

ANNEX

Response of the competent authorities of Sweden to the recommendations of report ref. DG(SANTE)/2018-6383-MR of the audit carried out from 18 September 2018 to 27 September 2018 in order to evaluate the system of official controls relating to microbial safety of food of non-animal origin

<i>N°</i>	<i>Recommendation</i>	<i>Action Proposed by the competent authority</i>
1	<p>Ensure that all FBOs are registered as required by Article 6 of Regulation (EC) No 852/2004.</p> <p><i>Recommendation based on conclusion: 24.</i></p> <p><i>Associated findings: 17 and 19.</i></p>	<p>The NFA will update current guidance regarding registration of primary producers, make it more detailed, and clarify uncertainties regarding small producers. This will be finalised in November 2019.</p> <p>The status regarding registration of garden centres selling seeds for sprouting has been followed up. Two of the unregistered operators have stopped selling seeds for sprouting. All garden centres concerned are registered now, except for one where it is under investigation.</p> <div style="text-align: center;">  <p>Garden centres registration_status 2</p> </div>
2	<p>Ensure that approval of sprout-producing establishments is granted following the resolution of all non-conformities regarding infrastructure, equipment and the other relevant requirements of food law, as specified by Regulation (EC) 882/2004 article 31(c), (d) and (e).</p> <p><i>Recommendation based on conclusion: 25.</i></p> <p><i>Associated findings: 21, 22, 23, 68.</i></p>	<p>The NFA will update and clarify current guidance document covering approval and control of sprout producers. This will be finalised in September 2019.</p> <p>A new checklist for approval and control of sprout producers has been sent directly to the CA:s concerned and will be published on Kontrollwiki, NFA:s web site for guidance to the official control.</p> <div style="text-align: center;">   <p>Checklist control of sprout establishn Approval Checklist for control of sprou</p> </div>

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		<p>During 2019, there will be an on-line training or seminar with a following discussion. The seminar/training, which will be based on the guidance document and checklist, will be documented on NFA's website for e learning.</p> <p>The NFA will also perform shadow audits as a tool to improve the control system.</p>
3	<p>Ensure that official controls include the certification requirements for imports into the EU of sprouts and seeds intended for the production of sprouts as required by Regulation (EU) No 211/2013 and Regulation (EU) No 208/2013.</p> <p><i>Recommendation based on conclusion: 118.</i></p> <p><i>Associated findings: 81, 82, 83, 84 and 107.</i></p>	<p>The NFA will updated current guidance document about control of imports into the EU of sprouts and seeds intended for the production of sprouts. The updated guidance will include how to perform the official control, examples of correct certificates and examples of wrong certificates.</p> <p>The strategy for information of the legislation and implementation of the improved guidelines is that all CAs will receives information and training during 2019.</p> <p>The strategy includes information in the information letter that is sends to all CAs 2-3 times a year, information at the National Control Conference in May 2019, information and case studies at meetings with CABs and municipalities during the autumn 2019 and information and case studies at Livstecknet, the NFA website for inspectors.</p>
4	<p>Ensure that CAs verify compliance with the rules and criteria laid down in Regulation (EC) No 2073/2005, Annex 1, Chapter 1 and Chapter 3.3 in accordance with Regulation (EC) No 882/2004.</p> <p><i>Recommendation based on conclusions: 119 and 120.</i></p>	<p>During 2019, there will be an on-line training or seminar with a following discussion. The seminar/training, which will be based on the guidance document and checklist, will be documented on NFA's website for e learning.</p>

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	<i>Associated findings: 87, 88, 90, 91, 96, 97 and 99.</i>	The NFA will also perform shadow audits as a tool to improve the control system and verify compliance with the regulation, including derogation from the microbiological criteria.
5	<p>Ensure that NFA guidelines regarding microbiological parameter for sprouts are in compliance with EU legislation, in particular with Regulation (EC) No 2073/2005.</p> <p><i>Recommendation based on conclusion: 120.</i></p> <p><i>Associated findings: 88, 89, 90, 91 and 96.</i></p>	<p>The NFA guidance document will be updated and clarify under which conditions a food business operator may be exempted from testing of all batches of seeds for sprouting in Regulation (EC) No 2073/2005, Annex 1, Chapter 3.3.B and also clarify under which conditions note 23 in Regulation (EC) No 2073/2005, Annex 1, Chapter 1, is applicable. This will be finalised in September 2019.</p> <p>In Article 2 (a) of Regulation (EU) No 208/2013 on traceability requirements for sprouts and seeds intended for the production of sprouts, sprouts are defined as a product produced by germination of seeds and development of them in water or other medium and harvested while still only developing the heart leaves, and which is intended to be eaten in its entirety, including the seed.</p> <p>Annex I to Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs contains microbiological criteria for foodstuffs including sprouts. In chapter I in the same appendix, there are food safety criteria for sprouts. These criteria are provided with a footnote (23) which states that sprouts that have undergone a treatment that effectively eliminates Salmonella spp. and STEC are excluded from the criteria.</p> <p>The NFA's interpretation is that the seed in this case can be equated with the sprout even before sprouting because the seed and the spout are intended to be eaten in their entirety as one unit.</p>

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		<p>Thus, if the seeds, since they by the definition of sprouts the seed after sprouting is a part of the sprout, undergoes a treatment that effectively eliminates Salmonella spp. and STEC these sprouts are excluded from the criteria in Annex I to Regulation (EC) No 2073/2005.</p> <p>Concerning the treatment, the NFA agrees that sprout producers need to validate decontamination treatments (time/temperature combinations or chemical treatments) which are used for different types of seeds. The current guidance document will be updated to better describe this. The Codex guideline (CAC / GL 69 – 2008) acknowledges a range of approaches to validation, which may be used independently or in combination, as appropriate. Apart from approaches mentioned in conclusion 121, there is also a possibility to e.g. base the validation on a “collection of data during operating conditions in the whole food operation”. The NFA will consider which validation approaches that are most appropriate and update the guidelines accordingly.</p>
6	<p>CAs should increase the qualification of the inspectors involved in official controls by providing them with the relevant tools (i.e. training and technical support including sufficiently detailed checklists) in order to ensure effective and appropriate official controls as required by Article 4 and Article 6 of Regulation (EC) No. 882/2004.</p> <p><i>Recommendation based on conclusions: 13, 117, 118, 119, 120 and 121.</i></p> <p><i>Associated findings: 9, 59, 74, 79, 80, 82, 84, 96, 109, 110, 111 and 112.</i></p>	<p>To strengthen the competence of the inspectors in Sweden the NFA is currently working on developing an e-learning based training program. The aim of the program is to increase the basic knowledge of official controls. To this date four basic e-learning courses has been developed:</p> <ul style="list-style-type: none"> - Inspection and control methods (launched December 2017) - Risk and hazards in food stuff (launched 2018) - Tasks of the competent authorities (launched spring 2018)

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		<p>- Temperature checks (will launch spring 2019)</p> <p>As a part of this program, an e-learning course on detecting non-compliances and dealing with sanctions will be developed during 2019.</p> <p>The NFA will develop more e-learning courses based on a skill inventory (of the inspectors) which will be done in 2019.</p>
7	<p>CAs should implement enforcement measures in order to give effect to the requirement set out in Article 54 of Regulation (EC) No 882/2004 and thus, to allow official controls to be effective in raising/maintaining the level of compliance.</p> <p><i>Recommendation based on conclusions: 25, 42, 117 and 143.</i></p> <p><i>Associated findings: 23, 37, 68, 77, 78, 80, 83, 96, 98, 110, 115, 139, 140, 141 and 142.</i></p>	<p>During 2019, the NFA will improve the guidance on actions in case of non-compliance. The plan is to further develop existing guidance to help CA:s identify non-compliance and take appropriate action in a more uniform way.</p> <p>This development has already started but was put on hold temporarily, awaiting the new regulation on MS annual report to the EU. Several MS concluded that the term non-compliance has different practical meaning in different MS and sought a more unified operative approach to the matter. This, however, did not work out and it is still up to each MS to explain to the EU how non-compliance are dealt with and defined.</p> <p>The NFA:s own work on this issue will resume during 2019 and result in a more in-depth guidance via online training (an e-course) and training opportunities (workshops) with CA:s. From 1 January 2020, a more standardized approach and training will be available for all CA:s in Sweden.</p>