ÖKOLOGISCHE/BIOLOGISCHE ERZEUGUNG

HINWEIS: DIES IST – IN DEUTSCHER ÜBERSETZUNG – EIN AUSZUG AUS DEM BERICHT ÜBER DAS OBEN GENANNTE AUDIT. VERBINDLICH IST NUR DIE LANGFASSUNG DES ORIGINALBERICHTS (DG(SANTE)/2017-6068).

ZUSAMMENFASSUNG

Dieser Bericht beschreibt die Ergebnisse eines Audits, das die GD Gesundheit und Lebensmittelsicherheit vom 22. November bis zum 1. Dezember 2017 durchgeführt hat, um die Anwendung der Standards und Kontrollmaßnahmen für die ökologische/biologische Erzeugung durch eine anerkannte Kontrollstelle in der Türkei zu bewerten. Ergänzend zum Audit in der Türkei erfolgte ein Audit am Hauptsitz der Kontrollstelle in einem EU-Mitgliedstaat.
Dem Bericht zufolge wendet die Kontrollstelle im Großen und Ganzen die Produktionsvorschriften und Kontrollmaßnahmen an, für die sie im Hinblick auf die Gleichwertigkeit von der Europäischen Kommission anerkannt wurde. Jährliche Inspektionen werden zu den am besten geeigneten Zeitpunkten angesetzt, und zusätzliche Inspektionen erfolgen unangemeldet. Die beobachteten Inspektionen erwiesen sich insgesamt als wirksam. Die Kontrollstelle nimmt eine große Anzahl von Proben und verfolgt alle Fälle weiter, in denen bei den Analysen Stoffe nachgewiesen werden, die in der ökologischen/biologischen Erzeugung nicht zugelassen sind. Bei einem bestätigten Verstoß werden von der Kontrollstelle in der Regel angemessene Durchsetzungsmaßnahmen ergriffen.

Die Wirksamkeit des von der Kontrollstelle angewandten Kontrollsystems wird jedoch herabgesetzt, da die Planung zusätzlicher Kontrollen und Probenahmen bei Unternehmern sowie der Warenuntersuchungen von Sendungen, die für die Ausfuhr in die EU bestimmt sind, nicht immer nach dem Risikoprofil des Unternehmers erfolgt. Zudem konzentrieren sich die Kontrollen nur auf die ökologische/biologische Erzeugung und Verarbeitung und vernachlässigen die Ausführung der Tätigkeit der Unternehmer im Bereich konventioneller Erzeugnisse.
Da die Zweigstellen Informationen über die durchgeführten Kontrolltätigkeiten verspätet an den Hauptsitz der Kontrollstelle weiterleiten, kann diese sich keinen richtigen Überblick über deren Durchführung verschaffen und daher nicht entsprechend reagieren, um zu gewährleisten, dass alle Tätigkeiten planmäßig durchgeführt werden. Die Kontrollstelle war sich dieses Problems bewusst und führte zum Zeitpunkt des Audits gerade eine neue Datenbankverwaltung und ein neues Zertifizierungssystem ein, um die Situation zu verbessern.
Der Bericht enthält eine Reihe von Empfehlungen an die Kontrollstelle, wie die festgestellten Mängel behoben und die Durchführung der Kontrollmaßnahmen verbessert werden können.

EMPFEHLUNGEN

Nr.	Empfehlung
1.	Es sollte sichergestellt werden, dass die Kommission gemäß Artikel 12 Absatz 1 Buchstabe a der Verordnung (EG) Nr. 1235/2008 über alle Änderungen bei den von der Kontrollstelle angewandten Maßnahmen informiert wird und dass der Kommission in dem in Artikel 12 Absatz 1 Buchstabe b dieser Verordnung genannten Jahresbericht genaue Informationen über die Kontrolltätigkeiten vorgelegt werden. *Empfehlung auf Grundlage der Schlussfolgerung 4* *Damit zusammenhängende Feststellungen: 2 und 15*
2.	Es sollte sichergestellt werden, dass die Kontrollstelle durch die Verwaltung der Informationen über die weltweit durchgeführten Tätigkeiten garantieren kann, dass: - alle geplanten Kontrollen gemäß Artikel 65 Absätze 1 und 4 der Verordnung (EG) Nr. 889/2008 durchgeführt werden; - alle für die Vorbereitung der Audits erforderlichen Informationen vor dem von der Kontrollstelle festgelegten Datum vorgelegt werden, darunter die in Artikel 71 sowie in Artikel 63 Absatz 1 der Verordnung (EG) Nr. 889/2008 genannten Informationen. *Empfehlung auf Grundlage der Schlussfolgerung 26* *Damit zusammenhängende Feststellungen: 7, 14, 17, 18 und 51*
3.	Es sollte sichergestellt werden, dass die von der Kontrollstelle durchgeführte Risikobewertung gemäß Artikel 92c Absatz 2 Buchstabe a der Verordnung

	(EG) Nr. 889/2008 eine gute Basis für die Festlegung des Ausmaßes der angekündigten und unangekündigten Inspektionen bietet und insbesondere, dass alle vorgeschriebenen Kriterien gemäß Artikel 65 Absatz 4 dieser Verordnung bei der Risikobewertung berücksichtigt werden. *Empfehlung auf Grundlage der Schlussfolgerung 27* *Damit zusammenhängende Feststellung: 20*
4.	Es sollte sichergestellt werden, dass: - gemäß Artikel 92c Absatz 2 Buchstabe b der Verordnung (EG) Nr. 889/2008 bei mindestens 10 % der unter Vertrag stehenden Unternehmer zusätzliche Kontrollbesuche gemäß Artikel 65 Absatz 4 dieser Verordnung entsprechend der Risikokategorisierung durchgeführt werden; - gemäß Artikel 92c Absatz 2 Buchstabe d dieser Verordnung die Entscheidung darüber, bei welchen Unternehmern unangekündigte Inspektionen und Besuche durchzuführen sind, auf Basis der Risikobewertung erfolgt und diese je nach Höhe des Risikos geplant werden. *Empfehlung auf Grundlage der Schlussfolgerung 27* *Damit zusammenhängende Feststellungen: 21 und 22*
5.	Es sollte sichergestellt werden, dass Unternehmern Ausnahmeregelungen nur im Einklang mit den dokumentierten Verfahren und nur nach Überprüfung aller notwendigen Informationen durch die Kontrollstelle gewährt werden, um zu gewährleisten, dass die Unternehmer alle Bedingungen erfüllen. *Empfehlung auf Grundlage der Schlussfolgerung 37* *Damit zusammenhängende Feststellungen: 34 und 36*
6.	Es sollte sichergestellt werden, dass die Probenplanung gemäß Artikel 65 Absatz 2 der Verordnung (EG) Nr. 889/2008 je nach Risikoprofil der Unternehmer gegebenenfalls auch die Probenahme bei unangekündigten Kontrollen vorsieht. *Empfehlung auf Grundlage der Schlussfolgerung 44* *Damit zusammenhängende Feststellung: 42*
7.	Es sollte sichergestellt werden, dass die Liste der Unternehmer die in Artikel 11 Absatz 3 der Verordnung (EG) Nr. 1235/2008 verlangten Informationen enthält und dass v. a. nur unter Vertrag stehende Unternehmer aufgeführt werden. *Empfehlung auf Grundlage der Schlussfolgerung 47*

	Damit zusammenhängende Feststellung: 46
8.	Es sollte sichergestellt werden, dass die Kontrollen wirksam sind und sich auf alle Anforderungen der Standards der Kontrollstelle erstrecken, und insbesondere, dass: - Inspektoren gemäß Abschnitt 2.2. von D-EN_001 der Standards der Kontrollstelle die Ergebnisse der Bewertung der von den Unternehmern angewandten Vorsorgemaßnahmen aufzeichnen; - Inspektoren gemäß Artikel 72 der Verordnung (EG) Nr. 889/2008 die Aufzeichnungen über den Grund für den Einsatz von Dünge- und Pflanzenschutzmitteln überprüfen; - Kontrollen sich gemäß den Abschnitten 2.2. und 2.3. von D-EN_004 der Standards der Kontrollstelle auf die Handhabung von konventionellen Erzeugnissen durch die Unternehmer erstrecken. *Empfehlung auf Grundlage der Schlussfolgerung 58* *Damit zusammenhängende Feststellungen: 50, 51 und 52.*
9.	Es sollte sichergestellt werden, dass die von den Unternehmern auf dem Enderzeugnis für den Export aufgebrachten Etiketten überprüft werden, um zu gewährleisten, dass die Unternehmer nur Etiketten verwenden, die Artikel 24 der Verordnung (EG) Nr. 834/2007 des Rates entsprechen. *Empfehlung auf Grundlage der Schlussfolgerung 59* *Damit zusammenhängende Feststellung: 55*
10.	Es sollte sichergestellt werden, dass gemäß Artikel 13 Absatz 4 der Verordnung (EG) Nr. 1235/2008 eine dokumentierte Risikobewertung erfolgt, um über die Durchführung von Warenuntersuchungen der für die Ausfuhr in die EU bestimmten Sendungen zu entscheiden. *Empfehlung auf Grundlage der Schlussfolgerung 66* *Damit zusammenhängende Feststellungen: 63, 64 und 65*