

Comments on the factual content of the draft report to the competent authorities of Sweden to the FVO audit DG(SANTE)/ draft report of an audit carried out in Sweden from 18 September 2018 to 27 September 2018 in order to evaluate the system of official controls relating to microbial safety of primary production of food of non-animal origin

Para.	Finding	Comment
Nr på stycket	Kopiera texten i det stycke (para.) i den <i>engelska</i> rapporten som vi kommenterar.	Motivationen till varför vi håller med / eller inte. Förslag till hur vi tycker det borde stå på <i>engelska</i> .
10	The 21 CABs which report to the Ministry of Enterprise and Innovation are the regional CAs and are responsible for official controls of FBOs in primary production of FNAO at harvest and pre-harvest stage, including sprout-producing establishments. The 260 MUPs which report to the NFA are the local CAs and are responsible for control of FBO of FNAO in all steps of production after primary production, including control of retailers, internet sales and importers. If a sprout-producing establishment is importing seeds for sprouting, the control of this activity falls under the responsibility of the CAB.	<p><i>Comment:</i> According to the instruction from the Government shall the NFA lead, coordinate and follow up the official control of food at national, regional and local level. NFA issue regulations and guidelines for the official food control at all levels. All CAs reports their results from the official controls to NFA. This is regulated in LIVSFS 2009:13.</p> <p><i>New text:</i> The 21 CABs which report to the Ministry of Enterprise and Innovation are the regional CAs and are responsible for official controls of FBOs in primary production of FNAO at harvest and pre-harvest stage, including sprout-producing establishments. The 260 MUPs which are independent authorities are the local CAs and are responsible for control of FBO of FNAO in all steps of production after primary production, including control of retailers, internet sales and importers. If a sprout-producing establishment is importing seeds for sprouting, the control of this activity falls under the responsibility of the CAB.</p> <p>NFA, which is reporting to Ministry of Enterprise and Innovation, leads coordinates and follow up the official control of food at national, regional and local level. NFA issue regulations and guidelines for the official control at all levels. Results from the official controls performed are reported to NFA.</p>
15	No derogation for small producers as described in Article 1 of Regulation (EC) No. 852/2004 is foreseen in Sweden for FNAO.	<p><i>Comment:</i> The regulations concerns producer's direct delivery of <i>small quantities</i> of primary products to final consumers and local retail establishments directly supplying the final consumer, not small producers.</p> <p><i>New text:</i> No derogation of direct supply, by the producer, of small</p>

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		quantities of primary products as described in Article 1 of Regulation (EC) No. 852/2004 is foreseen in Sweden for FNAO.
16	<p>PRIMÖR is the national electronic system for the registration of primary producers of FNAO including sprout-producing establishments. All CABs have access to the system.</p> <p>The primary producers are obliged to provide information relating to the produce being produced, the volume of production and the main crop being produced at the time of registration. The primary producer may also give additional information about third party certification schemes used and approval or certification according to these systems. This information is part of the risk assessment for the planning and implementation of official controls.</p>	<p><i>Comment:</i> PRIMÖR is used for registration of all primary producers, not only FNAO and sprout-producing establishments. At the time of registration, the producers provide information about the main activity (main production volume) within primary production and all other sub activities within primary production. As an example, the main activity could be milk production and the sub activity could be production of berries and honey.</p> <p><i>New text:</i> PRIMÖR is the national electronic system for the registration of all primary producers including FNAO and sprout-producing establishments. All CABs have access to the system.</p> <p>The primary producers are obliged to provide information relating to the produce being produced, the volume of production and the main activity within primary production and sub activities at the time of registration.</p> <p>The primary producer may also give additional information about third party certification schemes used and approval or certification according to these systems. This information is part of the risk assessment for the planning and implementation of official controls.</p>
17	<p>From the data obtained by NFA from the CABs, in 2017 there were 1,371 primary producers of FNAO registered in PRIMÖR, in the scope of this audit. At CAB level it is estimated that 20% of such primary producers are not registered yet. The CABs stated that mainly small producers are not registered. The NFA informed the audit team that missing registrations are caused by uncertainty of the CABs which primary producers would need to be registered or not. Therefore, NFA plans to develop a detailed guidance regarding registration of primary producers.</p>	<p><i>Comment:</i> The level of registration of primary producers differs between the CABs. One of the CABs visited estimated that 20% of all primary producers in the county not yet are registered.</p> <p>According to Sweden's annual report of the official control in food chain 2017 is the estimation on a national level that 13,5 % of all primary producers, including FNAO, not yet have registered their establishments.</p> <p>There is already a guidance for registration but it will be improved with guidance that is more detailed.</p> <p><i>New text:</i> From the data obtained by NFA from the CABs, in 2017 there</p>

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		were 1,371 primary producers of FNAO registered in PRIMÖR, in the scope of this audit. At CAB level it is estimated that 13,5% of all primary producers are not registered yet, including primary producers of FNAO. The CABs stated that mainly small producers are not registered. The NFA informed the audit team that missing registrations are caused by uncertainty of the CABs which primary producers would need to be registered or not. Therefore, NFA plans to improve current guidance regarding registration of primary producers and make it more detailed.
24	Procedures are in place for the registration of primary producers in a national electronic database at CAB level and for the registration of all other food establishments at MUP level. However, by estimation, at least 20% of primary producers are not registered and not all garden centres selling seeds for sprouting are registered yet. Thus, not all FBOs are under official controls.	<p><i>Comment:</i> The level of registration of primary producers differs between the CABs. One of the CABs visited estimated that 20% of all primary producers in the county not yet are registered.</p> <p>According to Sweden's annual report of the official control in food chain 2017 the estimation on a national level that 13,5% of primary producers, including FNAO, not yet have registered their establishments.</p> <p><i>New text:</i> Procedures are in place for the registration of primary producers in a national electronic database at CAB level and for the registration of all other food establishments at MUP level. However, by estimation on a national level, at least 13,5% of primary producers, including FNAO, are not registered and not all garden centres selling seeds for sprouting are registered yet. Thus, not all FBOs are under official controls.</p>
32	The priority module and experience module is combined in a risk-experience matrix which is used both for classification the FBOs and for prioritisation and planning of the control. The system takes into account the CAs' experiences from previous controls. On a national basis, the majority of the FBOs selected for controls shall be in the highest category.	<p><i>Comment:</i> There is an inbuilt flexibility in the model in order to take into account local variations and the CABs' experiences from previous controls. The control can also, in line with NFA guidance document, be performed on project basis.</p> <p><i>New text:</i> The priority module and experience module is combined in a priority-experience matrix which is used both for classification the FBOs and for prioritisation and planning of the control. The system takes into</p>

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		<p>account the CAs' experiences from previous controls. On a national basis, the majority of the FBOs selected for controls shall be in the highest category.</p> <p>Based on experiences from previous controls, the CA can adjust the classification and reduce or increase the control priority of a unique FBO. The CA can also adjust the control priority for a sector, based on regional variations and experiences from previous controls of FBOs within the sector.</p>
38	<p>Importers of seeds for sprouting must, as well as FBO who import FNAO in general, register their establishment at the MUPs. Importers are placed in a risk class depending on their activities, the type of product, labelling, inspection history and assessment from the local authority. The NFA informed the audit team that no inspection of importers within the scope of this audit have been performed in the last three years.</p>	<p><i>Comment:</i> Import of products is an activity, which can be done by different types of establishments, such as wholesalers and retailers. It's not bound to a specific type of establishment. The CAs add this kind of information to the registration of the FBO.</p> <p><i>New text:</i> FBOs who import of seeds for sprouting must, as well as FBO who import FNAO in general, register their establishment at the MUPs. The FBOs are placed in a risk class depending on their activities, the type of product, labelling, inspection history and assessment from the local authority. The NFA informed the audit team that NFA doesn't have information if inspections of importers within the scope of this audit have been performed in the last three years, since importers are not defined as a unique type of establishment in the reporting system.</p>
50	<p>In line with NFA instructions, farms must have a water risk analysis in accordance with NFA guidelines. Origin of the water, condition of use (type of irrigation and crops) and justification of the presence or absence of a sampling plan have to be indicated in the risk assessment.</p>	<p><i>Comment:</i> The requirement in legislation is to that the farmer should use potable water, or clean water, whenever necessary to prevent contamination. In line with NFA guidelines, the CAs control how the farmers identify hazards and prevent contamination due to the water quality.</p> <p><i>New text:</i> In line with NFA's guidelines and national guidelines for good hygiene praxis, the farms need a water risk analysis in order to identify hazards, minimise and prevent the risk for contamination of the</p>

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		products and equipment. Origin of the water, condition of use (type of irrigation and crops) and justification of the presence or absence of a sampling plan have to be indicated in the risk assessment.
51	For the risk assessment, when a drip irrigation system is used, according to NFA guidelines, the CABs do not require specific microbiological tests, regardless of the origin of the water. Whereas, in case of an overhead water sprinkler system, microbiological analyses are required. However, NFA guidelines did not provide analytical parameters against which to perform the assessment.	<p><i>Comment:</i> The NFA guidelines, as well as the guides to good hygiene praxis, includes a number of questions and decision tree to be used in order to facilitate the assessment if the risk assessment done by the farmer. Regarding use of pot water, NFA guidelines refers to the microbiological criteria in national legislation LIVSFS 2001:30 which includes microbiological criteria.</p> <p><i>New text:</i> For the risk assessment, when a drip irrigation system is used, according to NFA guidelines, the CABs do not require specific microbiological tests, regardless of the origin of the water. Whereas, in case of an overhead water sprinkler system, microbiological analyses are required. However, NFA guidelines did not provide analytical parameters against which to perform the assessment. Regarding use of pot water, the microbiological criteria in the national legislation LIVSFS 2001:30 about pot water are recommended to be used, according to NFA:s guidelines.</p>
54	The NFA and the CABs informed the audit team that regarding irrigation water, both FBOs are in compliance with the national law.	<p><i>Comment:</i> There is no national legislation for irrigation water.</p> <p><i>New text:</i> The NFA and the CABs informed the audit team that regarding irrigation water, both FBOs are in compliance with the recommendations in NFA:s guidelines and the national guide to good hygiene praxis.</p>
56	For this well there was no risk assessment in place which is not in line with NFA's requirements . This non-compliance was noticed by the CAB which will require regular microbiological analyses and a new water risk assessment.	<p><i>Comment:</i> There is no national legislation for irrigation water.</p> <p><i>New text:</i> For this well there was no risk assessment in place which is not in line with the recommendations in NFA's guidelines. This non-compliance was noticed by the CAB which will require regular microbiological analyses and a new water risk assessment.</p>

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88	<p>The NFA informed the audit team that FBOs that were granted the derogation could reduce the frequency of the preliminary test of seeds according to Regulation (EC) No 2073/2005 and could test the sprouts only for <i>Salmonella</i> and <i>E.coli</i>. STEC analysis is not obligatory. The monthly frequency for sprout analyses is still compulsory.</p>	<p><i>Comment:</i> The basis is an assessment of the FBOs process of decontamination of seeds for sprouting and historical data proving the effectiveness of the process.</p> <p><i>New text:</i> The NFA informed the audit team that FBOs that were granted the derogation must, as verification of the effectiveness of the decontamination process, test the sprouts for <i>Salmonella</i> and <i>E.coli</i> at least once a month. STEC analysis is not obligatory. The monthly frequency for sprout analyses is still compulsory. These FBOs could also reduce the frequency of the preliminary test of seeds according to Regulation (EC) No 2073/2005.</p>
96	<p>However, in the sprout-producing establishment visited, which gained of the derogation, the audit team observed that:</p> <ul style="list-style-type: none"> <input type="checkbox"/> there was no evidence of established monitoring procedures, proper records for CCPs, critical limits, preventive and corrective actions as required by NFA; <input type="checkbox"/> critical limits were expressed as a range, contrary to HACCP requirements where a critical limit must have a specific value; <input type="checkbox"/> the monthly frequency of own microbiological tests as required by EU legislation and NFA guidelines was not respected; <input type="checkbox"/> the NFA referred to Regulation (EC) No 2073/2005, Chapter 1, footnote 23 "Excluding sprouts that have received a treatment effective to eliminate <i>Salmonella</i> spp. and STEC" to exclude sprouts from being analysed for STEC. However, without validation it is not possible to conclude on the effectiveness of such a treatment; <input type="checkbox"/> the audit team could not obtain evidence confirming 	<p><i>Comment:</i> The NFA guidelines are not legal binding documents.</p> <p><i>New text:</i> However, in the sprout-producing establishment visited, which gained of the derogation, the audit team observed that:</p> <ul style="list-style-type: none"> <input type="checkbox"/> there was no evidence of established monitoring procedures, proper records for CCPs, critical limits, preventive and corrective actions as recommended by NFA;

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	that the effect of the decontamination procedure was verified by the FBO and assessed by the CABs.	
114	The central CA also stated that in case of non-compliant FBOs or products, proportionate and dissuasive administrative measures and penalties are in place along the FNAO food chain. In some cases, the FBO is required to provide documentary evidence of corrective measures or a follow-up visit may be required to verify the implementation of the measures.	<p><i>Comment:</i> In some cases where the operator agrees with the CA that there is a non-compliance, depending on the nature of the non-compliance and the CAs previous experience of the FBO, the business can be required to provide documentary evidence of corrective measures. In other cases follow-up visits may be required to verify the implementation of the measures. Where an FBO does not agree that there is a non-compliance or where corrective measures are not adequately taken the CA's have a wide range of administrative sanctions available to ensure compliance including injunctions, prohibitions and administrative fines.</p> <p><i>New text:</i> The central CA also stated that in case of non-compliant FBOs or products, proportionate and dissuasive administrative measures and penalties are in place along the FNAO food chain. In some cases, the FBO is required to provide documentary evidence of corrective measures or a follow-up visit may be required to verify the implementation of the measures. Where an FBO does not agree that there is a non-compliance or where corrective measures are not adequately taken the CA's have a wide range of administrative sanctions available to ensure compliance including injunctions, prohibitions and administrative fines.</p>
121	The NFA, in its guidelines, considers a treatment effective in eliminating pathogens based only on verification analysis of the finished product (sprouts) without requiring its validation, thus confusing verification with validation. Validation ⁶ differs from monitoring and verification. Validation of a CCP requires an in-plant study to ensure that a critical limit, that is supported by literature or	<p><i>Comment:</i> 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 and that the current guidelines need to be revised 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</p>

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<p>advised by CAs, is controlling the identified hazards under the operating conditions of the plant, especially when these conditions are different from what is described in the literature. In-plant studies for microorganisms usually rely on indicator organisms and require inoculation of the products to complete the study. The studies should be statistically designed to ensure the required reduction of the hazard and an appropriate number of samples need to be collected to demonstrate its robustness (i.e. the paper of Bari et al.4).</p>	<p>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>
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