Cross Border Livestock Health I Proceedings
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Speakers:
Dr. Mary-Jane Ireland
Dr. Steven Vaughn
Dr. Cheryl James
Tammy Switucha

The first person to speak in this session was Dr. Cheryl James, who presented via teleconference on the Canada-US Regulatory Cooperation Council's zoning for foreign animal diseases. She started by saying that that the Regulatory Council had had an update on animal zoning since their last presentation in Saskatoon. The next steps that they are facing are working towards establishing a common framework and a common understanding of how zoning is done in each country. The core objective is to protect against diseases and, in the case of an outbreak, continue bilateral relations in the safe zones. Developing the protocol of mutual recognition required for this is currently an Action Item that the council is pursuing.

Disease outbreaks will effect and have economic costs on both sides of the border due to the high levels of trade that occurs between Canada and the US. There are many integrated cross border business relationships. A disease outbreak could cause major economic losses and stakeholder interests would like to address this risk. It is important to keep in mind that there is already a lot of this type of recognition occurring (i.e. the 2004 outbreak in British Columbia). The goal here is to put some additional structure and rigor into place.

One of the accomplishments to date is the evaluation process that has taken place in both Canada and the United States. The scientific information necessary to proceed has been given and it was decided that the outcomes were similar enough in both countries in regards to the managing and controlling of disease. This was the first time that a formal evaluation of this sort had been done. It was revaluated in 2007 and will continue to be reviewed and updated on a regular basis because industry is constantly changing. An arrangement was reached to recognize each country's zoning establishments and that if an outbreak happened the rest of the country outside of that zone would be clear. It is not a treaty or a binding legal agreement, it is just a document saying that both countries have looked at this and that this is the intention.

Framework to guide the arrangement was previously released in the United States and its process is now complete. However things got a little bogged down in Canada. These are intended to be evergreen documents and there are always opportunities for partners to see into the process.

A cross border workshop on Outbreak Surveillance Toolbox was held in Washington in March. At this event there were a wide variety of representatives from Canadian industry. It was a very useful workshop. Unfortunately, it had to be put together in a fairly short period of time and there were issues with resources. Due to this, not all of industry or states were engaged. At the workshop a number of situations were discussed to develop a greater understanding of how the country responds to a disease outbreak. The approaches were different but the outcomes were the same. This understanding between countries is needed to build trust.

The draft framework was developed a USDA-CFIA bilateral working group. It was decided that the scope would be limited to foreign animal disease in domestic livestock and not to include endemic diseases or pets. The draft has been made available for public comment. The first version of the document will be looking a complication results as the bilateral groups gets back together to see what needs to be changed.

The objective is to have an operational plan for zoning recognition. One thing to consider is how to maintain this arrangement over time, not just writing up the document and walking away and forgetting about it. The strategy is to engage with stakeholders (will be looking at changing the word to 'partners', which a more appropriate term as it is definitely more of a partnering strategy). Good support from industry is necessary to make this work. It is important to look at these guiding principles and really understand them as zoning for foreign animal disease is a shared responsibility, as is preparing for and limiting the impact of a highly contagious disease. Every one is affected and it is every one's responsibility to mitigate the impact, so we need to work together and find better solutions. Ongoing cooperation is crucial and we need to have a structure and a sustained effort in place. We need to encourage openness and information sharing; credibility is vital. Although things function differently in each country, that isn't an excuse to judge. Developing the knowledge about the systems is vital to having credibility in the arrangement.

The framework is split into three parts. Part one is all about how this will be implemented during an outbreak. One of the big questions was who has the legal authority to develop the zones, and that took a while to establish, as well as who has the authority to recognize the zone. This is the part that is all about emergency preparedness. The second part is about the procedures for the recognition of zoning decisions. Notification will be given at the first warning of an outbreak. This is currently done on an informal basis; this new framework is striving towards formalizing it. Once a warning has been issues, each country can take charge of their own health. At this point there can be border closures but hopefully they would be

limited in terms of time. Once the inspector country has established an area of control that contains the diseases cases, and is reasonably sure that it is contained, at that point communication is made that the situation is under control and to ask the other country to formally acknowledge the zoning decision. The host country will follow OIE guidelines. There cannot be any trade until those guidelines have been met (i.e. incubation periods) and then restrictions can be lifted. We recognize that there can be extenuating circumstances (mostly small outbreaks, sometimes massive) and if that is the case the infected country will not ask for zoning until the incubation period has passed outside the area of control. If the infected country does ask, the other country can delay approval until appropriate time period has elapsed. The border is only going to open if the disease is controlled in a zone.

The next area of focus was looking at monitoring during outbreak and how to communicate and stay on top of it. There is not a lot of time to put together documents during an outbreak. The solution to this is that the unaffected country is invited to become embedded in the command structure. A person would be welcome into the structure to observe and communicate, among other functions depending upon the situation. This practice was already in place, but now it has been formalized. Nothing can be hidden if the person is right there in the midst of the situation. Communicating between partners is important during an outbreak. The CFIA has its own communication and would be looking at having a coordinated response. Once a zone has been recognized trade from outside may resume with a heath certificate to prove that the animal did not originate from the zone.

Now government is needed to promote these decisions and to take responsibility over the documents. There are organizational changes all the time and this can change how infrastructures are evaluated. APHIS-CFIA's Steering Committee and working groups are responsible for maintaining the supporting documents. The work on the initiative is done through a series of projects that look at emergency preparedness. Most of these projects are lead by working groups and will be collaborated with stakeholders, who are also encouraged to participate in their own projects. Other outside groups are more than welcome to participate as well. With respects to resources, no additional resources were provided.

We need to be promoting stakeholder awareness and engagement, as well as emphasizing the importance of both NGO and government stakeholders. There is a broad target audience. In initiating the annual review of activities proposals will be solicited and then the group will select what activities will be attempted in that year. This does highly depend upon available resources. A large amount of communication and consultation is required so ideally using established groups would be preferred.

In summary there have been many evaluations of veterinary and zoning processes, a guidance framework has been developed, and have talked about implementation and engagement. As to what is next, we are really excited about the whole initiative; it is a great foundation for cross border collaboration. The initiative is still in short

supply of time and resources. Continuing to look at emergency preparedness is important, as well as incorporating the zoning process into emergency processes. When talking about opening and closing borders we really need to have a firm understanding of whether it is better to keep the border open or close it. It is hard to predict everything that could happen. More structure is needed around the whole question. What is left now is to figure out what will it take to get states and provinces to sign on? It is important for governments to understand the situation fully and support it in principle.

Next it must be decided how to build consensus among industry and stakeholders. There has been a wide range of responses from highly supportive at adamantly opposed, and work will have to be done to engage the groups that are opposed. Another issue to address is how to get recognition from the OIE. When looking at their guideline zoning by states or provinces is treated differently than zoning decisions made by countries. This needs to be addressed, since some of the provinces and states are bigger than many smaller countries and thus shouldn't be treated any differently in this situation. There has been a lot of interest in what we are doing and the world is watching. Going back to the toolbox workshop, there has been some good feedback and it was informative to work through situations and share understanding. There is a desire to do more projects of that sort, though again constrained resources are consistent difficulty. The initiative needs to be proactive in seeking out new funding and learn to be creative during budgetary cuts. There has been a lot of commitment at high levels to move the initiative forward.

The framework process is being finalized in both countries, and comments are encouraged. Once all the comments have been received then the bilateral working group will consider them and have a discussion on the changes that need to be made. After that the initiative will seek approval through governmental processes. There is another project going on right now that looks at the consequences of border closings/openings. There is also a virtual disease-modeling center that is currently under way. It took a lot of work to put the model together and to validate it, and the end goal is to have a tool to help make quick decisions during an outbreak. It will be possible to take the model, out in the information, and will come up with an answer that is defendable. Drafting a bilateral work plan is also in process. Work is still continuing although the initial group ended a while ago.

Then the floor was opened to questions. Martin Rice, with the Canadian Pork Council, asked two questions. The first was if the initiative was aware of any precedence for this for this bilateral initiative (i.e. EU)? Secondly in terms of foreign animal diseases, are they assumed to be the same as the OIE roster? Dr. James answered that they did recognize zoning in the EU, which has taken a long time. In the EU if there is an outbreak from one country the whole EU is not shut down. The problem that we are running into is that zoning by state or province doesn't have the same recognition as a country. It is not quite the same but that is the precedence for out initiative. She was not aware that any other place has done anything like this. The decision has been made to stick with the names and definitions of the OIE.

Ron Baker with Canada Health asked, in regards to one of the toolboxes that the CFIA is in the process of creating, if an update of the traceability file was possible. Dr. James replied that was something separate and full under the category of infrastructure. The documents concern traceability within Canada and the United States are available for review. Those would be considered part of the whole evaluation. The working group will get back together in September, and is planning an event with Canadian stakeholders on August 18 so the consultation is extended till then.

Another individual inquired about a passport system for show livestock. Dr. James said that she did not believe that this fell under this particular initiative.

The next speakers were Dr. Mary-Jane Ireland and Dr. Steven Vaughn, who were speaking about veterinary drugs. At the beginning they announced that this was the same presentation that they co-presented at the 2012 Cross Border Conference. In Canada and the United States any one who sells veterinary drugs needs approval from Health Canada and the Food and Drug Administration. Large presentations of data must be submitted for regulatory perspective in which it is decided if that drug has a positive risk profile. This role starts after the submission of the drug. The Food and Drug Administration has established a fairly solid relationship with Health Canada over the years. Lists of drugs are discussed at the management level and drug submissions are highly carbonized. There is also a harmonization of food safety that is done through a codex. A lot of collaboration for science is done ad hoc and as needed. When one organization was reviewing and had questions, they could call the other to get guidance for approval. Unfortunately there would be a disparity of timelines in drug approval. Products approved in the Unites Stated are generally not available in Canada at the same time because the two countries do not have the same toolboxes. The vision is to create an environment for simultaneous filing. Scientists could look at the data at the same time and have real time discussions. Decisions could be made at the same time. To do this some basic principles need to be acknowledged, the first and foremost being that safety comes first. Each country has their own regulatory framework and laws, all that would be provided would be an independent review of the data and then the countries could make their own sovereign decision.

The work plan for this project is available on multiple websites. One of the major stumbling blocks to facilitating simultaneous filing of drugs was trying to get the same data sets. Three key action items were required for further alignment. The first was to complete one simultaneous review pilot project. It was necessary to get a company to file at the same time with the same data set. Not too long after formally starting, simultaneous approval was achieved in 2012. Another was completed just a couple of months ago. The drug was evaluated and discusses together and was approved on both sides of the border. When looking at the labels it is apparent that they are highly aligned, the only big difference being due to different geography and climate. It is interesting to note that they really had to sell

the program at the beginning but now it is something that companies are interested in participating in. There has been collaborative review for six additional pilot drugs, three of which were for food producing animals. Generic drugs are not accepted. Others are just going through some formalities. Another result was that is was learned that collaborative review can also include each countries organizations or any else really that has anything to do with regulatory discussions. The second action item was developing mechanisms. This process has been completed and is just undergoing fine-tuning. The third action item was discussion on actual data to discuss difference and why there are differences. This process is seeking data for further alignment.

Going forward, there will be continued work on simultaneous and collaborative review pilots well into the future. There has been tremendous support from stakeholders and other groups. The next phase will be developing and fine-tuning the mechanisms involved and reaching out to stakeholders. There is still an initial product difference because market discrepancy is still in place and it is markets role to close that gap. Stakeholders have been incredibly important to the whole process. There have been sessions in Washington and joint press releases. The FDA and Health Canada try to advice on a six-month process. When looking at where the gaps come up, price differentials seem to be one of the key places. This is outside of the control for this program.

Then it was time for questions. The first question was whether this was the same process that will be used to change the labels or potentially pull some drugs from the shelves, and if those processes have been synchronized. Dr. Vaughn answered that in terms of adding claims or indications, once approved expansion has to be done through an application process. If there is a difference, one country can approach the other with supplemental information. This process is already available. In regards to withdrawing drugs, we so discuss those and probably the highest priority is when human food safety is involved. We have our own statutory provisions to remove drugs from the market place. Those processes are independent of each other because of differing legal processes. Then Dr. James added that they always have strong communication.

Jack Janssen asked if this process applied to horses and if it will harmonize the use of off-label pharmaceutical. Dr. James replied that the process could include drugs for horses but that there had not been a request for that to date. It isn't outside the scope though. The first two drugs were for companion animals. For Canada this is a funny thing as it is a vet issue. Health Canada has a feel of how they think this should occur and thinks that it needs to be done judiciously. If it was for a companion animal it can be done at the vets' discretion. Dr. Vaughn added on by talking about the Animal Drug Use Verification Act and how it specifically precludes extra-labeling and describes the conditions that must be in place to use an extra label set out in regulations. There is a nexus with safe practice acts. As for the horses, yes, all series of animals are included. Extra labeling is outside of this initiative, as it focuses of the pre-market. The second part is regulated by another agency in both Canada and the

United States. Dr. James wrapped up the answer by stating that hopefully this will stop the need for extra labeling.

Meat and Poultry Export Certification

The last speaker was Tammy Switucha with CFIA, who presented via teleconference on meat and poultry export certification. It was agreed, between Canada and the United States, to reduce or eliminate redundant certification. The countries have been working together to identify issues and cross-references. Objectives to streamline the certification process have been identified. The hopeful industry outcome would be a reduction in the complexity of export requirements since many of the requirements that are currently in place could be eliminated.

The CFIA had been jointly reviewing procedures, some of which was undertaken while doing equivalency efforts as well. Good progress has been made, especially with veterinary requirements. One of the biggest developments was the announcement of BSE comprehensive rules, which allows for non-vets to sign export documents where the infrastructure is equivalent. This should be confirmed shortly and will allow for flexibility. Some changes have been made in Canada as well. Amendments have been made to streamline approval and policy. This will allow for greater flexibility to activities in federal environments. United States inspectors will be able to sign for meat. Work is currently underway across the border to design a worksheet. The staff of CFIA is looking to finalize all the good work that has been done to date and will be following up on the approval of the actual certificate and the implementation of electronic certification. When this has been finalized it will facilitate moving forward. The CFIA is committed to collaboration on these efforts as well as examining other electronic certification efforts.

Discussion around initiative would not be complete without overview. Over the last two years CFIA has witnessed quite a bit of collaboration and this project is a good starting point for deeper cooperation between countries, a potential transition to achieve greater regulatory cooperation and alignment. The next phase is currently under discussion, but every one is hoping to put into place a more systemic approach. It has been recognized that there is a need to address certain issues, and the ultimate goal is to establish new processes in governance to avoid some of these irritants in the first place. A broader process has been established to identify issues. After that comprehensive consultation exercise looked at the comments received. More information will be released on this in days to come.

Then the floor was opened to questions one last time. Jeff Warrack from the National Cattle Feeders Association asked if there were any e-certification processed for live animals. Tammy replied that they had heard from stakeholders fairly consistently over the last couple of years of the desire to move towards e-certification. These discussions are happening with the United States, and medium and long-term approaches will be taken to address these issues. Another participant

expressed an interested in e-certification for hogs. There was a comment that a lot of those questions would be addressed in one of the later Cross Border Livestock Health sessions the next day.

The next question asked how they intended to get around the legal protection of information. Tammy replied that it was an interesting question and may need follow up because she did not have the answer on hand. It was agreed they connect after the call to deal with the question directly.

The final question asked if equivalent plans that were talked about were based upon the Food Modernization Act? Tammy answered that they mainly dealt with food inspection services and was done under the preview of the Food and Drug Administration.

Action Items

After all the speakers were finished the session then moved to decide upon Action Items. The 2013 Action Items were reviewed. It was then decided upon that the Action Items would be decided upon later after the other sessions.