A Discussion of Options for Canada's Next Captive Cervid Chronic Wasting Disease Control Program

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EXECUTIVE SUMMARY

Chronic wasting disease (CWD) is an infectious prion disease of North American captive and wild cervids with an expanding geographical range. Since its first detection in Canada, the disease has been found in wild cervids from significant parts of Saskatchewan (SK) and Alberta (AB). To date, CWD has been diagnosed on 68 cervid farms in SK and on 2 cervid farms in AB.

At the request of the Minister of Agriculture and Agri-Food, the CWD Task Force was enacted to develop options, complete analysis, and recommend a preferred option for a new CWD disease control program in Canadian farmed cervids. The Task Force successfully completed the development of five program options for consideration (eradication, farm-based risk, provincial zoning, sub-provincial zoning, and voluntary herd certification [VHC]). The Task Force then reviewed the challenges and benefits of each option, and conducted an analysis and ranking, using five key criteria: 1) disease control effectiveness, 2) impact on commercial viability, 3) international credibility/recognition, 4) scientific soundness, and 5) cost to all stakeholders. The eradication and VHC program options were excluded after preliminary ranking, due to the unacceptable financial cost and impact on commercial viability, and lack of disease control effectiveness, respectively. The remaining program options were subjected to further analysis and discussion. Although no option was clearly superior, based on the final ranking, the Task Force recommended that the examination of the farm-based risk option be pursued, provided the critical challenge of cost can be addressed.

The final CWD program options remaining for consideration are the farm-based risk approach, provincial zoning, and sub-provincial zoning. A thorough written and pictorial description of each option, including an analysis of the strengths and weaknesses of each option, are included for discussion in this paper. All Canadian stakeholders have an opportunity to comment on the contending CWD disease control programs prior to a final program recommendation and decision by the Minister during the fall of 2013.

1. PURPOSE

To describe the work of the CWD Task Force, explain the range of CWD program options developed, and discuss the contending options to be considered for the CFIA's next CWD control program in captive cervids. This document serves as the basis for national consultation on the CWD disease control program options being considered for development.

2. BACKGROUND

2.1 The disease

CWD is a progressive, invariably fatal neurodegenerative disease known to affect cervids (e.g. deer, elk, and moose). First recognized in North America in the 1960s, it is a member of the group of prion-related diseases known as the transmissible spongiform encephalopathies, which include bovine spongiform encephalopathy (BSE) in cattle, scrapie in sheep and goats, and Creutzfeldt-Jakob disease in humans.

CWD is a reportable disease under the *Health of Animals Act*. The CFIA's eradication program, developed in the year 2000, was based on 1) an understanding of the science of CWD at that time; 2) the commitment of both industry and the provinces to active surveillance, strict inventory control, and the tracking and reporting of animal movements via animal identification; 3) a limited presence of CWD in Canada, with most captive CWD cases traceable in a clear network pattern; and 4) a perceived absence of established disease in the wild populations.

Initially, positive captive cases of CWD were epidemiologically linked to the movement of captive cervids, and the CFIA's national eradication program was deemed successful.^{1,2} In recent years, however, positive cases are increasingly independent of the movement of captive cervids, with exposure to wild cervids and/or their contaminated environment or feed, often being considered as the suspected source of disease transmission. In addition, current research has proven the susceptibility of reindeer (Rangifer tarandus tarandus) to CWD via experimental transmission.³ Because reindeer are closely related to caribou, this development raises concerns regarding the possible spread to caribou populations of northern Canada.

In North America, management efforts in wild cervids have been unsuccessful at curbing the geographic spread of CWD. Since the discovery of Canada's first wild case in a mule deer near the Alberta-Saskatchewan border in 2000, the disease has been detected in wild cervids from significant areas of SK and AB. At present, CWD has been diagnosed on 68 cervid farms in SK and on 2 cervid farms in AB.

Infected cervids shed the CWD agent in saliva, urine, and feces, thereby contaminating the environment (e.g. soil). Research has demonstrated that prions are extremely stable in the environment and that healthy cervids can become infected solely from environmental exposure.

No environmental decontamination procedures for application to prion-contaminated premises currently exist. Consequently, the <u>CFIA maintains any imposed declaration of infected place and associated quarantine for premises</u> wherein there is evidence of environmental transmission. Such <u>premises remain under indefinite quarantine</u>, requiring the CFIA to ensure full maintenance of perimeter fencing for the exclusion of wild cervids. On premises with no evidence of environmental contamination, after the quarantine was lifted, of those that chose to re-stock and are known to have continued cervid farming, there was an alarming 50% re-occurrence rate of CWD. Thus, the current evaluation of risk factors for re-occurrence is insufficient.

Various solutions have been proposed to help control this disease, some implemented by stakeholders, who recognize the need to manage this complex, multi-faceted problem. Some provinces have implemented strict intra-provincial movement controls in an attempt to prevent geographic spread of CWD to their area. While there is currently no federal policy by the CFIA to control cervid movement based on CWD status, any province can set higher standards over and above the minimum federal requirements (provided they have the regulatory or legislative authority to do so).

³Mitchell GB, Sigurdson CJ, O'Rourke KI, et al. (2012) Experimental Oral Transmission of Chronic Wasting Disease to Reindeer (*Rangifer tarandus tarandus*). PLoS ONE 7(6): e39055. doi:10.1371/journal.pone.0039055.

¹Kahn S, Dubé C, Bates L, Balachandran A. Chronic wasting disease in Canada: Part 1. Can Vet J 2004;45:397-404.

²Argue C, Ribble C, Lees V, McLane J, Balachandran A. Epidemiology of an outbreak of chronic wasting disease on elk farms in Saskatchewan. Can Vet J 2007;48:1241-8.

In 2011, multi-stakeholder meetings⁴ to update Canada's National CWD Control Strategy proposed that the ultimate objective is "eradication of CWD from Canada, or failing this, the tightest possible control of CWD so that it does not spread to new geographic areas or new species, and so that its environmental, economic, social and public health impacts are minimized."⁵

Effective January 2013, legislative changes to the *Health of Animals Act* enable zoning for a variety of domestic and foreign animal diseases. Zoning is a geography-based disease control strategy, recognized and defined by The World Organisation for Animal Health (OIE) in cases where it is challenging to establish and maintain disease-free status for an entire territory or country.

Many of the assumptions of the CFIA's original CWD eradication program have come under scrutiny, prompting an evaluation of whether this program was meeting the intended goal. The review concluded that it is not currently possible to eradicate CWD through quarantines and stamping-out measures in areas where the disease is enzootic in the wild. The program has been costly to government and industry and, in its current form, is unsustainable. In response, the CFIA is shifting its CWD strategy for captive cervids from that of eradication to control.

2.2 CWD Task Force

Recognizing the unsustainability of the current CFIA eradication approach, a change in programming from eradication to control of CWD was identified as an approved deficit reduction action plan (DRAP) initiative in 2012. Specifically, the implementation of an internationally accepted zoning model was put forward as a means to control the spread of CWD within Canada, at a reduced cost to taxpayers.

Early discussions relating to zoning of Canada for CWD were contentious, and the concept was poorly received by the cervid industry in SK and AB.

In May 2012, the Minister of Agriculture and Agri-Food Canada announced that a task force would be formed to help identify the direction of CFIA's next captive cervid CWD disease control program. At the request of the Minister, participation in the CWD Task Force comprised representation from CFIA; AB, SK, and Manitoba (MB) ministries of agriculture and environment; AB, SK, and MB cervid industry associations; and the Canadian Cervid Alliance.

The Task Force was expected to identify and develop CWD disease control program options and to assess those options against established criteria. Through bi-monthly and weekly teleconference meetings between September 2012 and June 2013, the Task Force completed the following: 1) finalized terms of reference; 2) finalized the key criteria to be used for analysis; 3) reached consensus on options to be developed; and 4) reached consensus on the development of each option.

The working assumptions utilized by the Task Force were as follows: 1) that options developed are for a federal disease control program to control CWD in the Canadian farmed/captive cervid population; 2) the programs developed must be within the existing regulatory framework (i.e. no changes required to

⁴Meetings to update Canada's National CWD Control Strategy: February 2011, Edmonton AB and April 2011, Saskatoon, SK.

A Proposal for Canada's National Chronic Wasting Disease Strategy: Available: http://www.ccwhc.ca/publications/A Proposal for a National CWD Control Strategy 2011 final.pdf.

current acts or regulations); and 3) the cost, to the CFIA, of the final disease control program chosen could not be higher than the status quo.

The Task Force explored a range of program options to control CWD spread in Canada's captive cervid herd. Five plausible program options, along a CWD disease control continuum, ranging from aggressive to minimal, were agreed to and developed by the group.

The first approach along the continuum was a much more aggressive eradication option that involved "stamping-out" of disease, no restocking of positive premises, and tight movement controls applied to all cervid farms. Along the middle of the continuum, three control approaches were developed – the first being a farm-based risk approach where disease is controlled at the individual farm level, using onfarm CWD risk mitigation assessments which would assess eligibility to move certain live animals and to qualify for full CFIA-supported disease control actions. The next control approaches developed were provincial and sub-provincial zoning, which involve geographic risk-based disease control, strict movement controls, and fully supported CFIA disease control actions outside of the CWD infected zone. The final approach considered, at the other end of the continuum, was the minimal voluntary herd certification (VHC) approach, whereby the CFIA would support the current VHC program, and no federal government-mandated movement or disease control actions related to CWD would exist.

The Task Force agreed to use the current CWD eradication program as a benchmark during the analysis process. In June 2012, the Task Force met in person to complete the ranking and analysis of the five program options developed. There were five pre-established criteria that were used in the ranking and analysis: 1) disease control effectiveness, 2) impact on commercial viability, 3) international credibility/recognition, 4) scientific soundness, and 5) cost to all stakeholders.

The face-to-face Task Force analysis and ranking meeting began with a thorough discussion of the benefits and challenges of all program options developed, followed by a preliminary ranking process, using the five established criteria.

Discussion of the tabulated results from the preliminary ranking outcomes identified some points of consensus. One main point of consensus was that the eradication option would be removed from further consideration, due to the unsustainable cost to all stakeholders, as well as the greatest negative impact to commercial viability. Further, there was consensus that the VHC option would be removed from further consideration, due to its inability to control CWD on any meaningful level.

The farm-based risk, provincial zoning, and sub-provincial zoning options were the top three contending options, but a clear consensus was lacking for each criterion in the preliminary ranking. The remainder of the meeting involved further discussion on these three options, with the focus on clarifying any conceptual issues, on identifying areas that required further development, and on attempting to gain consensus on issues that related to the five key criteria in order to obtain a final table of relative ranking and comparison.

3. NECESSARY ELEMENTS OF A CWD DISEASE CONTROL PROGRAM

A framework of elements, necessary for any Canadian captive cervid CWD disease control program, was created to ensure consistent, thorough, and scientifically sound development of each program option. This framework takes into consideration key components of reportable disease programs, the best

available CWD science, epidemiology, the presence of CWD in wild cervids, and lessons learned from managing numerous cases since 2002, with respect to eradication.

Program Strategy

The strategy is a statement, indicating the overarching goal or purpose of the program. A clear strategy is essential to understanding what the program strives to accomplish, and to recognizing where along the continuum of disease control options the program lies. Further, a defined program strategy is necessary for effective goal setting and program design on a national level.

Surveillance

Surveillance is an epidemiological practice by which the spread of disease is monitored to establish patterns of progression, as well as to increase our knowledge of what factors might contribute to changes in progression of the disease within a population. Depending on a program's goal, surveillance may serve different purposes. There must be a clear statement on what information the surveillance data would support regarding disease distribution and/or CWD health status of the Canadian captive cervid herd.

The design of the surveillance program would be undertaken collaboratively by the CFIA, and be the product of an epidemiological assessment. The targeted locations for surveillance will be considered to ensure best use of all available resources by all parties involved. Due to the multi-jurisdictional nature of CWD, the collaboration of many CWD stakeholders is necessary to obtain the most accurate picture of CWD in Canada.

CFIA Disease Response

This element refers to the actions that the CFIA would conduct on individual premises. The CFIA may carry out disease control actions on the following: live animals, infected premises, products, trace-in premises (sources of CWD), and trace-out premises (having received animals from an infected farm, which are now a possible source of infection). The options for action by the CFIA on CWD-positive and suspect premises will differ, depending on the program strategy. In fact, within some of the program strategies developed, there are variations in actions required; for example, in areas of different health statuses or farms of different levels of CWD risk.

Movement Controls

Due to the insidious nature of CWD, geographic areas where the disease has become established in wild cervids, along with a lack of a currently validated individual live animal test, movement controls relating to CWD will be a critical element of the next disease control program. Currently, the CFIA issues cervid movement permits, and though these permits are unrelated to an animal or herd's CWD health status, they do relate to health status for other diseases. Given current information on CWD, and the CFIA's legal responsibility to fulfill its mandate, CWD-related movement controls must be included in the captive cervid disease control program. Program options take into account what controls (if any) would be necessary to transfer live animals for breeding purposes or direct to slaughter, and to move other animals such as hunt farm bulls. In addition, potential controls for cervid products and by-products (e.g. meat, velvet, and high-risk tissues) are essential items. Depending on the program strategy chosen, movement controls will vary.

Biosecurity

Biosecurity can be defined as the implementation of measures that reduce the risk of introducing and spreading disease agents that require the adoption of a set of attitudes and behaviours by people to reduce risks in all activities involving domestic, captive exotic, and wild cervids (and their products).

Given the many direct and indirect routes of CWD transmission, and its enzootic nature in Canada, biosecurity will be an essential element in the next CWD disease control program. Successful implementation of biosecurity, in relation to CWD, will require the collaboration of all involved parties. Essential biosecurity elements include quality assurance schemes, procedures for animal and human movement control, cervid health measures, the use of primary fencing enhancements, control over vehicles, security of feed and water sources, and control of pests.

Depending on the program strategy, the adoption of biosecurity on individual farms will vary from voluntary to mandatory, and a range will exist, describing to what extent such measures are to be followed. The CWD voluntary herd certification program (VHCP) is under re-development to better address the current enzootic nature of CWD in Canada, and will include the program pillar of biosecurity going forward. Within each CWD disease control program developed, the future role (if any) of the VHCP was taken into consideration.

4. DISCUSSION OF FINAL DISEASE CONTROL PROGRAM OPTIONS FOR CONSIDERATION

After careful deliberation by the CWD Task Force (as described previously), the farm-based risk, provincial zoning, and sub-provincial zoning program options remain for final consideration. Both zoning options are part of the same concept, and thus share the same program framework, and general strengths and weaknesses. Both zoning options are considered separately for analysis and ranking, as the placement of geographic boundaries significantly changes the impact of each option. The following options were only developed to a point that would enable adequate analysis and ranking, relative to one another, and many areas require further development to create a viable program.

4.1. Farm-based risk approach

What is it?

This program is a CWD disease control strategy in which producers can choose to participate (voluntary), if they wish to mitigate the CWD risk on their individual farm, either for business purposes or for their own disease management purposes. The control of CWD in Canada would be decided on a farm-by-farm basis, using a risk-based dual approach, whereby those producers who attempted to adequately mitigate CWD risk would receive full federal government disease control support and the ability to move live animals and products.

Each farm in Canada will have the opportunity to be assessed under on-farm risk assessments, and will receive a CWD risk mitigation score (a score out of 100), based on the following factors: 1) proximity to a known focus of CWD (30 points), 2) on-farm surveillance (25 points), 3) on-farm biosecurity (35 points), and 4) movements into the herd (10 points). There is flexibility within the on-farm risk assessment on which elements can be met, and the various point combinations that may be used to achieve the cut-off or pass score of 55%. This program is designed to enable producers, anywhere in Canada, to become eligible to move products or animals and to carry out full disease control actions by taking a variety of

steps to significantly reduce the CWD risk on their farm. Appendix 1 outlines the draft individual farm-risk assessment.

Only farms that wish to be eligible to move live animals, limit the risk of CWD on their farm, and become eligible for disease control actions by the CFIA (should they contract CWD), would need to fulfill these requirements.

Program Strategy

The goal of the farm-based risk approach is to reduce the risk of CWD spreading from an infected premises to an uninfected premises.

Surveillance

The goals of surveillance on this program are as follows: 1) to determine where in Canada CWD is present, not present, or unknown (referring to national surveillance); and 2) to be an essential element in the on-farm risk assessment for CWD (referring to individual on-farm surveillance).

CFIA Disease Response

To determine what level of disease response the CFIA would take on-farm to control CWD, a target on-farm CWD risk mitigation score (cut-off score) of 55% was established. Accordingly, those farms that have taken adequate steps to mitigate the CWD risk are good candidates for full resources and support to attempt to eliminate CWD from the premises. Alternatively, on farms that do not take sufficient measures to mitigate the CWD risk, it would be difficult to justify the use of public resources to attempt to eliminate the disease from that premises, especially given the high disease re-occurrence rate on farms that have chosen to restock with cervids.

CWD-positive premises whose risk mitigation score is at or above the cut-off would receive full disease response, similar to current actions taken by the CFIA (depopulation and testing of all animals, cleaning and disinfection, destruction and disposal, and investigation of trace-in and trace-out herds and animals).

CWD-positive premises with a risk mitigation score below the cut-off score would only have investigation of trace-ins and trace-outs take place. No depopulation would take place on the aforementioned premises, and consequently, no issuance of compensation either.

Policy provisions may exist for the purposes of national disease control; that is, to respond to the first new case of CWD in a given geographic area, regardless of risk mitigation score.

Movement Controls

To be eligible to move animals, products, and by-products from any farm in Canada, a target on-farm CWD risk mitigation score (cut-off score) of 55% was established. The rationale is that the control of CWD spread is based on the efforts to mitigate the risk of disease on individual farms, and only allow movement of low-risk animals and products.

Premises whose risk mitigation score is at or above the cut-off would be permitted to move any animals or products to any location. Premises with a risk mitigation score below the cut-off could only move animals directly to slaughter or possibly to hunt premises (terminal) for a finite period of time, and entry into the food chain would be subject to CWD test results.

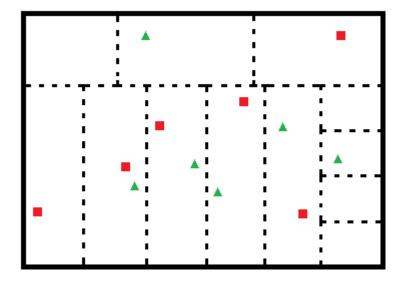
Consumption of tissues from known positives would still not be recommended, and known positives would still be disallowed to enter the food chain. Accordingly, movement of high-risk tissues and associated cervid products would be restricted or prohibited from premises below the risk mitigation cut-off score.

Biosecurity

Producers may achieve a score in the biosecurity portion of the on-farm risk assessment in a variety of combinations within six defined biosecurity elements: 1) having written procedures, 2) ensuring fence integrity, 3) enhancements to the separation between wild and farmed cervids, 4) measures to enhance safe feed sourcing, 5) feed protection, and 6) water protection. Appendix 1 provides point values that are assigned to each biosecurity element on the on-farm risk assessment.

Appendix 2 details the farm-based risk policy option, and Figure 1 of this document includes a schematic overview of this option.

Figure 1: Schematic overview – farm-based risk approach



- National border
- Provincial border
- At or above 55% CWD risk mitigation score Eligible to move live animals anywhere Eligible for full CFIA disease control actions
- Below 55% CWD risk mitigation score Not eligible to move live animals off premises Not eligible for full disease control actions

Strengths and weaknesses of farm-based risk option, compared with current CWD program

The strengths of this approach include 1) allows individual producers to have control over whether they are permitted to move animals and receive federal disease response (regardless of geographic location in Canada); 2) offers some movement control within a province, which could help control CWD spread in enzootic areas; 3) may ease implementation for producers who are already on the VHCP; and 4) provides successful producers with a mechanism to distinguish themselves from producers who are not taking risk mitigation measures based on CWD risk, for business opportunities.

The weaknesses of this approach include 1) overall, it is a more expensive program than that of the current one, the most expensive of the final options considered to all stakeholders; 2) may not limit geographic spread of CWD nationally, as positive herds in various geographic areas are not depopulated (which may also result in public relations issues for industry and challenges for acceptance of these animals at slaughter); and 3) international recognition and acceptance is unknown, as this system does not follow any single current internationally recognized disease control model, but does incorporate some elements of currently accepted disease control models.

4.2 Zoning approach

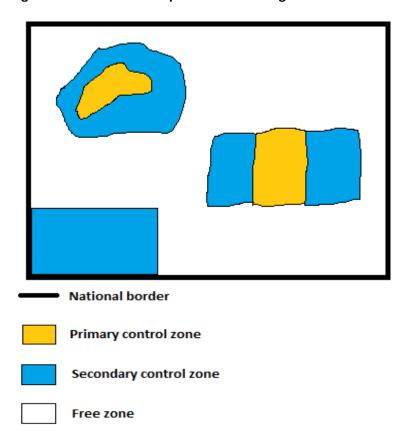
What is it?

Zoning (regionalization) is an OIE-recognized disease control principle, and the concept of a zone was introduced as a means of establishing and maintaining an animal subpopulation with a distinct health status based on geographical separation for disease control and international trade purposes.

Zoning is applied globally, and particularly within the European Union (EU) where it forms the basis for the EU common market for live animals and animal-based products. Further, zoning is a common measure that many countries use in disease eradication/control programs. Zoning, for example, has been widely applied in countries affected by foot-and-mouth disease (FMD), allowing them to maintain exports while being infected with FMD in some parts of the country. A specific chapter on zoning and compartmentalization (Chapter 4.3 of the *Terrestrial Animal Health Code*) has been adopted by the OIE International Committee. Canada has also used zoning to recover export markets, following avian influenza (AI) outbreaks.

The control of CWD via zoning would require the declaration of zones, which would be determined by using a risk-based approach. Current legislative abilities in Canada allow for zoning on a national level. Three zones would exist in this concept: 1) the primary control zone, where the Minister believes the disease to exist; 2) the secondary control zone, which is a zone of protection, or "buffer zone," focusing on aggressive surveillance for CWD; and 3) a free zone (remainder of the country). A variety of zone configurations can exist under such a model, including stand-alone secondary control zones in geographic areas that share a border with enzootic areas in another country. Figure 2 depicts some examples of possible zone configurations in Canada.

Figure 2: Schematic examples – Canadian legislative abilities for zoning



In light of the current CWD disease distribution in specific regions of Saskatchewan (SK) and Alberta (AB), two approaches to the zoning concept were considered: provincial and sub-provincial. While the concept and program elements are the same for both approaches, the placement of geographic boundaries of each option significantly changes the impact; therefore, the two zoning options were analyzed and considered separately. The common program elements and overall strengths and weaknesses will first be discussed, followed by schematic depictions, and a description of the specific strengths and weaknesses of each zoning approach, compared with that of the status quo.

Program Strategy

The goal of the zoning approach is to limit the geographic spread of CWD by reducing the risk of spread out of the primary control zone.

Surveillance

The goals of surveillance in the zoning approach are 1) to detect (as early as possible) CWD spread outside of the primary control zone and 2) to have assurance that CWD does not exist in the free zone.

Considering the program and surveillance goals, and the most efficient use of financial and human resources, a significant proportion of CWD national surveillance would be focused within the secondary control zone, and minimal amounts of surveillance would be required in the primary control and free zones. The exact CWD surveillance plan for Canada would depend on the zoning option that is chosen (if any), and would be developed to be epidemiologically and statistically appropriate within the available resources for this program.

CFIA Disease Response

Similar to the farm-based risk concept, CWD disease response under a zoning concept would be a two-tiered approach. The two tiers differ in that, with zoning, the risk is tied to geographic proximity to an enzootic area.

CWD-positive premises in the secondary control zone and free zone would receive full disease response, similar to current actions taken by the CFIA (depopulation and testing all animals, cleaning and disinfection, destruction and disposal, and investigation of trace-in and trace-out herds and animals).

CWD-positive premises in the primary control zone would only include investigation of trace-ins and trace-outs (with no depopulation or compensation). If a trace-in or trace-out is also in the primary control zone, no further investigation or disease control actions would take place. If, however, a trace-in or trace-out were determined to have originated from, or had moved to, the secondary control zone or free zone, respectively, then aggressive disease control actions would be taken on those animals or herds.

Existing declarations of highly infected premises' (permanent) quarantines in the primary control zone could be lifted under this approach, because all farms in this zone would be of the same health status (i.e. high risk). In addition, no new federal quarantines or declarations of infected place would take place in the primary control zone.

The discovery of a highly infected premises (evidence of environmental contamination and risk of transmission) in the secondary control zone or free zone could result in downgrading of status, necessitating either expansion of the current primary control zone, or declaration of a new primary control zone (and associated secondary control zone). At present, current science does not provide any provisions to allow a zone to upgrade to a higher status. Any advances, however, that address the gaps in CWD science and that may provide additional management tools in the future (e.g. an environmental treatment for CWD) may allow for a zone to upgrade to a higher status. As part of the ongoing program development process, any scientific developments are considered part of the ongoing program review process.

Movement Controls

As described in the corresponding OIE chapter,⁶ intensified movement controls are a key principle of zoning. For CWD, the current lack of a validated individual live animal test and the inability to vaccinate therefore places greater importance on the integrity of the movement control system in order to meet the program goal of limiting geographic spread out of the primary control zone.

The zoning concept that was developed allows animals or products to move without restriction from any zone of higher status to a zone of lower status, or within or between zones of equal status. Basic movement restrictions that were proposed for each zone are subsequently described, and Appendix 3 elaborates further on the movement controls for each zone.

⁶2012 OIE-Terrestrial Animal Health Code, Chapter 4.3 Zoning and Compartmentalisation.

Free zone

All live animals and products from the free zone would be allowed to move to any zone. In contrast, the free zone would only be allowed to receive breeding and hunt animals (with stringent risk mitigation conditions) and slaughter animals (with risk mitigation conditions pertaining to transport and testing at slaughter) from the secondary control zone. The free zone would be permitted to receive meat and velvet, but not high-risk tissues, from both the secondary and primary control zones.

Secondary control zone

All live animals and products from the secondary control zone would be allowed to move to the primary control zone. Breeding and hunt animals with stringent risk mitigation conditions, slaughter animals with risk mitigation conditions pertaining to transport and testing at slaughter, and low-risk products such as meat and velvet from the secondary control zone would be allowed to move to the free zone. In contrast, the secondary control zone would be allowed to receive all live animals and products from the free zone and slaughter animals from the primary control zone, with some additional risk mitigation conditions.

Primary control zone

Meat and velvet would be allowed to move to any zone. Slaughter animals would be permitted to move to the secondary control zone. Breeding animals, hunt farm animals, and high-risk tissues would not be permitted to move to any zone. On the other hand, the primary control zone would be allowed to receive live animals and products from any zone.

Biosecurity

A national biosecurity standard that addresses CWD would be developed and made available on a voluntary basis across the country.

In the secondary control zone, enhanced biosecurity requirements would be assessed upon application by a producer to qualify for a cervid movement permit, allowing the movement of an animal or product to a free area. The enhanced biosecurity elements required would likely be based on the six elements described under the biosecurity section of the farm-based risk approach. The standards and enforcement of this program component could be approached by using the VHCP.

It was discussed during the concept development that the CWD VHCP would be unavailable in the primary control zone; however, given the analysis and discussion at the CWD task force meeting, this decision may require revisiting to provide producers in the primary control zone with a means to distinguish themselves with respect to the CWD disease status of their herd.

Overall strengths and weaknesses of zoning, compared with current CWD program

The strengths of zoning include the following: 1) it is an internationally accepted and scientifically sound risk-based approach for controlling CWD when disease cannot be eliminated from an entire country; 2) it allows for the best use of available resources by targeting surveillance and response; and 3) no new quarantines would be placed on infected herds, and existing high-risk quarantines may be removed in the primary control zones (allowing previously non-existent freedom of movement for those farms).

The weaknesses of zoning include the following: 1) possible decreased profitability, loss of commercial viability, and lost business opportunities for producers in the primary control zone; and 2) significant collaboration and coordination would be required among the federal government, wildlife, and

environmental stakeholders to obtain the robust surveillance that is required for the secondary control zone.

4.2.1 Provincial zoning

The provincial zoning option proposes using the current existing provincial boundaries of British Columbia (BC), Alberta (AB), Saskatchewan (SK), and Manitoba (MB) as zone boundaries. It proposes that the provinces of AB and SK be the primary control zone, with the flanking provinces of BC and MB as secondary control zones. Figure 3 provides a schematic overview of the provincial zoning approach. This zoning option allows for the most efficient use of existing infrastructure, personnel, and resources for disease control, and provides a consistent regulatory framework that can be applied and easily communicated to the public.

BC National border **Provincial border** Primary control zone Meat and velvet allowed out Slaughter animals allowed out with conditions Meat and velvet allowed out, breeding and Secondary control zone hunt animals allowed out with stringent conditions, slaughter animals allowed out with conditions All animals and products allowed out Free zone All animals and products allowed out

Figure 3: Schematic overview - provincial zoning

Strengths and weaknesses specific to provincial zoning

The strengths of provincial zoning include the following: 1) a zone boundary that is based on provincial borders allows existing infrastructure to be utilized, resulting in less overall administrative cost and burden; 2) a larger primary control zone would mean less impact on current level of commerce within Canada, compared with a sub-provincial zone; and 3) international recognition of a provincial zone may be higher than that for a sub-provincial zone.

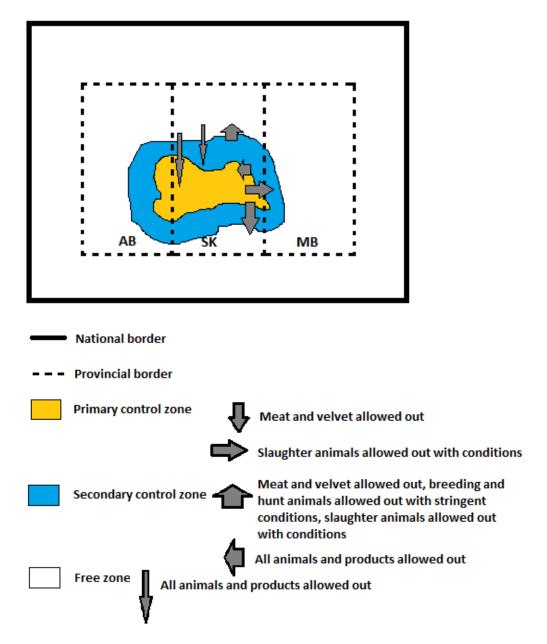
The weaknesses of provincial zoning include the following: 1) although part of an internationally accepted disease control model, a provincial zone boundary would not be as precisely based on risk as a sub-provincial boundary line; 2) limited disease control actions in the primary control zone could allow for unchecked CWD spread up to the boundaries of the primary control zone (a much larger area than that of the sub-provincial zone); and 3) possible loss of commercial viability and business opportunities for AB producers to the United states (U.S.), as well as other potential business opportunities, if AB becomes part of the primary control zone.

4.2.2 Sub-provincial zoning

The primary control zone is defined as the area where the disease is believed to exist; therefore, it is proposed that the currently enzootic areas of AB and SK, and locations of highly infected premises in SK be included in the primary control zone. Given the translocation of wildlife and lag in annual CWD surveillance reporting, a reasonable perimeter around known focuses of CWD would be included in the primary control zone. Thus, the primary control zone would include a portion of Eastern AB and Southern SK, extending across SK to MB, due to a highly infected premises in the far southeastern quadrant of SK.

Figure 4 provides a schematic overview of the sub-provincial zoning approach.

Figure 4: Schematic overview - sub-provincial zoning



Strengths and weaknesses, specific to sub-provincial zoning

The strengths of sub-provincial zoning include the following: 1) it allows for a geographically larger free zone in Canada; 2) a smaller secondary control zone enables better targeting of surveillance and disease response; and 3) continued disease control actions in non-infected parts of SK and AB may facilitate containment of CWD to a smaller area for a longer period of time.

The weaknesses of sub-provincial zoning include the following: 1) defining the boundaries of the primary control zone could be extremely challenging and controversial; 2) enforcing movement controls would be more challenging and resource intensive than would the current program or provincial zoning; and 3) a lack of commercial viability, and loss of markets and future business opportunities to all

producers in the primary control zone, due to movement being limited to a small zone, as well as having a lower CWD health status could occur. In general, a significant number of cervid producers in a small primary control zone would not be commercially viable.

5. RECOMMENDATION – CWD TASK FORCE

The results of the discussion and final ranking process, completed by the CWD Task Force, are illustrated in Figure 5. The farm-based risk, sub-provincial zoning, and provincial zoning options each had its strengths and weaknesses, areas identified for further research to inform decision making, and one key critical challenge per program. The results demonstrate that no clear best option emerged from the three options available.

Figure 5: Table of relative ranking – CWD program options

	Disease Control	Cost	Commercial Viability	International Credibility/Recognition	Scientific Soundness
Farm-Based Risk	1	3*	1	3	3
Sub-Provincial Zoning	2	2	3*	2	1
Provincial Zoning	3*	1	2	1	2

*Critical challenge

The Chair noted that industry members in the group had a strong preference for the farm-based risk option, and suggested that this program be recommended for examination first to assess whether the critical challenge of cost could be resolved in order to make this a viable option.

The farm-based risk option was identified as the preferred option by the CWD Task Force. The critical challenge to address is cost to the CFIA, as this program has the highest total cost to all stakeholders. The Task Force recommended that the farm-based risk option be developed further, including exploration of whether the critical challenge could be addressed through alternate service delivery arrangements for the risk assessment and verifications. Given the final ranking outcome, if the critical challenge for the farm-based risk option could not be resolved, either of the other two program options could be considered for development, provided that their respective critical challenge could be addressed.

6. KEY CHALLENGES IDENTIFIED

Farm-based risk

The critical challenge to address is cost, as there is no further CFIA funding available for this disease control program over the status quo. Of the final options considered, the farm-based risk program has the highest total cost to all stakeholders. The bulk of the cost was believed to be in the new

infrastructure required to set up this program, the regular on-farm risk assessments and verifications to deliver the program, and ongoing audit and oversight to ensure credibility and compliance.

Provincial zoning

The critical challenge to address was disease control. Task Force members believed this was a challenge from the perspective that the program lacks disease control effectiveness in the entire provinces of Alberta and Saskatchewan (likely to be the primary control zone). On the other hand, on a national level, and according to the OIE, this model could be considered effective at limiting the geographic spread of disease in the whole country, as the OIE recognizes that there are circumstances and diseases for which it would be difficult or unrealistic to have a disease-free status for the whole country.

Sub-provincial zoning

The critical challenge identified is lack of commercial viability of the cervid producers in the primary control zones. Some Task Force members believed that farms in a small primary control zone would be separated from the rest of the country and the majority of their market (including access to federal slaughter). In addition, without a means to distinguish their farms (with respect to CWD status) from other farms in the primary control zone, producers in this zone may be at a further disadvantage.

7. POSSIBLE SOLUTIONS TO KEY CHALLENGES

Farm-based risk

Setting up the infrastructure that is required to implement this program would involve an initial investment, in addition to the significant cost of day-to-day delivery of this program. A cost-shared approach via alternative service delivery (ASD) may be one solution to cover the delivery of this program. (That is, complete the on-farm risk assessments and verifications of the various components of the risk assessment, such as verifying that the surveillance requirements have been met in order to assign a score.) A third party, for example, veterinarians who are accredited to deliver the CWD VHCP would be good candidates to deliver these components and would receive compensation for their time, directly from a non-CFIA stakeholder (e.g. producer or the province). The cost of testing and implementing the necessary biosecurity, as well as other requirements to meet the individual farm's passing score, would be at the cost of parties, other than the CFIA. The CFIA would assume the cost of the infrastructure, required to set up the farm-based risk program, and ongoing oversight of the program. The CFIA's roles and responsibilities could include identifying and maintaining links to where known wild and captive focuses of CWD exist, carrying out full disease control actions on premises that meet the minimum risk mitigation score cut-off to be eligible, and carrying out the audit and oversight of the third party delivery of this program.

Provincial zoning

Those farms in the proposed primary zone (AB and SK) were a concern with respect to disease control effectiveness. Possible solutions proposed by industry Task Force members included a required terminal response and "clean-up" to allow restocking of every herd that is positive for CWD in Canada. To control and contain the disease from spreading off-farm, environmental representatives require some sort of disease control (not necessarily terminal) for every herd. One possible solution to this critical concern includes a cost-shared approach, whereby the CFIA would complete full disease control actions in the secondary control and free zones (as described in the zoning approach), and any additional disease

control response over what is proposed (i.e. a terminal response or containment response) in the primary control zone could be delivered and paid for by a third party.

Sub-provincial zoning

A possible solution to addressing the challenge of commercial viability in the primary control zone consists of making the VHCP available in that zone, which may alleviate both of the major commercial viability issues raised by the Task Force by 1) providing producers with a means to distinguish their farms with respect to CWD risk; and 2) allowing the CFIA to explore, with international trading partners (primarily the United States Department of Agriculture [USDA]), the acceptability of moving breeding and hunt animals from the primary zone, if they originate from certified herds on the VHCP (which are eligible to move within Canada).

8. NEXT STEPS

The CFIA recognizes the multi-jurisdictional nature of CWD management and the effect that a new disease control program will have on various stakeholders. To this end, the CFIA invites comments on the options developed from other government departments and agencies (federal and provincial/territorial), the industry, and other stakeholders. Please submit comments in writing, which will be accepted until October 31, 2013. By the end of 2013, there will be a final recommendation and decision regarding the chosen program option for the CFIA's next captive cervid CWD disease control program.

9. GLOSSARY OF TERMS

Alternative service delivery (ASD) – a form of partnership or arrangement made by an organization with another party to deliver services and programs.

Biosecurity – the implementation of measures that reduce the risk of the introduction and spread of disease agents, which requires the adoption of a set of attitudes and behaviours by people to reduce risks in all activities, involving domestic, captive exotic, and wild cervids and their products.

Cervid – any member of the Cervidae family considered at risk to CWD, including, but not limited to, mule deer (*Odocoileus hemionus*), elk/red deer (*Cervus elaphus*), white-tailed deer (*Odocoileus virginianus*), black-tailed deer (*Odocoileus hemionus*), fallow deer (*Dama dama*), Sika deer (*Cervus Nippon*), reindeer/caribou (*Rangifer tarandus*), and moose (*Alces alces shirasi*).

CFIA – Canadian Food Inspection Agency.

CWD Voluntary Herd Certification Program – a voluntary program established and maintained to reduce the occurrence and spread of CWD and to identify herds that have been free of evidence of CWD over specific time periods.

Direct movement to slaughter – animals that are transported to a facility for slaughter without unloading en route and that are not commingled with any other animals during transport.

Farm-based risk approach – a disease control approach, whereby individual cervid farms are evaluated via on-farm risk assessments for their level of CWD risk mitigation to qualify for a cervid movement permit or full disease control actions by the CFIA.

Free zone – a geographic area where CWD does not exist.

Enzootic – present or usually prevalent in a population or geographical area at all times, in contrast to epizootic.

Epizootic – temporarily prevalent and possibly widespread in an animal population.

On-farm risk assessment – evaluating the CWD risk level of an individual premises.

Premises – the ground, area, buildings, and equipment occupied by, or used for, one or more herds of cervids.

Primary control zone – a declared geographic area where the Minister of Agriculture and Agri-Food believes that CWD exists.

Secondary control zone – a geographic area declared for the purposes of preventing spread of CWD.

Stamping-out – the destruction of all infected and potentially contaminated animals. The carcasses are not introduced into the food chain, but disposed of by, for example, incineration or burying. The premises in which the animals are kept are cleaned and disinfected.

Surveillance – a program to assess the health and disease status of a given population and to promote the early detection of disease to maximize the effectiveness of control measures and minimize the costs and economic losses.

Terrestrial Code - the World Organisation for Animal Health (OIE) Terrestrial Animal Health Code.

Trace-in herd – the source herd or herd of origin of a CWD-positive cervid.

Trace-out herd – the herd of destination of a CWD-positive cervid.

Zone – a clearly defined part of a territory that contains an animal subpopulation with a distinct health status with respect to CWD for which required surveillance, control, and biosecurity measures have been applied for the purpose of disease control and international trade.

Appendix 1 – Farm-based risk assessment

RISK FACTOR OF PROXIMITY TO A KNOWN FOCUS OF CWD

Risk factor and risk	Risk Level	Risk Level	Risk Level
reduction score	High	Medium	Low
Proximity to a known focus of			
CWD*	<u><</u> 10–50 km	> 10–50 km but <u><</u> 15–100 km	> 15–100 km
Risk score out of 30	0	15	30

^{*}Known focus in captive population: Any premises, which in the CFIA's opinion, poses a risk of CWD spread, or on which CWD has been transmitted.

Known focus in wildlife: A positive diagnosis in a wild cervid would be considered evidence of infection in a geographical unit. Cases not epidemiologically linked might not be considered. The level of surveillance, geographical unit, and expiry date also warrant further discussion at a later date.

RISK FACTOR OF SURVEILLANCE

Risk factor and risk	Risk Level	Risk Level	Risk Level
reduction score	High	Medium	Low
Surveillance	< surveillance targets identified under medium risk level.	Research the middle percentile of producers in the AB study and characterize the surveillance targets they were able to meet (over 5 years +)	Research the top percentile of producers in the AB study and characterize the surveillance targets they were able to meet (over 5 yrs +)
Risk score out of 25	0	12.5–15	25

AB = Alberta

RISK FACTOR OF BIOSECURITY

Risk factor and risk reduction score	Risk Level High	Risk Level Medium	Risk Level Low
Biosecurity	0–5 "points"	6-20 "points"	21–35 "points"
Risk score out of 35	0–5	10–15–20	25–30–35

Note: Definitions of biosecurity sub-elements are listed in the program elements framework for the farm-based risk option.

Proposed points assigned to each sub-element:

1) Written procedures – 3 pts. 2) Fence integrity – 20 pts. 3) Separation enhancements – 3 pts. 4) Feed source – 5 pts. 5) Feed protection – 2 pts. 6) Water protection – 2 pts.

RISK FACTOR OF MOVEMENT INTO HERD

Risk factor and risk reduction score	Risk Level High	Risk Level Medium	Risk Level Low
Movement into a herd	Herd not closed Commingling occurs Introductions from anywhere	?	Closed herd No commingling or introductions, other than from certified herds on VHC
Risk score out of 10%	0	5	10

VHC = Voluntary Herd Certification

Note: Total score out of 100%/points

Appendix 2 – CWD Task Force farm-based risk option

PROGRAM NAME	CWD Farm-Based Risk Approach
e.g. Farm-based risk approach PROGRAM STRATEGY What is the overarching goal of the program? e.g. eradication of CWD in farmed cervids e.g. limiting spread of CWD between individual farms SURVEILLANCE What is the goal of surveillance?	Reducing the risk of CWD spreading from an infected premises to an uninfected premises. The goals of surveillance in this farm-based risk control program option are as follows:
i.e. What statement about the disease distribution and/or CWD health status would the surveillance data support? e.g. Enhanced early detection in areas where CWD is not known to exist	 To determine where in Canada CWD is present, not present, or unknown (referring to the national surveillance). To be an essential element in the CWD risk determination of an individual premises/farm (referring to on-farm surveillance).
Where would the surveillance be targeted? e.g. at edges of "free zone"	
 DISEASE RESPONSE What actions are to be carried out on infected premises? live animals? products? trace-in premises (sources of CWD)? trace-out premises (animals from an infected farm that are now potential sources of disease to another farm)? What variation of the actions is to be required based on the control strategy chosen? e.g. in zones of different health statuses e.g. in herds of different CWD risk levels 	A target risk mitigation score is established at 55%. On premises whose risk mitigation score is at or above the cutoff, full disease response would take place (similar to status quo). On premises whose risk mitigation score is below the cut-off score, only trace-in and trace-out investigations would take place. Control of animals and products from infected premises are addressed under Movement Controls below. A variation in the policy would be required for national disease control purposes, whereby the first CWD case in captive cervids in an area where CWD is not known to exist would be subject to full disease response, regardless of the risk mitigation score.
MOVEMENT CONTROLS What controls are required on movements of live animals? e.g. direct to slaughter e.g. breeding e.g. other What controls are required on movements of products and by-products?	A target risk mitigation score is established at 55%. Premises whose risk mitigation score is at or above the cut-off could move any animals or products anywhere. Premises whose risk mitigation score is below the cut-off could move live animals directly to slaughter or to hunt premises (terminal) for a finite period of time; entry into the food chain would be subject to testing results.

e.g. meat	Consumption of tissues from known positives would still not be	
e.g. velvet	recommended, and such tissues would not be allowed to enter	
e.g. other	the food chain.	
What variation on controls is required based on the control strategy chosen?	Movement of high-risk tissues and associated products would be restricted.	
BIOSECURITY	1. Have written procedures, including basic farm biosecurity	
In light of the control strategy chosen, what level of biosecurity is required to prevent/limit CWD	that is specific to CWD (e.g. visitor control, dedication or cleaning of equipment, clothing).	
acquisition and where?	2. Fence integrity: fence must be intact and adequate to	
e.g. increased biosecurity is required in proximity to a	prevent ingress or egress of cervids, taking into	
newly identified focus of CWD	consideration the type of cervids farmed and local	
	topography/geography.	
	3. <u>Separation enhancements</u> : additional measures taken to	
What biosecurity requirements/management practices would need to be mandatory to achieve the	ensure the separation between captive and free-ranging cervids.	
required level of biosecurity, taking into	4. <u>Feed source:</u> biosecurity plan that includes management	
consideration both captive/farmed ⇔captive/farmed	practices that are followed to minimize fecal or salivary	
and wild ⇔captive/farmed transmission?	contamination and/or source feed from areas where CWD	
e.g. securing of feed from wild cervids	is not known to exist.	
e.g. fencing	5. <u>Feed protection:</u> measures are documented and	
	implemented to prevent access of wild cervids to feed.	
	6. <u>Water protection:</u> measures are documented and	
	implemented to protect watering systems (e.g.	
What is the role (if any) of the CWD voluntary herd certification program (CWD VHC)?	troughs/lines) from access by wild cervids.	

Appendix 3 – CWD Task Force zoning option

PROGRAM NAME	Zoning Canada for control of CWD
PROGRAM STRATEGY What is the overarching goal of the program? e.g. eradication of CWD in farmed cervids e.g. limiting spread of CWD between individual farms	Limiting the spread of CWD by reducing the risk of CWD spreading out of the 1° control zone.
SURVEILLANCE What is the goal of surveillance? i.e. What statement about the disease distribution and/or CWD health status would the surveillance data support? e.g. Enhanced early detection in areas where CWD is not known to exist	The goals of surveillance in this zoning program option are as follows: 1) To detect (as early as possible) spread outside of the 1° CZ. 2) To have assurance that CWD does not exist in the free zone. A significant proportion of surveillance should be focused within the 2° CZ.
Where would the surveillance be targeted? e.g. at edges of "free zone"	Minimal amounts of surveillance would be required in the 1° CZ and the free zone. Exact surveillance plan would be developed to be epidemiologically and statistically appropriate within the available resources.
 DISEASE RESPONSE What actions are to be carried out on: infected premises? live animals? products? trace-in premises (sources of CWD)? trace-out premises (animals from an infected farm that are now potential sources of disease to another farm)? What variation of the actions is to be required based on the control strategy chosen? e.g. in zones of different health statuses e.g. in herds of different CWD risk levels 	In the free areas of Canada (outside the 1° and 2° CZ) and 2° CZ full disease response would take place (similar to status quo). In the 1° CZ: Only trace-in and trace-out investigations would take place. Determine in what zone those trace-ins and trace-outs were located. If trace-ins and outs are also in the 1° CZ, then there would be no disease control actions. If the trace-ins or trace-outs were determined to either originate in, or have moved to, the 2° CZ or the free zone, respectively, then, take aggressive disease control actions on those animals or herds. Existing declarations of highly infected premises (permanent quarantines) in the 1° CZ would be removed. Identifying a highly infected premises (evidence of transmission risk from the environment) in a 2° CZ or free area would necessitate the expansion of the current 1° CZ or the declaration of a new 1° and 2° CZ.
MOVEMENT CONTROLS What controls are required on movements of live animals? e.g. direct to slaughter e.g. breeding e.g. other	Free area OUT Could move any animals or any products to any zone IN Could receive animals from free area and 2° CZ (see 2° CZ below)

What controls are required on movements of products and by-products?

e.g. meat

e.g. velvet

e.g. other

What variation on controls is required based on the control strategy chosen?

2° CZ (depends on size and nature of zone)

OUT

Breeding animals could move to 1° and 2° CZ

Breeding and hunt farm animals could move to free zone with additional (stringent) risk mitigation conditions.

Slaughter animals could move to free zone, with conditions pertaining to transport and requirement for testing at slaughter.

Products

Meat and velvet: no CWD restrictions going anywhere 2° to 1° CZ: no restrictions on any products

2° to free zone: high-risk tissues not allowed (other than

cleaned and disinfected skulls)

IN

Could receive breeding animals from free area and 2° CZ Could receive animals from 1° CZ only for slaughter, with additional risk mitigation conditions

Products

Could receive meat/velvet from anywhere High-risk tissue products prohibited from 1° CZ High-risk tissues permitted from free area

1° CZ (all designated animals/products would require permits (but could be general permits available on the web)

OUT

Breeding animals and hunt farm animals could NOT move out of the 1° CZ (or hunt farm animals could only move with extremely stringent conditions).

Slaughter animals could move to 2° CZ, with additional conditions.

Products

Meat and velvet could move to any location.

High-risk tissues and products could not move out of the 1° CZ

IN

Could receive animals or products from anywhere

BIOSECURITY

In light of the control strategy chosen, what level of biosecurity is required to prevent/limit CWD acquisition and where?

e.g. Increased biosecurity is required in proximity to a newly identified focus of CWD

National biosecurity standard that addresses CWD, would be provided to the entire country – available voluntarily across the entire country. (Include items such as not sourcing feed from 1° CZ).

What biosecurity requirements/management practices would need to be mandatory to achieve the required level of biosecurity, taking into consideration both captive/farmed ⇔captive/farmed and wild ⇔captive/farmed transmission?
e.g. securing of feed from wild cervids
e.g. fencing

2°CZ

Enhanced biosecurity requirements which would be assessed on application to move to free area in order to qualify for a movement permit. Consider items developed for the farmbased risk approach. The standards and enforcement could be approached through the use of the VHC.

What is the role (if any) of the CWD voluntary herd certification program (CWD VHC)?

The VHC would not be available in the 1° CZ.

CWD = chronic wasting disease; CZ = control zone; VHC = voluntary herd certification