2012 Industry Session
Industry Questions & Answers

CFIA Inspection - General

1. What is the Role of CFIA today? And what is their decision making process at the Inspector in Charge level and in Ottawa. Where did common sense go? Is history, data, and trend analysis considered? Are they "Risk Averse" only?

CFIA is a regulatory authority. The CFIA uses a risk-based approach to verify that domestically produced and imported products meet Canadian standards and regulations. The risk based approach includes considerations to history, data and trends.

However, there are regulations in place that cannot be ignored. The Inspector in Charge is responsible to verify that the regulated party is in compliance with applicable Acts and Regulations. The Inspector in Charge verifies compliance in any given situation by first gathering information, and then considers various factors before making a determination of compliance.

Industry must work with their associations to identify the need for regulatory change where appropriate.

2. How will the Inspection staff get the information that we (Industry) are receiving at these Industry sessions? Our Inspectors were asking us to relay the information to them.

The FSEP Manual was posted to the CFIA external website on May 1, 2012. All inspectors have now been notified of the revised manual. This list of Q & A's will be posted on our internal website for meat inspectors. A notification will be sent to alert inspection staff that the questions have been posted.

3. How is industry notified of CFIA personnel changes?

When there are changes in local inspection staff, introductions at 3rd party premises are usually handled by the supervisor or a senior inspector. Communication of changes in management or Director level positions are handled at the discretion of the Area and/or Regional Office personnel. The CFIA Senior Management Organizational Structure is available on the inspection.gc.ca website.

4. Who at the establishment is required to sign the annual CFIA work shift agreement renewal?

The work shift agreement must be signed by a representative of the operator. It is not stated in the MOP exactly who must sign this document; however it should be someone with the authority to ensure that the establishment operates in accordance with the agreement.

5. How does industry know who to call within the CFIA? It is hard to navigate on the website to find this information. Many of us don't know who to go to when there are issues with the I/C.

We acknowledge the CFIA website is large and performing a search can be frustrating. However all plant, facilities, establishments etc. that are subject to CFIA inspection have a local inspector, supervisor, Inspection Manager and Regional Director that may be contacted when there is an issue. Issues that can not be resolved by the local inspector should be brought to the attention of the supervisor and, where required, may be put forward to the Inspection Manager and/or the Regional Director, through the chain of command.

If there is a need to make certain information more readily available to industry and more easily understood it will be looked at.

6. To whom in CFIA can we provide comments/feedback other than our local inspector.

It is always best to address concerns through the chain of command; however you may contact the supervisor or Inspection Manager for your complex or Region.

In addition, a new CFIA page called "*Complaints, Comments and Compliments*" has been added to the CFIA web site. This page outlines how you can contact the Canadian Food Inspection Agency (CFIA) to register a complaint, comment or compliment about our activities or programs. Complaints and appeals can be made:

- when you are not satisfied with our staff's approach;
- when you perceive undue delays; and
- when you disagree with decisions made by CFIA employees related to licensing, registration, permits, orders, inspection results, seizure, labelling and other items.

The CFIA takes complaints and appeals very seriously, so these are handled in an efficient and transparent manner.

7. How do we improve communication between field staff (IIC) and management? There are inspectors who will not/do not communicate even when an email from programs sent to them indicates that the inspector is supposed to distribute this info. Can there

be some sort of feedback system or clarification/direction to the VIC/IIC's to ensure info is given to the operators?

Clear instructions are given to inspection staff when information must be distributed to industry. If you have a specific concern, please discuss with your local inspector and/or supervisor.

8. Is there any onus on CFIA and the plant representatives to have a working relationship?

It is in everyone's best interest to sit down and discuss issues before they grow into bigger problems. If you establish a good rapport with each other, day to day work tends to go a lot smoother. The CFIA is committed to be consistent and uniform in our approach. We are in the process of developing and implementing a national uniformity project to identify and address consistency issues.

9. New inspectors sometimes don't have good "bed side manners". What can you say about this?

All inspectors new to CVS are subject to a one-on-one coaching and evaluation process. Communication and interaction with the regulated party is covered during this process. When an inspector is "new", there may be challenges for both the inspector and the regulated party as that relationship is established. Courtesy and professionalism must be extended from both sides.

10. Are ALL documents required to be shown to CFIA staff, for example QA notebooks?

Legislation enforced by CFIA requires that the regulated party:

"shall give the inspector all reasonable assistance to enable the inspector to carry out his duties and functions under this Act and shall furnish the inspector with any information the inspector may reasonably require with respect to the administration or enforcement of this Act and the regulations."

11. Does CFIA have the right to take copies of documents? Does CFIA have the right to take pictures when necessary?

Yes. The legislation enforced by CFIA provides that an inspector may:

"require any person to produce for inspection, or for the purpose of obtaining copies or extracts, any book, shipping bill, bill of lading or other document or record that the inspector believes on reasonable grounds contains any information relevant to the administration or enforcement of this Act or the regulations."

Also, we may use cameras when necessary, but it should not be part of the regular inspection duties.

12. FSIS has an "Ask FSIS" website, On this site industry posts similar questions to what we are discussing today, FSIS posts responses to questions that have already been answered. Does CFIA have something similar to this that is centrally located, and accessible to everyone?

The CFIA is working towards implementing a similar format. We definitely need this type of mechanism for the benefit of both inspectors and industry.

13. Can an operator of a meat establishment insist that a CFIA inspector complete compulsory hygiene training before being allowed into the facility?

Under the *Meat Inspection Act*, inspectors have the right to enter federally registered meat establishments and owners/operators must not interfere with this right. For example, CFIA staff has been specifically instructed not to provide finger print/biometric/photograph information to owners/operators of a regulated third party in order to gain access to a facility. Placing a mandatory requirement on an inspector as a prerequisite to enter the facility could be viewed as a contravention of this legislation.

However, CFIA does require CFIA inspection staff to follow operator sanitary practices when these measures are written into the operator's HACCP system, they do not interfere with an inspector's ability to perform their inspection duties, and they do not create a health and safety risk for the inspector. Generally this approach has worked well when it is prefaced with an open and collegial discussion between the CFIA inspector and the operator. In specific situations, involving the inspector's supervisor in the discussion is often worthwhile so the requirements are clear to everyone.

Consistency

14. This question is related to non-compliances identified by both the local inspection staff and also the regional inspection staff. For companies that have national coverage, why do we continue to see very specific non-compliances raised only at 1or 2 specific plants in one region (for a long period of time) and never see hints of this in other regions or even the same region?

a. Are there discussions among local inspection staff from the same region?
b. Are there discussions among local inspection staff between regions?

We recognize that uniformity issues do exist. We strive to address consistency on all levels. We have several training initiatives planned for the upcoming fiscal year to enhance uniformity

among inspectors with respect to outcome based inspection and completion of Inspection Report – Corrective Action Requests.

There are opportunities for inspection staff to meet and discuss inspection issues. For example, Quality Verification file reviews (QMS), Regional Management Team (RMT) meetings, National Regional Veterinary Officer (RVO) meetings, National Processing Team meetings, National Inspection/Program Manager meetings etc.

If clarification is necessary regarding a specific situation, please discuss the issue with your local inspector. There are many resources available to the inspector to verify uniformity issues including the Area CVS and FSEP Coordinators, Regional HACCP Specialists, Regional Program Officers and Area Program Specialists. Bear in mind that the process for "request for Review of a CAR" is also available to operators.

15. If a question (e.g. CVS, Programs, FSEP) is raised by either industry or regional CFIA and answered by National CFIA, how does the answer get shared with all regions so that a consistent approach is taken?

Any minor questions/responses or policy interpretations that affect all establishments/operators are communicated through the National CVS Coordinator and/or National FSEP Coordinator through to the Area CVS and/or FSEP Coordinators. Depending on the situation, the Area Operation Coordinators may also be contacted.

Major issues are typically communicated through Listserv. Listserv is a notification process that communicates electronic messages to appropriate CFIA inspection staff when a policy clarification, program update or regulatory change etc. occurs. These notices also instruct the inspectors to ensure that the information is shared with industry, as applicable. CVS Meat also now has a webpage where we will post these Q&A's for all inspectors to view.

16. How often are you updating training of the inspection staff?

We are doing CVS update training every year, and FSEP updates. We have 6 initiatives for training for CVS and FSEP. Recommendation for training from Weatherhill has been implemented. Coaching training is also being implemented. We have a 5 year plan developed so you will start to see that roll out.

17. In the US, there is a lot of collaborative training with industry. Are we considering this in Canada? This would help us collaborate better and build our industry to better standards.

It is harder for us in Canada because the US has specific training establishments capable of performing these functions. One of our initiatives is to test this concept by holding 3

workshops with the CMC dealing with the Listeria Policy, Recall procedures, etc. to ensure both CFIA and industry have an opportunity to have input. In the end our priority resides in the fact that we are obligated to ensure CFIA staff is trained. It must be recognized that there will be differences in the requirements for training industry and CFIA staff.

18. For national companies, should we follow up on inconsistencies at the national level?

We recognize that uniformity issues do exist. We strive to address consistency on all levels. We have several training initiatives planned for the upcoming fiscal year to enhance uniformity among inspectors with respect to outcome based inspection and completion of Inspection Report – Corrective Action Requests.

If clarification is necessary regarding a specific situation, please discuss the issue first with your local inspector and, if unable to resolve the situation proceed through the chain of command.

Inspection Frequency

19. Will the meat industry will ever require less than daily inspection/ presence.

This will not occur any time soon. While the requirement is primarily based on risk, it is also related to public perception. Some negotiations/discussions for alternate approaches are being considered, but it is too early to know how procedures may eventually change.

20. Will the meat inspection program one day see the same inspection frequency as other commodities?

Inspection frequency, regardless of the commodities, will be based on risk. The meat program has traditionally had a higher presence than other commodities. Our current inspection frequency for meat processing establishments is for CFIA inspectors to be present at least once during every 12 hours of production. This is for all federally registered establishments in Canada and is also the frequency expected by the US at establishments eligible to export to the US. The CFIA is currently negotiating with the US to look into alternative frequency based on risk. When we compare the dairy risk category (quarterly inspection) to the meat risk category (every 12 hours inspection), we have to wonder why this is the case. If we look back in history at FSEP in 1991 and compare that to what FSEP looks like now, the program has improved greatly.

21. Do you see a day when inspection at the meat plant will be the same a dairy program inspection?

With the onset of inspection modernization, there is intent to amalgamate certain inspection competencies. For example a thermal processing specialist should be able to evaluate this process no matter what commodity. A building / facilities specialist should be able to evaluate any premises where food products are manufactured.

Export

22. In relation to Foreign Country Audits, are the requirements of the country, going to be made available to the plants ahead of the audit?

Yes, however it is the responsibility of the operator to be fully aware and in compliance with the importing requirements of any country to which they export.

23. How long does it take to conduct a foreign country pre-audit visit?

The pre-audit visit requires the inspector to complete a checklist verifying foreign country requirements. The length of the checklist will vary depending on the number and type of requirements.

24. How do the countries choose the plants?

Every country is different; this selection process will differ between the countries involved.

25. When will industry expect the next round of USDA audits?

At this point in time, we have not been advised of any planned USDA audits of federally registered meat establishments. The US is currently using the establishment specific information that was collected in April 2010 with the FSIS Self-Reporting Tool (SRT) to retrieve information about specific Canadian establishments and to determine where and when to focus their next audit.

The National Inspection Division is currently leading an initiative to compile establishment profile information into one database, much like the FSIS Self-Reporting Tool (SRT).

The USDA is currently performing a review in some of the other commodities.
The USDA is working on a pilot project to try to “move the import inspection system away from the border”. A few of the large US-based corporations are likely going to be participating in this project.

26. We have a “Pre-shipment review” Policy that we implement in our 2 plants. The policy states that we only do a pre-shipment review on our product being exported to the USA.

Pre-shipment review CVS task#_____ Do we have to do a pre-shipment review on domestic product in our plant or just on product that will be exported to the USA? NOTE - We received a CAR at one of our plants for not including the domestic product but our other plant's inspector did not write a CAR while doing the same CVS task.

If you are an establishment eligible to export to the USA and you choose to not perform a pre-shipment review on certain meat products, you must be able to clearly demonstrate that:

The meat products in question are:

- shipped directly from the establishment to a facility not federally registered for meat (leaves the federal system)
- destined exclusively for sale in the Canadian retail market
- destined exclusively for sale to the Canadian Hotel Restaurant Institution (HRI) market (for ex., tray pack steaks or poultry cuts, 9 cut chicken for HRI)

CVS – Meat Program

27. Does CVS apply to meat only?

For the purpose of the commodities present at these industry sessions, yes, it currently only applies to meat establishments. However, CVS is also implemented in the Feed and Rendering Programs and the Livestock Traceability and Humane Transportation of Animals Programs. We are currently working on developing CVS for the Imported and Manufactured Food Program.

28. What has CFIA learned through the CVS tasks, positives and negative feedback from the inspectors?

The CVS has proven to be not only a valuable tool for inspectors, it also promotes communication between inspection staff, program staff and senior operational management. Inspectors have indicated that it is satisfying to know that when comments or suggestions are brought forward, they are responded to and changes/updates/revisions are visible to everyone.

29. Are we getting good value with the CVS program?

The CVS is a tool for the use of CFIA inspectors that provides a consistent inspection and documentation approach. The CVS has provided managers and directors with detailed compliance data that was not available with previous inspection systems. The CVS has also been a positive consideration when our trading partners come to audit the Canadian Food (Meat) Inspection System. For example, the recent Russian, Chinese, European Union, Korean and US audits have all benefited from the CVS process.

The CVS has shown that it is flexible and improvements can be easily and quickly made to facilitate the changing demands resulting from risk considerations, compliance data, high visibility issues and trading partner requirements.

30. CFIA performs CVS audits as to what is written in the program but often the audit goes beyond what is in the program and delves into "other" activities. In fact – some audits start on program "A" but then questions and concerns pertain to program "B". How can CFIA guide their auditors better? What are the RVO QMS reviews identifying in terms of CVS inspector performance?

The CVS provides inspectors with guidance regarding when to change or add to the scope of the verification. In addition, inspectors are encouraged to delve deeper into an issue if necessary. These are decisions that must be made by the inspector onsite.

QMS criteria are broken down into very specific activities. Performance is assessed through each activity being conducted. The CFIA analyzes quality verification results and implements corrective action where necessary. For example, completion of Inspection Report-Corrective Action Requests (CARs) was identified as an activity that required improvement therefore we've established a National Training Initiative for this issue.

31. In our opinion, inspectors do not always understand the CVS task and process; expertise on the subject is not there; they just follow the company program. How can industry deal with this situation?

The Meat Program and Operations have several training initiatives planned for the upcoming fiscal year to enhance uniformity and expertise. In addition, we plan to utilize our Coaching and Evaluation Process to ensure proper practical application of training concepts. If serious concerns exist, please contact the inspector's supervisor.

Inspectors are to be coached and mentored, and should not be working alone prior to the completion of this training. We use QMS to identify the need for program and training improvements.

32. Is there a reason the tasks are not posted on the website.

<u>The tasks are an operational guide for inspectors only.</u> The regulations, the Manual of Procedures, and the FSEP Manual are the established requirements for the regulated party to follow.

The CVS tasks do not limit or prohibit the authority of the CFIA inspector. For example, even though the inspector is doing Task "A", it does not preclude him/her from taking action or

looking into Situation “B”. That being said, we do provide copies of the tasks to industry when major revisions occur and any time we receive a request for a copy. We are open and transparent and will share all information as requested.

33. Are there other reference documents given to the inspectors besides the CVS Tasks in order for them to complete their tasks?

The references documents used by inspectors are listed in each CVS Task (section of the regulations, Meat Hygiene Manual of Procedures, FSEP Manual etc.) There are also certain training documents that may explain some requirements in greater detail. These can also be used by inspectors when conducting their verifications.

34. Why is the information on the CVS tasks sheets not updated to correlate with the corresponding reference information of the MOP?

The CVS tasks have been updated as of April 1, 2012 with the current MOP references. Please keep in mind that the MOP is sometimes changed prior to the tasks being updated. We are working to ensure this situation does not happen, but it might.

Historically, an internal communication problem allowed for this discrepancy to occur…an internal procedure for approving new information upgrades/releases has been implemented, requiring sign-off by all affected sections of the CFIA (Operations, Programs, Training, etc.)

***35.* Can we obtain a copy of the establishment task profile for our establishment?**

The establishment task profile is an internal CFIA document; however you may request that your inspector or their supervisor provide you a copy.

***36.* If an establishment has 2 shifts, does that mean twice the number of CVS tasks need to be conducted?**

No. CVS tasks are conducted at the prescribed frequency and will be distributed across all shifts at an establishment.

37. Does the IIC have to notify us when they plan on doing a CVS task?

We encourage operators and inspectors to build a rapport and determine a mutually acceptable system for conducting compliance verification activities. Part of this system includes the inspector advising you of their upcoming activities and requesting documentation where practical and possible however it is important to recognize that situations may arise that require unplanned or unscheduled tasks or activities to be conducted by the inspector.

38. How much time does the operator have to provide documentation and records to the inspector when they are planning to conduct a CVS task?

There is no set amount of time. CFIA and the operator must work together to establish a mutually acceptable system for obtaining documentation.

39. For small plants with only 1 QA staff, it can be difficult to accommodate accompanying the inspector without advance notification. If we are given a "heads up" we can leave the program/records to be available, or schedule the allotted time to review with the onsite inspector. It's no notification or a change to the schedule that is difficult to accommodate.

We recognize that scheduling can be difficult for certain plants. We encourage you to discuss these issues with your local inspector and supervisor. However keep in mind that CFIA inspectors must also vary their inspection activities so that verifications occur at varied times at all plants. It must be understood that even with notification, it may be necessary to adjust planned activities and task.

We need to develop good communication and rapport between CFIA and industry. Common sense must be used.

40. There is an issue with the CFIA Inspectors demanding programs and records to do the CVS tasks at times when the QA staff is busy with other responsibilities. Can't the Inspectors give advance notice of what tasks are going to be performed and when? That way we can get the programs out and have them ready for them.

We need to work together. This is why having a good rapport between the establishment and the inspector is so important. Asking for the records in advance is one solution.

However, as a regulatory Agency, the CFIA is authorized to request documentation and records in order to verify compliance. Please understand that the inspector may not be able to wait for two hours for records. Issues may arise that are immediate food safety concerns and thus records/programs may be required immediately as well.

41. Can a CVS task be done in an overtime or second shift?

If the company is operating, a CVS task can be done at any time. The company can be notified ahead of time.

42. When will the CVS Meat tasks include the updates to the FSEP Manual discussed at this session? When will the IIC be given the new tasks?

There will be information sessions held with inspection staff to explain the FSEP Manual Updates prior to the date on which industry must comply with the changes. The tasks will be available to inspection staff during these information sessions.

43. Can CVS put a system to qualify when to require formal deviation reports as defined in the generic program (Deviation procedure)? Example, most of the plant's monitoring reports have spaces for deviation and corrective action taken and we use this to record such. Do we still issue another deviation report to duplicate this action?

This is not a CVS issue. CVS is a tool for inspectors – not a requirement for operators.

The manner in which operators deal with and document deviations and corrective actions can differ greatly. The FSEP Manual is what stipulates the information that is required when a deviation occurs – it is up to the operator to structure their deviation procedures (HACCP System) so that they are effective and capture all of the required information.

44. Does the CVS task go beyond the requirements? Do we have to document the times for certain activities? (Example: Are we obligated to document the completion time of a pre-op and the start up time of operations?) Is this something that CVS can mandate?

CVS does not create requirements. The MOP states pre-op activities have to be completed prior to operations. How can you prove what you are doing? Records are the proof. The records are used to assess that you are meeting the requirements. In order for these records to demonstrate that your operations are able to meet these requirements, these records must document measurable facts (ie: time, temperature, etc.).

45. When CFIA are conducting their record reviews as part of their verification activities are they required to look at every single record, in detail, back to the last time the verification activity was performed? I.e. a quarterly task would mean 3 months of records reviewed, every single day?

The inspector is trained that it is not necessary to examine all the documentation that is available; a sample of the records produced since the last verification is sufficient. If any significant deviations or problems are encountered, the inspector will expand the record review to determine the extent of the problem.

46. Can an inspector do a task at the same time as the forecasting task? For example during the ventilation task, the inspector is doing forecasting at same time and finds condensation.

Forecasting is an activity- NOT A TASK. The forecasting activity provides the inspector an opportunity to assess the entire facility and then prioritize the tasks to be completed during the

month. If during the completion of the forecasting activity, the inspector identifies non-compliance where the operator is not in control, they will select the task related to the non-compliance and issue a CAR. This is called a “stumble on”. It is outside the scope of the forecasting activity.

47. For Forecasting Activities how much time is given to correct the item? Why does it show up on the following CVS Verification worksheet the next week.

There is no timeframe as it depends on what is seen during that forecasting activity. Forecasting is an internal activity done by the inspectors to identify possible issues that can be seen during a tour of the facility. Remember no record review is done during the forecasting activity. When the inspector identifies an issue, they then determine the CVS task that should be conducted to assess the facilities control over that issue. Therefore, the issue and the CVS task associated with the issue will appear on a verification worksheet. The task has been selected that pertains to the issue identified during the forecasting activity. It is suggested that plant staff accompany the inspector during the forecasting activity so they too can see what the inspector sees and correct any issues that arise, preferably before the task is done.

Inspection Report – Corrective Action Request (CAR)/ Action Plan/ Follow Up

48. Should a plant be informed of an impending CAR?

Yes. The inspector verbally informs the the operator of his/her intention to issue a CAR as soon as the non-compliance is identified. See MOP 18.7.4.3

49. Industry wants more communication so they are not blindsided by CARs, we want to work together.

As a regulatory agency, the CFIA inspector is required to issue an Inspection Report – Corrective Action Requests (CAR) when non-compliance is identified. Where establishment employees accompany the CFIA inspector during verifications, both parties are usually aware of the non-compliance simultaneously.

50. Do CARs have to be reviewed by the supervisor first?

No. The inspector is designated to write and issue a CAR. The only exception is that at a slaughter establishment, the Veterinarian In Charge must sign the CAR.

51. There is a broad statement identified in the CAR (regulatory requirements related to xxx are not met). Is it possible to have that statement reviewed and possible removed as

CAR's are ATIP-able and sometimes it does not identify the actual issue that warranted the CAR.

That is something we will look at however, an Inspection Report – CAR is issued when there is a situation of non-compliance. Non compliance occurs when regulatory requirements are not being met

52. Could you please ask CFIA staff to specify which bullet or deficiency needs to be met and what needs to be changed to meet requirements?

When non-compliance occurs, the CFIA is required to identify the non-compliance on an Inspection Report CAR and request corrective action. The operator is required to analyse the non-compliance, determine the root cause and develop an action plan that will effectively correct and prevent the issue from re-occurring. The CFIA inspection is not required to "consult" or make suggestions as to how you must meet requirements, or as to what needs to be changed in your written program.

53. Do CAR's need to be signed right away?

If CAR's are not signed right away, Chapter 18 dictates what will be done on the part of the inspector. The inspector records the information associated with the findings on the CAR and the CAR is presented to the representative of the operator. Please remember that the signing of the CAR is an acknowledgement that the CAR was presented to the operator.

54. Is there a way to find out how we, as an establishment, rank with other establishments in respect to the number of CAR's given?

No. That would be a breach in confidentiality. We do not share information about other plants.

55. If I meet minimum temperature requirements of the MOP but my program says my temperature requirement is higher than that for a specific customer and I'm not producing for that customer on the day the inspector audits can I receive a CAR for that?

Yes. You write your program and are expected to follow what you write. You need to write your program to allow for this temperature change for specific customers if this is what you are going to do. The inspector does not know when the product is destined for a specific customer and will act on what is seen in relation to what is written in the program.

56. If a CVS task report is submitted to Ottawa by the inspector, but the information is not accurate, how can this be changed or rescinded?

There seems to be a misconception that the CVS Task is a “requirement” for operators (the regulated party). It is not. The CVS is a tool for CFIA inspectors only. The tasks are there for inspectors to follow a logical and consistent approach to inspection activities and documentation of these activities.

The regulations, the FSEP Manual and the Manual of Procedures are the “requirements” that apply to the regulated party. Changes to these are implemented only after the established process of consultation occurs between industry and the Meat Program Division.

The Inspection Report is the legal document that provides a description of non-compliance as identified by the initial inspection, as well as the follow up inspection findings. The “Request for Review of an Inspection-Report CAR” provides industry with a process to deal with concerns over inaccurate Inspection Reports.

We also do periodic reviews of the data, to ensure it is consistent across the Areas, and use QMS to assess the quality of the training provided to CFIA staff.

57. Why does it take a long time to receive a response to a request for CAR review?

An operator may request a review of a CAR before the date specified for the submission of an action plan. The operator will not be required to submit an action plan until the review results have been communicated to the operator and CFIA staff. The Area CVS Coordinator is mindful of the time sensitivity involved, but must also conduct a thorough review before making a decision.

58. What appeal procedure is there if differences of opinion or interpretation arise? Who is on the appeal board (both CFIA and industry)?

The Area CVS Coordinator is responsible to assess all requests for review / appeal. The Coordinator has many resources to consult in any given situation in order to make the best decision. For example: Area, Regional and National HACCP Specialists; the National Inspection Manager; the National CVS Coordinators as well as Area and National Program Specialists.

59. Industry wants to be more involved with reviews, ie to be able to be on conference call or online with VIC/IIC and Programs Specialist.

The MOP Chapter 18 policy states that the Area CVS Coordinator will contact the operator when necessary to gather information and perspective. As a regulatory agency, it is the CFIA’s obligation to specify dates for compliance, follow up and take enforcement actions as necessary.

60. What is the dead line for the IIC to get back to the company for accepting a CAP?

The inspector is responsible to review all written action plans within seven calendar days from the date the action plan was submitted by the operator. If you have not heard from the IIC you should talk to the IIC or the supervisor.

61. How long after a CAR is issued, should it be followed up?

The inspector is responsible to follow up on the resolution of the non-compliance identified on the CAR within 30 calendar days of the specified date of the completion of the action plan. The inspector may begin to conduct follow up immediately, but will not make a final determination until the date specified for completion of corrective measures.

62. Why does it take so long to get an answer from CFIA, to an "extension request" (CAR/CAP)

If you have a specific concern, please discuss the issue with your local inspector. There are many resources available to the inspector to verify uniformity issues including the Area CVS and FSEP Coordinators, Regional HACCP Specialists, Regional Program Officers and Are Program Specialists.

63. Action Plan Extension: can you please give an example of "beyond the operator's control"?

An example would be if repairs are needed to the roof and it is the middle of December. Operator has no control over the weather.

64. Why are non-compliances found during the forecasting activity and related to the same CVS Task, issued as more than one CAR?

The intent of the forecasting activity is for inspectors to consistently be aware of the conditions and processes occurring in the entire plant. Prior to implementing the forecasting activity, some inspectors in larger plants found they were focusing on the individual tasks and not always the "big picture". This was also raised during a foreign country audit.

Non-compliances may not be able to be "grouped" on the same inspection Report – CAR because they are not related to the same task. Keeping non-compliances aligned with the task they pertain to, allow us to provide reportable data on specific areas of non-compliance and better manage risk when determining inspection frequencies.

65. Each CAR contains a "negative" statement that states in very broad and generic terms what requirements have not been met – and there are apparently only a limited number

of these "statement options". In many cases, either the wrong statement is chosen to reflect the issue – or maybe a generic statement does not exist. Why is this generic statement necessary in addition to the actual details of the deficiency? If it is deemed necessary, then can CFIA issuing the CAR be given authority to revise the statement to actually reflect the nature of the deviation?

Since October 2010, there are no longer "options" for the opening statement of an Inspection Report – CAR. The statement that is used is the negative of what was assessed during the verification. For example, if "The operator meets the regulatory requirements related to lighting" was being assessed and non-compliance was identified, then the statement used would be "The operator does not meet the regulatory requirements related to lighting".

After this introductory statement is made, the specific non-compliance and related factual information is described.

66. CAR's – CAR's issued contain unnecessary details that are not pertinent. In fact – CAR appeals are almost entirely based upon revision to remove unnecessary information. Can the Agency provide written training to establishment CFIA such that CAR's be more "to the point"? Simplification will assist the establishment in terms of identifying what the issue really is without convoluting the issue with background details. Further, numerous reviews of CAR's during export audits have been performed and even foreign government auditors struggle to understand what the CAR was about and what the actual issue was in the first place due to the way deviations are described and back ground unnecessary info included.

The Inspection Report – Corrective Action Request (CAR) is a legal document. Details relating to a situation of non-compliance are pertinent; however we recognize that uniformity issues do exist. There is a National training initiative planned for the upcoming fiscal year to enhance uniformity among inspectors with completion of Inspection Report – Corrective Action Requests.

67. Why cannot only the employee title vs both the employee name and the employee title be used in the CAR details? (Note: if there is an ATIP related to the CAR, unnecessary company resources are required to remove the employee name).

From a legal perspective, when documenting non-compliance, employee names must be used where appropriate. i.e. signatures and recounting interviews with individuals. If you choose to use position titles, these titles must be clearly linked to one responsible individual. In the event of an ATIP request that will reveal third party employee names, a consultation takes place beforehand to ask permission whether the name can appear or not. If permission is not granted, names are blocked where possible (again this depends on the nature of the request).

68. There appears to be a recent change during Section 4 audits to have the entire audit results as a CAR, when not all of the observations warranted one as per the definition. Why is that? This makes responding to the CAR much more difficult in terms of minor program adjustments and their root causes / preventative measures.

The HACCP system design verification is essentially aimed at verifying the effectiveness of the operator's maintenance and reassessment procedures. If there are enough deficiencies noted to issue a CAR in the first place, any additional deficiencies, even relatively minor, may support the concern we have regarding the lack of effectiveness of the reassessment procedures. The verification task itself instructs the CFIA staff to look at each detail to ensure that all hazards are identified and controlled.

If a CAR has been issued, the message is that the combined maintenance and reassessment procedures have failed to sustain a system design which meets the criteria outlined in the FSEP Manual, and one detail more or less on the CAR doesn't change that.

69. Is it necessary to name the responsible persons for components of the action plan?

No. It is clearly stated in 6.8 of the FSEP Manual that you must identify the name **or** title of the person(s) responsible for the immediate/short term and preventive measures of your action plan.

***70.* Are the 5 questions, who, what, when etc. necessary in an action plan?**

The "5 questions" is a method that industry can use to find the root cause of a deviation. The root cause must be described in the action plan. The method used to find the root cause does not have to be included in the action plan.

71. In a non meat facility, how long should it take to follow up on a CAR?

As per 6.10 of the FSEP Manual, CFIA will follow-up after the date for completion of corrective measures has passed to ensure that the corrective measures have been completed as described and are effective.

72. In a situation where an inspector is conducting a CAR follow up – how many follow up inspections are necessary to close the CAR?

The number follow up inspections for a CAR is not pre-determined. The inspector must use their judgement and knowledge of the establishment while considering the non-compliance and the action plan content in order to determine when and how to follow up.

FOOD SAFETY ENHANCEMENT PROGRAM

General

73. When will the generic models be ready? Where will we be able to find them?

The generic models for poultry and swine are currently under revision. When these are completed they will be posted on the "Hazard Analysis of Critical Control Points/ Food Safety Enhancement Program CFIA webpage

74. Question from FSEP voluntarily recognized establishments. During CFIA scheduled verification of our HACCP system design and implementation, can the auditors formalize the notification report and include the scope of the audit (what requirement/standards/elements are to be audited)?

The short answer to this question is no. The verification scope will at least include a review of:

- the senior management letter of commitment;
- the HACCP system performance reporting process;
- the maintenance and reassessment procedures;
- one HACCP plan; and
- six prerequisite programs sub-elements.

The selection of the HACCP plan and the prerequisite programs to be verified will be done at the establishment. A copy of the verification scope will be provided to the company during the opening meeting at the establishment.

75. What are examples of regular CFIA inspection activities for FSEP Voluntary commodities?

Inspectors inspecting at dairy establishments conduct activities according to the Dairy Establishment Inspection Program (DEIM). Other commodities such as shell egg and processed products also have their own inspection requirements.

76. When a HACCP Plan is submitted to the FSEP Area Coordinator for review, is there an established time-line for the review to be competed?

As per Chapter 18.4.4.1 of the Meat Hygiene Manual of Procedures, a written review of HACCP plans submitted by Meat registered establishments must be carried out within 30 calendar days from the receipt of the new HACCP plans.
A written review of HACCP plans associated with high risk category products/processes must be conducted prior to the commencement of the new processes for commerce.

For FSEP recognized establishments other than meat, the CFIA internal procedures are as follow.

- A written review of HACCP plans associated with high risk category products/processes must be conducted prior to the commencement of the new processes for commerce. The review must be conducted by a CFIA team within 30 calendar days from the receipt of a new HACCP plan. A CFIA team must visit the establishment after 90 days of operation of the new process to verify effectiveness of CCP implementation.

- HACCP plans associated with lower risk products/processes must be reviewed by a CFIA team after 90 days of operation of the new process.

77. Do we have to use the generic deviation form?

It is important to note that generic forms are not a mandatory format. If a facility is able to meet all requirements of FSEP utilizing a different format, that format would also be acceptable.

***78.* Does the inspector have the right to write in the company log book?**

Before CVS implementation when inspectors conducted FSEP audits, the inspector was instructed to initial the log book to indicate which entries she or he had reviewed. This requirement no longer is specified in the FSEP manual; however there may be inspectors who continue this practice.

79. Are we required to change the version date on all of our documentation when we conduct our annual reassessment or can we just modify the documents only on which revisions are made?

It is not necessary to modify the version dates of all the documents that you have revised. However you must demonstrate with the exact documents that they were revised.

All modified documents must have a new date or revision number. It is up to the establishment to determine the manner in which modified versions will be identified.

Hazard Database

80. What is the most recent version of the Hazard Database and where can we access it? Is it available on-line yet?

The most recent version of the Hazard Database is dated 2008. CFIA is working on the electronic posting, but you may contact Tom Graham at tom.graham@inspection.gc.ca for a copy.

81. Is there CFIA training for inspection staff on the use of Hazard Data Base? Why do we have to prove hazards don't exist?

Inspection staff receives training in the use of the hazard database when they receive FSEP training. We should remind everyone again that the hazard database is only a tool to assist with hazard analysis. Not every hazard listed in the database applies for every process or in every facility. Hazards that have absolutely no relation with the process under review should not be considered. For example, at the Receiving step the Hazard database identifies the following hazard: Pathogen growth /toxins due to low brix or time to unload (milk product and transformed products). This hazard does not apply to a Hog slaughter plant and should not be listed in the Hog slaughter HACCP plan. This is common sense. However, CFIA must be able to see that you have at least considered hazards that may occur at your establishment and that you have documented your determination as to why it is not likely to occur.

Task vs. Monitoring

82. Can you please communicate at each meeting that implementing task and monitoring to remove verification is not a requirement. This has been documented on CVS reports for one of our facilities in the past. As long as we meet the HACCP Principal of monitoring, either approach should be acceptable and non-mandated to switch.

Implementing task and monitoring to remove verification is not a requirement. If an establishment wants to keep their verification activities in addition to the reassessment activities, it is their choice.

However, it clearly states in the FSEP Manual section 3.1 that each establishment must create a documented program that responds to each prerequisite program bullet requirement defined in section 3.1.1. The documented program shall include:

- Specific programs, procedures or policies as per prerequisite program bullet requirements;
- Monitoring procedures; and
- Deviation procedures.

For example, requirement C.1.2.1

The establishment has and implements a documented Preventative Equipment Maintenance Program which includes but is not limited to:

- A list of equipment that may impact on food safety requiring regular maintenance;
- A preventative maintenance schedule or frequency of preventative maintenance activities;
- The maintenance procedures to perform for each preventative maintenance task;
- Records to be kept to demonstrate that the preventative maintenance tasks have been completed.

The Preventative Equipment Maintenance Program will include tasks to be performed. This program will be monitored at a frequency X to ensure that it is effectively implemented.

83. Can you please provide us with clarification between conducting a task and conducting a monitoring procedure?

A task is part of a program that must be developed and implemented to prevent a hazard to occur. For example, equipment maintenance, equipment calibration, pre-operational sanitation check, training of new employees, pest control. A task is part of a control measure.

Monitoring is the act of conducting a planned sequence of observations, tests or measurements to assess whether a control measure or a prerequisite program is under control.

The task has the same importance as monitoring. If the task is not completed properly, a food safety hazard may occur. The monitoring will ensure that the control measure or the prerequisite program is implemented as written and is under control.

84. If the Task is part of the requirements of the new FSEP manual it needs to be in the FSEP manual for the industry to follow.. It means that a new version of FSEP manual has been published where the tasks are required. I don't accept that requirements are hidden / not clear in the manual and FSEP auditor will tell me "where ever you see records to be kept you have to treat it as a task. It needs to be clear in the manual.

Section 3.1 of the FSEP Manual states:

Each establishment must create a documented program that responds to each prerequisite program bullet requirement. The documented program shall include:

- Specific programs, procedures or policies as per prerequisite program bullet requirements
- Monitoring procedure
- Deviation procedure

For example, requirement F.1.2.1 Product Coding and Labelling

You must develop and implement a procedure to prevent incorrect labeling/coding which at least include:

- The names or title of personnel responsible for particular task;

- Frequency of activity;
- Description of the task to be performed;
- Corrective actions to be taken when product is mislabeled or miscoded;
- Operational records to be kept.

This is your operational procedure which includes tasks to be performed. This procedure will be monitored at a frequency X to ensure that it is effectively implemented.

85. The concept of tasks is visible only in the published new generic model. But are the generic models a summary of FSEP requirements? If yes why do you revise only the FSEP Manual with directives?

The prerequisite program generic model was created to help industry to develop their prerequisite programs. This is an example. It is not a summary of FSEP requirements. The FSEP Manual describes the requirements. If you don't need the generic model you don't have to use it.

86. Pre-Operational Inspection. I have condensation before pre-op, and I write "wipe condensation and sanitize" on the inspection report every week. It is part of the regular process. Is this an issue?

It depends on how your written program is developed. If you have written your pre-operation activities as monitoring activities, any findings would be considered a deviation. When you do the monitoring, everything should be under control. If wiping and sanitizing is part of the regular process, include it as a step in your sanitation program. This step should be done before the pre-op. You shouldn't have the same deviation over and over in a report, even if it's a task report.

87. If the Quality Assurance people are doing checks to ensure the monitoring is completed, are we reassessing the monitor assessing the equipment?

Yes, this can be covered under onsite reassessment.

88. We are cooking roast beef. I measure the internal temperature of the product, is this a "task" or is this monitoring?

Monitoring is the act of conducting a planned sequence of observations, tests or measurements to assess whether a control measure is under control.

The control measure is the cooking process. Taking measurement of the internal temperature of product is monitoring.

89. Who can perform the Reassessment? Can it be the same person who does the verification of CCPs?

Verification is a company's use of methods, procedures, tests and other evaluations, in addition to monitoring, to determine its conformance to and the effectiveness of a control measure. Reassessment is a review of the entire HACCP system to determine whether the system is up to date, identifies all food safety hazards, has control measures in place for all food safety hazards which may be controlled by the establishment, results in the desired outcome and conforms to all regulatory requirements.

Verification of CCP and reassessment activities may be conducted by the same competent person. Both procedures have different but complementary goals.

90. Reassessment is required 'whenever any changes occur'. However, it is a part of the maintenance procedures to 'reassess and update any implicated parts of the HACCP program'. What's the difference? Do we need to keep the records for both?

Whenever any changes or situations occur that could affect the hazard analysis or alter the HACCP system, the establishment shall reassess completeness and effectiveness of the updated part of the HACCP system and document the reassessment activities conducted in the HACCP system modification log book as described in the FSEP Manual section 3.4.1 (HACCP System Maintenance Procedures).

Prerequisite Programs

91. Please confirm that the wording of the new FSEP ventilation sub-element is intended to permit neutral air within compatible operations.

Yes.

92. How can positive air pressure be evaluated correctly?

We suggest that you contact a competent ventilation company to respond to this question.

93. We received an observation concerning shipping during the completion of task 1.2.13. We inspect our transport vehicles or the transport vehicles of companies whom we contract. We were criticized for not inspecting other customer vehicles when they come themselves to pick up their order. Are we required to ensure the compliance of trucks that are not under our direct responsibility (shipping only), even if they are not from a federally registered establishment and if so, what do we do in the case of non-compliance? Is it true that we must have the customer sign a letter specifying that

product returns will not be accepted? It seems illogical to refuse to sell a product to a customer because their vehicle does not comply with our requirements. Can we not say that as soon as a product is placed in a vehicle that is not under our direct responsibility, the product has left the establishment?

A registered establishment must have a written program that includes an inspection prior to the loading of all transport vehicles – even those that are not contracted by the establishment. The registered establishment must refuse to load a transport vehicle that does not meet the requirements of section 49 of the *Meat Inspection Regulations, 1990* otherwise; the establishment is in contravention with this section. If the establishment sells directly to a consumer, it is understood that this section does not apply.

***Meat Inspection Regulations, 1990* requirements:**

49. *No edible meat product shall be transported to or from a registered establishment unless the transport container in which it is transported*

*(*a*) is constructed of material that is free of any noxious constituent;*

*(*b*) has inside surfaces that are hard, smooth, impervious to moisture, in good repair and clean;*

*(*c*) is capable of protecting meat products and containers thereof against contamination;*

*(*d*) is equipped, where applicable, to maintain meat products in a refrigerated or frozen state;*

*(*e*) is equipped, where applicable, to prevent meat products from freezing where freezing could adversely affect them; and*

*(*f*) is not being used and has not been used for the transport of animals, control products as defined in the Pest Control Products Act or any other material or substance that might adulterate the meat product.*

94. Can Pre-requisite bullets B2.2.1 and B2.2.2, be used to control hazards created during the processing steps for a further processed meat product?

Without a description of the hazards in question, it is impossible to determine whether they are adequately addressed or not by B.2.2.1 and B.2.2.2.

These two bullets are under the sub-element “Storage”.
B.2.2.1 is used to control temperatures of any storage areas, coolers, freezers and processing areas.
B.2.2.2 is used to control

- the handling of ingredients, finished products and packaging materials in storage areas
- the storage conditions
- temperature abuse of ingredients and finished products when processing room temperatures could allow for increase in product temperatures above the standards.

B.2.2.2 is also used to control the rotation of ingredients and finished products

95. Do my raw ingredients (non-meat products like vegetables) need to be kept at the same temperature as my processing room?

If the temperature of the processing room allows an increase in the temperature of ingredients that require refrigeration (4^{o}C), these ingredients or the waiting period of these ingredients must be monitored in order to prevent temperature abuse. If the ingredient does not permit the growth of micro-organisms and does not require refrigeration to maintain its properties it is recognized that temperature control is not necessary.

96. With respect to C1.2.1 Equipment that impacts on food safety - what is the definition of equipment that impact on food safety. Some Inspectors/Auditors are looking for everything from stationary tables to fork lifts to furnaces located in offices. Can some clarity be provided to all with respect to this definition?

This note has been added to the revised FSEP Manual 2012

Note 2: Equipment and pieces of equipment requiring regular maintenance that must be included in the Preventative Maintenance Program:

- Processing equipment used to prevent, eliminate or reduce the likely occurrence of identified hazards. For example, pasteurizer.
- Pieces of equipment that come in contact with food.
- Equipment located above exposed food product that could contaminate food product if not well maintained.

97. We do not require establishments to document every time a person washes their hands. This is because a facility can demonstrate they meet this requirement through their training documentation. So if we train the pre-op person appropriately shouldn't this be sufficient?

We do not require that every instance of hand washing be documented, but we do expect oversight of this activity as part of the D.2.1.1 – monitoring of GMPs/hygiene. Training records cannot demonstrate that procedures and policies are being implemented.

98. Can you clarify how we should evaluate on a weekly basis if our employees have a food transmissible disease?

Your food hygiene program must clearly indicate that employees who are suffering from a food transmissible disease must alert their condition to management.

Conditions that must be reported are hepatitis, diarrhoea, vomiting, fever, infected lesions on the hands and nasal discharge.

Action must be taken if any of these conditions are observed during the course of daily monitoring of employee hygienic work practices.

99. Can Pre-requisite bullets D1.2.1 & D.2.1.1, be used to control hazard which are related to employee handling?

Yes, D.2.1.1 is the General Food Hygiene Program. It may include all controls associated with hygienic handling of food.

Again, without a description of the hazards in question, it is impossible to determine whether they are adequately addressed or not by D.1.2.1 & D.2.1.1. It also depends on how you write your General Food Hygiene Program. If you say that the hazard is controlled under D.2.1.1 and when the inspector looks at D.2.1.1 there is no procedure available, this is not acceptable.

100. G1.1.2 covers approved suppliers of allergenic ingredients, approved allergenic ingredients, supplier specs., supplier documentation must meet the plant's spec. and the supplier must notify the establishment when there is an allergen and/ or sulphite change. Does the G1.1.2 Pre-requisite Bullet Statement need also to reference Pre-requisite B2.1.1 (which covers some of these requirements)? If yes, why?

If all G.1.1.2 requirements are covered under your G.1.1.2 program, you don't need to reference B.2.1.1. If some of the requirements are covered under B.2.1.1 and are not covered under G.1.1.2, you need to reference B.2.1.1.

101. In slaughter operations, is water chlorination considered a processing agent?

Yes, chemicals that are added to water in order to reduce microbial loads on carcasses are considered processing agents.

102. Can we monitor several food additives and nutrients that are used in different locations within the same program?

Yes, the program must include:

- the name of the food additive or nutrient;
- the food product in or upon which the food additive or nutrient is added;

- the standards to be met (limit of acceptability);
- the names or titles of personnel responsible for particular tasks at the formulation and food additives or nutrients addition steps;
- the methods or instructions for the task(s) to be performed;
- the frequency of the task(s) to be performed;
- the corrective actions to be taken when the standards are not met;
- the operational records to be kept.

103. The Reassessment of a Prerequisite Program includes a description of HOW to conduct the on-site (component#2) however the Reassessment of a HACCP Plan does NOT include a description of HOW to conduct the onsite (component#2). Is this an oversight?

You are correct, the example related to the reassessment of a HACCP plan should have include how to conduct the on-site.

HACCP Plan

104. What is the procedure for adding or removing a CCP from the HACCP Plan?

As per the FSEP Manual section 5.2, when an establishment changes its recognized HACCP system, it must enter the changes in the HACCP log book as described in section 3.4.1 of the FSEP manual. The data must be available for future review by the CFIA.

We recommend that you notify the inspector in charge before making the change.

105. What kind of physical hazard would you expect to see described on Form 7 associated with Plant Schematic, cross contamination? Would physical hazards be more appropriately described as related to environmental issues (premises) rather that cross contamination issues related to people, product, garbage, packaging flows?

There is no physical hazard associated with the plant schematic identified in the Reference Data for Hazard Identification.

106. Can a PC be used and not be linked to a CCP?

At this time all PC's must be linked to a downstream CCP. **See FSEP Manual 3.2.8.**

107. Does CFIA accept that certain process steps are considered as process controls (PC) in the dairy industry?

Yes,

Process Control (PC) – Where more than one step in an overall process may contribute to the reduction of a particular hazard, process controls may be developed for the early points of the process where the hazard cannot be fully controlled, but a subsequent step will result in the elimination or reduction of this particular hazard to an acceptable level. This final control would be determined to be a CCP.

108. Do we need to re-validate CCPs if we did not make any changes throughout the year?

No. However, you do need to re-evaluate each CCP at least annually to ensure that these are up to date, that desired results are being met, that they meet regulatory requirements and that they meet the requirements stated in the FSEP Manual.

109. Review of a new HACCP Plan: With regard to high risk categories, are products that do not support the growth of Lm taken into consideration?

Utilization of the term « High Risk Categories » in section 5.1 of the FSEP Manual is not in anyway related to the term "High Risk Category" as stated in the Listeria policy.

The categorization of risk related to the process described in the HACCP Plan submitted by the establishment allows CFIA to evaluate if a review must conducted by CFIA before the start of a new process that will result in (high risk) products for commercial sale or possibly be reviewed after the start of the new process (lower risk).

High risk category products or processes may involve any of the following criteria:

- The process involves a kill step to eliminate microbial contaminants, or a step to reduce them to an acceptable level. For example, pasteurization, sterilization, cooking, drying, fermentation, acidification.
- Hazards are inherent to the process and the product is considered ready to eat, without further processing by the consumer.
- The production involves a complex recipe. It may involve the use of chemical hazards (e.g. nitrates) or involve a product that addresses serious nutritional concerns.

Validation

110. Which prerequisite programs might require validation? Do you have a list?

Any new operation or activity described within a prerequisite program that has a direct impact on food safety if not executed properly should be validated prior to implementation.

For example:

- Food additives and nutrients control program.*

- Modified atmosphere packaging control programs.*
- Food processing aids control program.*
- New sanitation procedures for equipment having surfaces that come in to contact with ready to eat food products.

* Historical, scientific, regulatory or technical data regarding existing operations or activities can be submitted to CFIA as validation documentation.

111. Are the validation checklist form and the maintenance & reassessment tools available on line?

No. To receive a copy of these, you can contact the FSEP Coordinator or Tom Graham at the following e-mail address: tom.graham@inspection.gc.ca

112. In regards to validation in Listeria. What is the turn around time for approvals? What if plants are in a lower risk category?

We are unable to provide a turn around time for validation study approvals. If you have submitted a validation study for approval, there will be a CFIA Food Safety Division representative assigned to your submission who will be better able to provide status updates to you.

113. Can you group theory sections (ie parts of Section 2 of the validation checklist) together?

Yes

114. In MOP 4.1.8: "Why does it state that meat must be cooked prior to dehydration? If proper validation can be done to prove control of the product where dehydration before cooking can produce a safe final product (i.e. Dehydrations time does not exceed a certain time and cooking temperature can be high enough to kill bacteria in dehydrated products) can this clause be negated?

Any alternative processes that do not reflect established policies must be validated and this information submitted for approval by the CFIA Meat Programs Division in conjunction with the Food Safety Division.

115. On the validation checklist, what is the difference between approaches J and L for gathering information?

Approach J – Historical plant data
Approach L – Gathering information during operations

Approach J is existing records used to demonstrate that a control measure that has already been implemented for several years at an establishment is effective. This is considered historical data.

Approach L is used to demonstrate, at the present time, that the conditions under which a control measure is implemented at an establishment do not differ from the conditions under which the same control measure referenced in a scientific or technical publication was validated.

116. What training do you require for individuals who will be responsible for conducting validation study work that needs to be submitted?

Depending on the process or the control measure that is being validated, the responsible person must have the necessary scientific knowledge and practical expertise in order to conduct the validation. The operator can obtain guidance regarding specific applications from scientific institutions (universities), competent authorities, processing experts or a combination of scientific sources.

Allergens

117. How will the new allergen labelling regulatory changes be enforced? Specifically referring to gluten sources?

Wheat and triticale are “allergens” by definition. Gluten sources (e.g., barley, rye, oats) are not allergens but may elicit negative effects with celiac individuals. Health Canada has required that gluten sources be labelled to help consumers make informed choices.

118. Will gluten sources require full allergen control (segregation, cleanup etc)? If yes, if wheat or any gluten sources are present in a product and common to the plant, Health Canada has identified that full allergen control is not required between gluten sources, because the presence of any gluten, regardless of source informs celiac consumers appropriately. Is this how CFIA will enforce or will it requires full segregation of all sources separately?

Operators of federally meat establishments must address the use of gluten in their HACCP system accordingly. CFIA will follow the lead of Health Canada. As long as the labelling requirements are met, full allergen control between gluten sources will not be required.

119. Has the labelling requirement for sulphites changed as a result of the recently updated allergen policy issued by Health Canada?

No. Health Canada sulphite labelling provisions are unchanged. They are as follows:
1. Any amount of sulphite added to a pre-packaged product by the plant has to be declared as an ingredient and be added to the ingredient statement. (per FDA B.01.009)
2. The amended allergen policy states that when sulphites are present (i.e. part of a component such as seasoning or flavouring), a declaration must be made when the sulphites exceeds 10 ppm in the final product. This can be done by sub listing sulphite along with the other ingredients making up the favouring or seasoning as part of the list of ingredients, or it can be added to the end of the ingredient list by way of a statement entitled "contains," along with any other allergens.

Listeria

120. Testing NRTE meat for pathogens:

a) If we test a non-ready-to-eat (NRTE) raw material for a pathogen and it is present (Listeria, Salmonella, etc) are we required to notify the local CFIA if we return it to the supplier?

If the product has been physically received at the establishment, even if it is held pending test results, CFIA must be advised.

b) What if it is intended to be fully cooked in-house or further sold as a NRTE mixed product requiring cooking by consumer?

Yes, the operator must advise CFIA in this case. The CFIA must ensure the requirements of **MIR 20.** (2) are met: "*Where an adulterated meat product in a registered establishment can be made to conform to the standards prescribed by this Part for an edible meat product, the meat product shall be held by an inspector until it is made to conform to those standards by the operator."*

c) What if a customer tested a finished NRTE product and it is positive for a pathogen but has validated cooking instructions? Do we have to notify CFIA?

Yes.

MIR 2. (1) *In these Regulations,*

"adulterated" means, in respect of a meat product intended for sale, use or consumption as an edible meat product in Canada,

containing or having been treated with

(iv) any pathogenic microorganism in excess of levels published in the Manual of Procedures,

MIR 20. (1) *No adulterated meat product shall be identified as edible.*

121. Do presumptive positive Listeria have to be shared with CFIA?

It is not mandatory for the operator to report presumptive listeria results to the CFIA. It is mandatory for the operator to report all food contact surface (FCS) and product positives for *Listeria spp* and *Listeria monocytogenes*. Non food contact surface (NFCS) positives are to be provided to CFIA upon request.

122. Listeria Policy: Chapter 4 Annex H. Example: A line normally operates full time and the sampling frequency is 4x/month / line. If the line does not operate for the first two weeks of the month, then sampling only in the remaining weeks (for a total of two samples) would be required. Additionally the establishment would be required to document that the line was not operational during the other two weeks. Is this statement above the correct approach that industry needs to take?

If the sampling frequency is 4 samples / line/month, and the line is shut down for two weeks, only two samples would be expected to be collected during the operational weeks because there is no risk during the two weeks of inactivity and no increased risk during the weeks of operation as a result of the line being idle during the first two weeks. Therefore, this statement is the correct approach to take.

The Meat Programs Division communicated a Listserv clarification on January 23, 2012 to all meat inspection staff to give guidance concerning this type of situation.

123. Why must all unsatisfactory pathogen micro results be reported to CFIA?

The CFIA has a responsibility to ensure compliance to the Food and Drug Act and Regulations (FDA) and for meat products produced in registered establishments, the Meat Inspection Act and Regulations (MIR) as a means of ensuring food safety.

Meat products with levels of pathogens that exceed levels published in the Meat Hygiene Manual of Procedures (MOP) (for example, Chapter 4, Annex H- Listeria policy or Annex O- E.coli policy) are considered adulterated (MIR).

The Food and Drug Act section 4 also states:

No person shall sell an article of food that (a) has in or on it any poisonous or harmful substance

MIR:

60.1 (1)
An operator who has processed, packaged, labelled, stored or distributed a meat product, or any person who imports a meat product, and who learns that the meat product might constitute a risk to the public health or might not meet the requirements of these Regulations shall investigate the matter and notify an inspector.

(2) If the results of the investigation indicate that the meat product constitutes a risk to the public health, the operator or importer shall notify the President immediately after becoming aware of the results.

Meat Program – Technical Questions

124. Why must all failed cooling "rapid or slow" be reported to CFIA?

We have addressed this issue with the Meat Programs Division. This type of prescriptive wording is being removed from the MOP.

125. Why must each lot (house) rapid or slow be monitored for cooling?

Every lot must be monitored for cooling, because there is no other way to assure that a deviation has not occurred on a given lot. This would be analogous for the need to monitor every cook or retort process.

126. If you fail a cooling, why is product testing for C. perfringens testing not considered by the risk assessment group?

Note that according to the MOP, "*end product sampling for Clostridium perfringens (viable cells) can be done as an additional safety measure <u>but is not sufficient on its own."</u>*

End product test results are considered in a risk assessment. However, lots for which greater than 1 log C. perfringens growth is predicted will generally not be released, even if C. perfringens test results (N5) are favourable, because the distribution of a pathogen in a meat product would not be uniform and it would therefore take a very large sample size to statistically provide enough confidence the hazard does not exist. Favourable N5 testing results do give reasonable assurance that levels aren't high enough to pose a concern if less than 1 log growth C. perfringens is predicted. Therefore, in general, lots for which less than 1 log C. perfringens growth is predicted are released, provided that N5 test results are favourable, but may not be released if high levels of C. perfringens are found.

127. Which pathogens, and at what levels, must be reported to CFIA?

The target pathogens for the Risk-based Verification Sampling of Ready-to-Eat (RTE) Meat and Poultry Products are L*. monocytogenes* and *Salmonella* spp. and *E. coli* O157:H7. For RTE meat and poultry products, zero tolerance applies for tested pathogens in products that support its growth.

128. **If *product cooling (after cooking) is out of spec, is that reportable to CFIA?***

With an outcome based approach, cooling deviations are not reportable to CFIA. However documentation that demonstrates the results of the food safety assessment and/or risk assessment performed by the operator must be available to the inspector. See MOP 4.5.2.