

ANNEX

FVO assessment of the Action Plan submitted by the Competent Authorities of Canada on 01 February in response to Report ref. DG(SANCO)/2011-8913-MR of an audit carried out from 13 to 23 September 2011 in order to evaluate the monitoring of residues and contaminants in live animals and animal products, including controls on veterinary medicinal products

<i>N°.</i>	<i>Recommendation</i>	<i>Action Proposed by the Competent Authority</i>	<i>Updated action proposed by the Competent Authority</i>
1	Address the identified shortcomings in planning and implementation of the NCRMP with regard to poultry and of the RMP for aquaculture products in order to ensure that the plans will offer guarantees on the residue status of exported food commodities which are at least equivalent to the standards set out in Article 29 of Council Directive 96/23/EC.	<p>Competent authority response dated 1 February 2012:</p> <p>The NCRMP with regard to poultry is implemented as planned. CFIA does not intend to modify it to cover the EU substance groups A1 and A4 in order to meet the provisions of Article 29 of Council Directive 96/23/EC. There are currently no chicken and or turkey establishments eligible to export to the EU. Should an establishment eventually show interest to become eligible, testing will be carried out as a stand-alone programme separate from the NRCMP. Currently the only EU-approved poultry slaughterhouse is a duck plant: the plant operator will be informed in February 2012 of the specific EU testing requirements. A stand-alone programme for product destined to the EU will have to be established, under CFIA supervision, before any shipments coming from the eligible plant is certified for export.</p>	<p><u>Update received from CA 24 April 2012</u></p> <p>A limited sampling and testing program will be implemented for the testing of substances in group A1 and A4 in poultry. Details of the sampling activities carried out under the NCRMP will be provided to you when the plan has been completed. Please note the sampling and testing program to be implemented for substances of group A1 and A4 in Canadian poultry, will not be specific to lots destined for the EU. Details of the National Chemical Residue Monitoring Plan is communicated annually to EU FVO; It will be sent by May 2012 to the Directorate General for Health and Consumers. For your convenience, we have provided the number of samples to be tested for both groups of substances: Chicken: 90 Duck: 60 Fowl: 60 Game bird: 60 Goose: 40 Turkey: 90 Testing will commence in these matrices once the laboratories have validated the method in this matrix as per your recommendation 7. We anticipate that routine testing will start</p>

ANNEX

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		<p>CFIA will adjust its Aquaculture/Fish residue monitoring plan to incorporate Nitroimidazoles (EU Group A6), Stilbenes (EU Group A1) and Steroids (EU Group A3) in the scope of testing as follows:</p> <p>(A6) Nitroimidazoles: Implementation of the monitoring of nitroimidazoles in domestic and imported fish would commence by August 2012.</p> <p>(A1) Stilbenes: The EU is aware that the CFIA is working on the method validation for stilbenes. This project is anticipated to be completed by April 2012. Implementation of the monitoring of stilbenes in domestic and imported fish would commence by December 2012.</p> <p>The above timelines take into account the time anticipated for Canadian accredited private laboratories (that provide analytical supports to Canadian Quality Management Program</p>	<p>by September 30, 2012.</p> <p>CFIA wishes to clarify that Group A3 substances (steroids) will be included in our aquaculture NCRMP within the next three years. This information complements the action list we previously provided that monitoring of EU Group A6 (nitroimidazoles) and EU Group A1 (stilbenes) will be implemented by August 2012 and December 2012 respectively. This approach is aligned with the EU and CFIA agreement of 2008 on prioritizing the incorporation of identified EU Group A substances in our residue monitoring plan.</p> <p>With regards to EU Group A3 (Steroids) in fish, since the audit of 2011, CFIA is moving forward on a 2 year method development and validation project. CFIA has reviewed the currently published literature and has identified some published methods which show potential for application to steroids in fish in CFIA laboratories.</p>

ANNEX

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		<p>Importers) to incorporate these substances in their scope of accreditation, and time for CFIA's IM/ IT and associated programming changes.</p> <p>(A3) Steroids: The method validation and monitoring for steroids would be initiated after completion of the stilbenes method validation project. A fully validated steroid method is expected to be available after the completion of a multi-year project (2 years) and the implementation of the monitoring of steroids in domestic and imported fish would commence within one year following project completion</p>	<p>CFIA laboratories are accredited by the Standards Council Canada to CAN-P-4E (ISO/IEC 17025). This international standard requires accredited laboratories to validate nonstandard methods to ensure that method performance parameters are known and are assessed as fit for purpose for the intended use, shall be relevant to the customers' needs (According to CAN-P-4E [5.4.5.3]). For methods published in scientific literature which have not been the subject of a Collaborative or Inter-Laboratory Validation Study, this requires that the methods undergo a full validation in the laboratory which is implementing the method.</p> <p>The methods that have been identified are literature publications which have not been Collaborative or Inter-Laboratory studied and may require modification and adaptation to ensure that the methods are relevant to CFIA's needs and fit for purpose in a regulatory environment.</p> <p>The project, as currently planned, will result</p>

ANNEX

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			in a validated method ready in April 2014 and CFIA will initiate monitoring of Group A3 substances (steroids) in July 2014 (slightly more than 2 years from now). Should the CFIA laboratory investigations demonstrate that one of the identified published methods is adequate for our needs the project may be completed sooner than expected and the methodology may be able to be implemented at an earlier date.
2	Address shortcomings identified for implementation or supervision of implementation of the NCRMP with regard to milk and honey in order to ensure that it will offer guarantees on the residue status of exported food commodities which are at least equivalent to the standards set out in Community legislation (Article 29 of Council Directive 96/23/EC).	Competent authority response dated 1 February 2012: The CFIA Dairy and Honey Programs, in consultation with Science and Operations, will discuss program improvements including: (1) the purchasing and distribution of bottles for Provincial sampling of raw milk, (2) procedures covering the collection, handling, storage and shipping of NCRMP samples, and (3) the follow-up procedures for non-compliant samples.	

ANNEX

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		<p>Using the information collected from these consultations, the NCRMP guidelines will be updated by April 1, 2012 to better explain the background, purpose and priority of the sampling program and to clarify sampling and shipping procedures.</p> <p>The progress of the NCRMP will be assessed throughout the fiscal year 2012 - 13, including consultations with the various Provincial Dairy Technical Specialists for dairy sampling and the Area Program Officers for honey, with the intent to improve sample delivery rates. Intelligence gained during this program review will inform recommended changes and improvements to the plan in subsequent years.</p> <p>The now draft Dairy Products Inspection Manual Sampling Chapter, will be finalized and published, with a proposed date of April 1st, 2012. This chapter provides guidelines to be followed in cases where follow-up is required.</p>	

ANNEX

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		<p>Similarly, the Sampling Plans and Guidelines for the Honey Program continue to be reviewed on an annual basis to ensure that the follow-up procedures provide adequate guidance.</p> <p>Given that raw milk sampling is shared with the Provinces, further discussions will be held with the various Provincial Dairy technical specialists to discuss issues with regards to the sampling and storage of raw milk samples. The Provincial Dairy technical specialists are tasked with coordinating the raw milk sampling in their respective Provinces. At the upcoming Dairy Technical Equivalency Committee (DTEC) meeting, the results of the NCRMP, as well as any audit findings will be communicated and assistance sought, at the managerial level to improve the delivery of the Program (This item is complete).</p> <p>The work-planning process within CFIA Operations Branch is being modified with the intent of planning inspection activities to the</p>	

ANNEX

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		<p>available resources (including the NCRMP). The new process is scheduled to be in place by April 1, 2012. Along with aligning sampling activities and inspection capacity, Operations Branch will be improving the tracking and reporting of program delivery in order to identify and take corrective actions in areas of under-delivery.</p>	
3	<p>Improve the procedure in place for storage and dispatch of samples to the laboratories in order to be at least equivalent to the Annex to Commission Decision 98/179/EC.</p>	<p>Competent authority response dated 1 February 2012:</p> <p>The CFIA Dairy and Honey Programs will update the NCRMP guidelines to better explain the background, purpose and importance of the sampling program. The updated guidelines will clarify sampling procedures, appropriate storage temperatures, as well as dispatch procedures including how to properly date samples.</p> <p>CFIA Operations Branch receives the raw milk sample plans from the Dairy Program at the</p>	

ANNEX

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		<p>CFIA Area Specialist level, and then distributes the plans as required.</p> <p>A tracking mechanism will be developed and implemented by April 1, 2012 to ensure that the required sampling frequencies and shipping activities are respected.</p> <p>Additionally, CFIA Operations and Science Branch will develop and communicate a procedure for the shipping and receipt of samples under the NCRMP, which will include laboratory protocols for samples received unsealed at the lab. The messaging will reflect previous communications to Operations staff. The procedure will be phased-in to allow for communication with laboratory and operations staff, and will be fully implemented by October 1, 2012.</p>	
4	Provide further detailed instructions on the prevention of cross-contamination in Annex E of Chapter 11 of the Meat Hygiene	Competent authority response dated 1 February 2012:	<u>Update received from CA 24 April 2012</u> The CFIA will develop a protocol for type 2 feed mills to facilitate their participation in

ANNEX

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	Manual of Procedures with regard to the participation of Type 2 feed mills in the ractopamine-free pork certification programme, with the aim to ensure that pigs slaughtered for export to the EU are not inadvertently exposed to these compounds during the rearing period, in accordance with the provisions of Article 11 of Council Directive 96/22/EC.	Although Annex E of the Meat Hygiene Manual of Procedures (MOP) provides for participation of Type 2 feed mills in the ractopamine-free pork certification, currently, Type 2 feed mills are not participating in the programme. CFIA considers this recommendation speculative at this time and should the need arise then CFIA will take appropriate actions.	the ractopamine-free pork certification process. It is anticipated that the CFIA will have a draft available for discussion by June 2012. In the interim, CFIA staff involved in the ractopamine-free pork certification process will be advised that they are not to include type 2 feed mills in approved programs until further notice due to the concerns raised by the EU during last residues audit.
5	Extend official controls with regard to the prevention of cross-contamination of un-medicated feedingstuffs with the feed additives melengestrol, zilpaterol and ractopamine in feed mills producing feed for cattle under the HGP-free cattle programme in order to ensure that cattle slaughtered for export to the EU are not inadvertently exposed to these compounds during the rearing period, in accordance with the provisions of Article 11 of Council Directive 96/22/EC.	Competent authority response dated 1 February 2012: Measures to prevent the cross-contamination between medicated and non-medicated feed are already Canadian requirements. To address this recommendation, provisions for enhanced oversight will be included in the Canadian Program for Certifying Freedom From Growth Enhancing Products (GEPs) for the Export of Beef to the EU (formerly presented as the HGP-free cattle programme). These new provisions	

ANNEX

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		should be implemented by June 2012.	
6	Ensure that, when non-compliant results are detected, the legal and/or administrative framework in place is strengthened in order to permit the application of follow-up procedures, which are at least equivalent to those described in Articles 16-19, 22 and 23 of Council Directive 96/23/EC, to be carried out in a timely fashion.	<p>Competent authority response dated 1 February 2012:</p> <p>Response to the detection of a contaminant in the production of food for sale in Canada is provided for through the application of the enforcement provisions of the Food and Drugs Act, which prohibits the sale of food that contains a harmful or poisonous substance or that is otherwise adulterated. Those provisions include the seizure and detention of the food in question. Also, food recalls may be ordered under the Canadian Food Inspection Agency Act.</p> <p>Strengthening the framework with respect to procedures equivalent to Articles 16-19, 22 and 23 of 96/23/EC has been considered by CFIA. Authority exists, under the Health of Animals Act to make regulations dealing with toxic substances, and the making of these regulations</p>	<p><u>Update received from CA 24 April 2012</u></p> <p>Canada is proceeding with new consolidated food safety legislation with authority to make regulations to require a broader licensing and registration system. Extensive work is underway with respect to a major inspection modernization initiative launched through the 2011-2012 federal budget. Implementation is expected to begin in the 2013-1014 fiscal years. This will strengthen our administrative framework as required. A specifically useful provision will be the ability to attach conditions to licenses and to vary those conditions. These provisions are deliberately made flexible enough for CFIA to be able to use them in a variety of situations, including enhanced control over serious contamination incidents. Additionally, revisions to the Health of Animals Act in progress requiring enhanced traceability of animal movement will provide</p>

ANNEX

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		<p>is on the CFIA's list of regulatory projects for completion at a future date.</p> <p>Provincial governments also have legislative jurisdiction over contaminations on farms, and the federal Government and provincial governments would coordinate their responses to any food safety issues relating to any contamination incident.</p>	<p>complementary new authorities related to toxic substances. These two legislative changes, coupled with the inspection modernization initiative will provide the required authority and broader range of administrative options to take stronger actions where significant non-compliance is identified.</p>
7	<p>Ensure that all analytical methods are validated for the species and matrices they are used for, that calibration standards used are suitable for the species and matrices analysed and that handling of the samples does not have an adverse effect on the reliability of the results obtained in order to guarantee that analytical testing meets standards which are at least equivalent to those required by Council Directive 96/23/EC and Commission Decision 2002/657/EC.</p>	<p>Competent authority response dated 1 February 2012:</p> <p>Procedures have been implemented in the labs to ensure that ion ratios meet EU criteria for confirmatory methods.</p> <p>The two affected private labs have updated their method validation SOP to require the validation of the different species. The confirmation procedures have also been updated to require the use of matrix matched standards</p>	

ANNEX

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		<p>Reproducibility/repeatability data of the methods as indicated by the auditors will be compiled and documented with the validation data. The lab has committed to a completion date of May 2012.</p> <p>Additional verification and validation of methodology is underway in all affected laboratories for additional species. The use of matrix matched standards will be part of this additional validation. Studies will be carried out to verify the homogenization process for each tissue method and stability of each residue. Procedures will be modified and adjusted as required pending the findings of the study. All labs have committed to have this completed by the end of 2012</p> <p>CFIA will evaluate the progress at the two private laboratories that conduct meat analysis as part of the annual on-site audit, to be done in spring of 2012.</p>	

ANNEX

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8	Implement a 'split system' for poultry, if further export of poultry meat is intended, in order to meet the provisions of Article 11 (2) of Council Directive 96/22/EC.	<p>Competent authority response dated 1 February 2012:</p> <p>Members of the Canadian chicken and turkey industry are currently not exporting to the EU and they have decided that they will not be establishing a `split-system` for poultry.</p> <p>However, in order to export to the EU, the only Canadian eligible duck plant will have to implement a separate programme to cover the substance groups A1 and A4 in order to meet the provisions of Article 29 of Council Directive 96/23/EC to sample and test the product intended to be exported to the EU. In such case, a `split-system` would be redundant and CFIA is suggesting that no such segregation protocol be required.</p>	<p><u>Update received from CA 24 April 2012</u></p> <p>In order to meet the provisions of Article 11 (2) of Council Directive 96/22/EC, should industry signal their interest in pursuing the export of poultry to the EU, a split system for ractopamine in poultry will be implemented, the draft outlines of which are expected to be ready for discussion by September 2012. This approach would be modeled in large measure on the existing split system for ractopamine in pork, and would allow review of considerations for exposure factors back to the farm and not simply point of slaughter testing. A draft overview of the approach proposed can be provided.</p>
9	Improve further the regulation of extra-label drug use and the importation of veterinary medicinal products for 'own use' in food producing animals to ensure that if	<p>Competent authority response dated 1 February 2012:</p> <p>There are a number of approaches that are in</p>	<p><u>Update received from CA 24 April 2012</u></p> <p>Extra-label drug use for those drugs requiring veterinary prescription in Canada, is a matter</p>

ANNEX

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	<p>such use is continued, appropriate withdrawal periods are observed in order to guarantee that residue concentrations present in the tissues derived from animals so treated and intended for export to the EU do not exceed EU MRLs as laid down in Commission Regulation (EU) No 37/2010.</p>	<p>place to help ensure that animal-derived food products do not contain violative drug residues as per Canadian regulatory requirements and that residue concentrations meet the requirements of EU legislation with respect to MRL's. These approaches may include the development and implementation of On-Farm Food Safety Programs at the producer level, or HACCP based food safety programs at the processor level. When implemented, the design of these voluntary programs includes the application of HACCP principles. Verifications are carried out on the controls identified in the producers' or processors' plan that address potential chemical food safety hazards. Further, CFIA regularly reviews the data from the NCRMP and RMP to identify, evaluate and address any areas of concern. Health Canada is also working on regulatory amendments to address amongst others the 'own use' importation provision for veterinary drugs.</p>	<p>of provincial authority as part of the oversight of veterinary practice by provincial veterinary licensing bodies. For those provinces allowing direct sale to producers, this falls under provincial control of livestock medicines outlets. Health Canada has been working on exploring various options to address the 'own use' importation provision for veterinary drugs and an amendment to the Food and Drug Regulations will be required. Amending the regulations to address "own use importation" is one of the goals of the Health Canada's Health products and Food Branch regulatory modernization roadmap. This initiative has already undergone internal consultation and an external consultation is being contemplated later this year. There are a number of active elements of an integrated approach that are in place to help ensure that animal-derived food products do not contain violative drug residues as per Canadian regulatory requirements and that residue concentrations meet the requirements of EU legislation with respect to MRL's. One</p>

ANNEX

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			<p>element is the development of CFIA's On-Farm Food Safety Recognition Program to recognize HACCP-based on-farm food safety programs developed by industry. These voluntary programs must undergo technical reviews by CFIA and other FPT government participants, and an implementation assessment audit prior to being recognized and beginning a perpetual 5-year CFIA evaluation cycle to ensure that the program remains technically sound and is fully implemented.</p> <p>"Health Canada, the Public Health Agency of Canada and the Canadian Food Inspection Agency maintain tight linkages to provincial/territorial partners who have complementary authorities for the control of residue and antimicrobial resistance concerns, as well as with the broader group of stakeholders including animal production and pharmaceutical production industries and the academic community. A recent example of a major initiative in this regard was the Antimicrobial Stewardship in Canadian Agriculture and Veterinary Medicine</p>

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ANNEX

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			<p>Conference, held in Toronto October 30th to November 2, 2011 in Toronto. Federal regulatory partner meetings were also held with provincial licensing bodies this past year to discuss those issues touching on veterinary practice and potential professional misconduct in this context that fall without their sphere of responsibility. These activities are but some of the ongoing contributing compliance promotion activities delivered on an ongoing basis through the federal regulatory partners. These issues of drug residues and antimicrobial resistance were also raised as a focal point of discussion and raising of awareness at one last year's semi-annual joint meeting of federal and provincial chief veterinary officers and chief medical officers to discuss options for joint and integrated control." Further, CFIA regularly reviews the data from the NCRMP and RMP to identify, evaluate and address any areas of concern. The high level of compliance identified attests to the effectiveness of the current system.</p>

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ANNEX

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