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National Center for Foreign Animal and Zoonotic Disease Defense

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Enhancing Ag Resiliency:

The Agricultural Industry Perspective of Utilizing Agricultural Screening Tools

Report from the Agricultural Screening Tools Workshop

April 5-6, 2011 | Washington, DC

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Summary

The Department of Homeland Security (DHS) National Center for Foreign Animal and Zoonotic Disease Defense (FAZD Center) convened an agricultural screening tools workshop on April 5-6, 2011, in Washington, DC. Workshop participants included leading foreign animal and emerging disease diagnostic experts from the US and UK, as well as leaders of the US livestock industry. Overall, the workshop was designed for participants to reach a consensus on the priorities for developing and utilizing agricultural screening tools.

The specific goals of this workshop were to:

- Obtain the animal industry's input into current and emerging animal husbandry trends and practical technologies that can be utilized to strengthen diagnostic screening tools for transboundary animal, emerging, and zoonotic diseases, including identification of any practices and technologies that are common to the animal industries.

- Gain a greater understanding of the animal industry's perspectives on the use of agricultural screening tools for transboundary and emerging diseases, focusing on issues, costs, and benefits of embedding testing into routine daily surveillance.

- Gain a greater understanding and prioritization of the needs and requirements for agricultural screening tools in the context of business continuity and enhancing resiliency in the livestock industry.

- Complete a policy gap analysis for the use of agricultural screening tools during the multiple phases of an outbreak, including pre-event surveillance, surveillance and response during an event, and recovery.

An initial agricultural screening tools workshop was held in November 2010 to formulate a definition of the term “agricultural screening tool,” evaluate the current status of agricultural screening tools, and identify the gaps and requirements for protecting the US agriculture and public health sectors. For the second workshop, participants were asked to identify and rank their priorities for the development and use of agricultural screening tools.

As discussed during the workshop, these priorities are:

- Develop agricultural screening tools that can be used to permit movement of animals that do not have clinical signs of disease and associated animal products (e.g., milk), especially during an outbreak or recovery period.
- Validate assays that are currently being used for PCR and ELISA testing for use with additional matrices, including
  - milk (such as from bulk milk tanks)
  - oral fluids (such as from saliva-drenched ropes)
  - meat juice
  - air and environmental samples
  - blood (especially for testing for foot-and-mouth disease (FMD) virus)
- Validate pooling of samples to test for foreign animal diseases, including
  - optimal pooling of swabs or similar specimens for key poultry diseases
  - optimal pooling of animal blood and/or swab samples, especially for FMD detection
- Develop simple, low-cost, field-deployable devices for nucleic acid extraction and/or amplification
- Develop and validate serological tests for “disease free” testing and develop associated policies for using those tests

Participants also discussed other critical needs, such as developing a more robust information technology infrastructure for reporting and sharing laboratory test results. This report presents an overview of the discussions among subject matter experts and industry leaders, as well as key findings from the workshop.

Workshop overview

This report describes the key findings, issues, and discussion points that arose during an agricultural screening tools workshop hosted by the Department of Homeland Security (DHS) National Center for Foreign Animal and Zoonotic Disease Defense (FAZD Center) in April 2011. Participants included approximately 40 personnel representing the FAZD Center, US Department of Homeland Security, the US Department of Agriculture-Animal and Plant Health Inspection Service (USDA-APHIS) and Agricultural Research Service (USDA-ARS), the UK Department for Environment, Food, and Rural Affairs (DEFRA) and a number of poultry and livestock industry organizations. Table 1 provides an overview of the workshop.

Table 1. Overview of the agricultural screening tools workshop

Category	Information for this workshop
Workshop title	Enhancing Ag Resiliency: The Ag Industry Perspective of Utilizing Agricultural Screening Tools
Type of event	Workshop with invited participants
Dates	April 5-6, 2011
Duration	18 hours
Location	Washington Room, Hyatt Regency Crystal City Arlington, VA
Sponsor	DHS, Science and Technology Directorate
Host	FAZD Center, Texas A&M System
Participants	Total of 40 participants, representing the FAZD Center, DHS, USDA-APHIS, USDA-ARS, Texas Animal Health Commission, Texas Veterinary Medical Diagnostic Laboratory, California Animal Health and Food Safety Laboratory System, Pirbright Institute for Animal Health, National Milk Producers Federation, Texas Cattle Feeders Association, National Pork Board, National Cattlemen's Beef Association, American Association of Swine Veterinarians, Canyon Veterinary Consultants, and Mountaire Farms
Facilitator	CNA

Objectives

The overarching objective of the workshop was to reach a consensus on priorities for developing and utilizing agricultural screening tools. Specific objectives were to:

- Obtain the animal industry's input into current and emerging animal husbandry trends and practical technologies that can be utilized to strengthen diagnostic screening tools for transboundary animal, emerging, and zoonotic diseases, including identification of any practices and technologies that are common to the animal industry
- Gain a greater understanding of the animal industry's perspectives on the use of agricultural screening tools for transboundary and emerging diseases, focusing on issues, costs, and benefits of embedding testing into routine daily surveillance
- Gain a greater understanding and prioritization of the needs and requirements for agricultural screening tools in the context of business continuity and enhancing resiliency in the industry
- Complete a policy gap analysis for the use of agricultural screening tools during the multiple phases of an outbreak, including pre-event surveillance, surveillance and response during an event, and recovery

Format

The workshop included presentations by subject matter experts, followed by group discussions. The presentations included the following topics:

- Overview of the DHS agricultural screening tools program
- Results and priorities from the first agricultural screening tools workshop
- Update and overview of current and developing technologies

- Overview, perspectives and needs of agriculture industries
  - Swine industry
  - Cattle industry
  - Sheep and goat industry
  - Poultry industry
  - Dairy industry
- Review of current policies related to foreign animal disease diagnostics.

The group discussions focused on the use of agricultural screening tools for business continuity and a policy gap analysis. At the end of the workshop, participants prioritized their list of recommendations for development and use of additional agriculture screening tools.

Follow-up from previous workshop

An initial agricultural screening tools workshop was held in November 2010. Goals for that workshop were to formulate a definition of the term "agricultural screening tool," evaluate the current status of agricultural screening tools, and identify the gaps in and requirements for protecting US agriculture. The workshop participants defined a livestock agricultural screening tool as:

> *A tool used to detect a potential disease or condition in an animal, group of animals, or animal product. The tool may be used in any phase of an outbreak response and is not required to be confirmatory (diagnostic) in nature, but rather is intended for rapid initial detection.*[1]

The first workshop produced the following findings, which were prioritized in this order by the participants:

[1] FAZD Center, Texas A&M University, "Protecting agricultural infrastructure: defining the needs and requirements for agricultural screening tools," Report from the Agricultural Screening Tools Workshop, November 2010, Washington, DC.

- Validate the FMD and CSF (classical swine fever) rRT-PCR (real time polymerase chain reaction) assays currently used by the National Animal Health Laboratory Network (NAHLN) for use with additional specimen matrices, specifically:
  - bovine bulk milk tank samples
  - swine and bovine oral fluids
  - blood
- Evaluate and, where possible, validate a procedure for pooling samples with multiple specimen types (matrices)
- Complete validation and deployment of available serological assays for use in proving freedom from disease
- Support development of a rapid, and accurate, ELISA (enzyme-linked inmmunosorbent assay) test to differentiate vaccinated from unvaccinated animals with FMD
- Invest in more-rapid, detection-sensitive technologies for use in pen-side/premises/processing point testing of animals or products. Specifically, continue to evaluate and, if warranted, validate commercialized lateral-flow antigen detection devices for FMD, in addition to pursuing the development of alternate portable technologies for pen-side use
- Invest in newer technologies for screening and continue to evaluate for development and validation

The second agricultural screening tools workshop focused on the industry perspectives for utilizing screening tools to protect agricultural infrastructure. Accordingly, the group of participants included leaders from the beef, dairy, swine, sheep/goat, and poultry industries. As in the first workshop, the group was tasked with developing a prioritized list of recommendations for developing and using agricultural screening tools.

Highlights of the workshop discussions

The agricultural screening tools workshop began with an introductory presentation by Dr. Tammy Beckham, Director of the FAZD Center. She presented the meeting goals and objectives and the results from the first agricultural screening tools workshop. Dr. Luther Lindler, a Scientific Advisor with the DHS Science and Technology Directorate, then presented an overview of the DHS agricultural screening tools program. Representatives from the National Veterinary Services Laboratories (NVSL), Dr. Bill White and Dr. Beverly Schmitt, provided an update and overview of current technology for foreign animal disease diagnostics. Their presentations focused on the "fitness for purpose" of new tests, which should drive both the type of agricultural screening tests to be developed and the desired diagnostic sensitivity and specificity.

Next, agriculture industry leaders presented overviews and the perspectives and needs of their respective industries. These presenters included:

- Dr. Patrick Webb, National Pork Board
- Mr. Ross Wilson, Texas Cattle Feeders Association
- Dr. William Edmiston, practitioner for the sheep and goat industry
- Dr. Don Ritter, Mountaire Farms (poultry)
- Dr. Jamie Jonker, National Milk Producers Federation.

On the second day of the workshop, Dr. Elizabeth Lautner, Director of the NVSL, and Dr. Jon Zack, Preparedness and Incident Coordinator for the National Center for Animal Health Emergency Management (NCAHEM), provided a review of current policies and resources related to foreign animal disease diagnostics and response.

Perspectives on the use of agricultural screening tools

During the workshop, participants from the livestock and poultry industries collectively agreed that it would be beneficial to have additional agricultural screening tools available. However, they also reported having many questions about when and how to use the tools. During the group discussion, several common factors emerged about the use of agricultural screening tools:

- Agricultural screening tools should *be strategically located*, such as in the hands of state animal health officials (SAHOs), area veterinarians in charge (AVICs) and/or foreign animal disease diagnosticians (FADDs).

- The reporting process for findings from agricultural screening tools should *include the customary decision-makers*.

- It will still be necessary to *proceed to laboratory confirmation* for any initial findings from an agricultural screening tool at least until additional information and confidence is gained in the performance of the tool for specific purposes. It will also be necessary to *control distribution* of those findings. NAHLN laboratories with support from NVSL should have a role in the monitoring of the performance of the tools.

- The agriculture community will need to *develop new definitions* in order to accurately communicate the findings from agricultural screening tools.

Further, the use of agricultural screening tools will vary throughout the phases of a disease outbreak. Thus, different requirements and responses may arise for using different tools during pre-event surveillance, response and surveillance during an outbreak, and/or the recovery phase.

Embedding agricultural screening tools in surveillance streams

Workshop participants discussed whether or not and how to embed agricultural screening tools into existing animal management and business practices in order to create effective surveillance streams. From the overviews presented by the industry representatives, it was clear that some industry practices are “sample genera-

tors" while others are not. Particularly, the swine, poultry, and dairy industries already generate many samples in the course of normal business operations for testing by regulatory agencies. Some examples of these existing surveillance specimens are bulk milk that is collected and tested before being marketed and meat juice generated during routine meat processing. Although tests for FMD in these matrices (milk, meat juice) are not yet validated, these samples could potentially be used for pre-event surveillance.

In contrast, some of the smaller and less industrial industries, such as sheep and goat farms, small-scale poultry production, and some beef producers, do not regularly generate sample streams. Furthermore, their industry current practices do not readily allow for embedding agricultural screening tools. To do so, participants stated that they would need to be able to collect and test bulk samples (e.g., from the water trough, meat juice, air or environmental, or fecal samples). Collection methods, screening tools, and confirmatory tests are not yet available for most of these types of samples.

Use of agricultural screening tools in the early outbreak phase

The group discussed at length the possibility of using agricultural screening tools in the early outbreak phase. Several cases were considered. The case scenarios occurred at progressively later points in an outbreak timeline. Each case described a different step in disease outbreak surveillance and decision-making.

To help ensure that all workshop participants had the same case scenario in mind, the group made several assumptions:

- The particular agricultural screening tool being discussed for these cases was a pen-side test that is rapid and non-confirmatory, such as a commercially available lateral flow device. It was however recognized that existing technologies, such as realtime PCR, as well as technologies yet to be developed, such as biosensors, could also serve as agricultural screening tools.

- The existing lateral flow tools have approximately 90% sensitivity for detecting FMD in individual animals and higher sensitivity when used for detecting FMD in a herd of animals.

- As an example, the agricultural screening tool that is currently available (SVANOVA) would be used *after* the USDA-APHIS Foreign Animal Disease Diagnostic Laboratory (FADDL) confirmed the first case of FMD. The policies that support the use of the lateral flow devices, as well as other not yet defined or validated agricultural screening tools, must be developed in the context of each individual assay's documented fitness for purpose and performance criteria.
    - Currently available penside assays are not sensitive enough to be utilized as an effective screening tool for "ruling-out" the presence of FMD. Therefore, the "fitness for purpose" for currently available assays includes 1) "ruling-in" clinical animals and 2) triage use in the laboratory. When and if additional penside technologies are developed, validated, and analyzed for fitness, new recommendations regarding their specific use should be developed.

With these assumptions, the group considered when an agricultural screening tool could or should, be used, under what conditions it would be used, and what requirements would be placed on using it.

For the first case, participants discussed using an agricultural screening tool for premises that have direct contact with the confirmed infected herd, such as adjacent farms or farms with epidemiological links. In this case, the screening tool could be used for making decisions about these suspect premises, and possibly also for "sick calls" outside of the control zone. Accordingly, the findings from the screening tool could help responders decide disposition of the suspect herd.

However, field responders would need to be trained and proficient prior to using the tool, and would need instructions for how to split the samples for subsequent NAHLN confirmatory testing. After being used at the potentially infected premises, the lateral flow device would contain inactivated virus or viral genome as a by-product of the screening test. The tool would then be sent to the corresponding NAHLN laboratory along with other samples that were collected.

For the second case, workshop participants considered how to use the agricultural screening tool for premises that are not direct contacts but are located inside the control zone. The group assessed that, based on performance characteristics of available tools, the discussed tool could be used only for animals or herds that exhibit clinical signs (e.g., rule in only). The findings from the tool could be used to triage samples at the NAHLN laboratory and/or to triage response actions for that farm. The screening tool samples could eventually be sent to FADDL, so that scientists could perform viral forensic studies and better understand the evolving epidemiology of the outbreak. Diagnostic and outbreak surveillance samples would be routed to the corresponding NAHLN laboratory for rapid outbreak response support.

The final scenario concerned possible FMD cases in a new state or in a new species. In this case, a new foreign animal disease investigation would be undertaken, and the responders would follow the sample collection and reporting steps outlined in Veterinary Services Memorandum 580.4.[2]

The group decided that the available agricultural screening toolstool existing lateral flow device example would be used most effectively for animals with clinical signs that are located within an already-defined control zone, or in a new zone within the same State. Although the pen-side tool could be used, samples should also be sent to the NAHLN laboratory for more sensitive PCR testing.

Currently available penside assays are not sensitive enough to be utilized as an effective screening tool for “ruling-out” the presence of FMD. Therefore, the “fitness for purpose” for currently available assays includes 1) “ruling-in” clinical animals and 2) triage use in the laboratory. When and if additional penside technologies are developed, validated, and analyzed for fitness new recommendations regarding their specific use should be developed.

In summary, the group agreed that, in this early outbreak scenario, the existing lateral flow device technology could be used as an ag-

[2] US Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services Memorandum 580.4, “Procedures for the Investigation of Potential Foreign Animal Disease/Emerging Disease Incidents (FAD/EDI),” October 2008.

ricultural screening tool. It could be used for triaging the samples, helping field responders "lean forward" (would have an indicator of which additional farms might be involved in the outbreak), and taking local-level actions on farms within the control zone. It was also agreed that related policies must be developed and communicated prior to use of the tools.

Use of agricultural screening tools for business continuity

Workshop participants also discussed the use of agricultural screening tools for business continuity and resiliency. During the recovery phase of an outbreak, participants suggested the tools could be used as part of the permitting process to move animals from premises located inside the control zone. However, the group was also concerned about the "fitness for purpose" and proper use of the tools to assist decision-making. Participants agreed that use of the tools should be monitored. For example:

- Approved screening tools should be in the hands of approved individuals —meaning their use should be monitored and controlled by state animal health officials (SAHOs) and/or area veterinarians in charge (AVICs) in conjunction with NAHLN laboratories and NVSL./or foreign animal disease diagnosticians (FADDs).

- In the absence of a disease outbreak, there should be strict federal regulatory control over access to the screening tools.

- During an outbreak, more responders should have access to, and use, the screening tools, but they will need prior training in how to correctly use the tools and report the findings.

The workshop participants also discussed the desired sensitivity and specificity of the tests used in agricultural screening tools. While participants acknowledged that agricultural screening tools are not required to be confirmatory tests, it seemed difficult to accept using a test on an animal without clinical signs that could have a high false-positive or false-negative rate.[3] For example, if re-

[3] According to the definition of an agricultural screening tool that was developed at the first workshop, such a tool is "not required to be confirmatory (diagnostic) in nature."

sponders were using an agricultural screening tool to permit animal movement, a false-negative finding could lead to further disease spread.

Workshop participants decided that when an agricultural screening tool is used during the initial disease investigation, lower sensitivity is acceptable because the animals will also have clinical signs. However, higher specificity is desirable at this stage in order to rule in, or rule out, certain diseases of highest concern. For continuity of business purposes, higher sensitivity is desirable. At the later stage of an outbreak, a false-positive finding may be tolerable, especially if it's obtained in the context of a "cautious" permitting system and is promptly followed by laboratory testing.

Workshop participants also noted that currently available agricultural screening tools should not be used for animals that do not have clinical signs because the sensitivity of the test is too low. To protect product and brand integrity, livestock producers would want a screening tool that could show that the animal is not infected and is not a carrier of disease. This "fitness for purpose" requirement differs from demonstrating that an animal is infected during the early phase of an outbreak. So while additional research and development would be needed, the group arguably saw the biggest gains from using the existing lateral flow devices in the later phases of an outbreak, in order to enhance business continuity.[4]

Policy gaps

As mentioned earlier, two of the workshop participants presented an overview of current policies for foreign animal disease diagnostic testing and response. Following this presentation, workshop participants identified additional policy needs for the use of agricultural screening tools. For example, they suggested that policies be put into place to address the following questions:

- After an agricultural screening tool is used, where would it be sent? What would be the end-stage of that sample? How long would samples be kept?

4 Specific lateral flow devices, that are currently commercially available in other countries, were used as an example of an agricultural screening tool for these case discussions.

- Who would be notified about the findings from an agricultural screening tool? How would the findings be communicated? What should the findings be called (e.g., suspicious, preliminary)?

- Who would be permitted to use the tool and what training would they need?

- How and where should agricultural screening tools be stored, both before and after they are used? Who would have access to them? Who would control the access?

- How should the agricultural screening tools be transported after being used? Should they be handled in the same manner as other diagnostic samples?

- Who could purchase an agricultural screening tool? Should it be available only to government agencies?

- What permits and waivers would be needed for the purchase, use, and transport of agricultural screening tools?

The workshop participants also developed a “wish list” of features for an agricultural screening tool. Ideally, they would like to have a screening tool that provides results within one hour, inactivates the pathogen, works at ambient temperature and in “dirty” environments, can detect both virus and antibodies, and has a sensitivity similar to that of existing PCR testing. While such tools are not currently available, this list provides some goals for future research and development.

Recommendations and next steps

In the final discussion session, workshop participants were asked to identify, and rank their priorities for the development and use of agricultural screening tools. A number of ideas were offered, and the group voted on the list to determine which findings had the highest priority. In rank order, the group’s recommendations for agricultural screening tools are:

- Develop agricultural screening tools that can be used to permit movement of animals that don't have clinical signs of disease, especially during an outbreak or recovery period.
- Validate assays that are currently being used for PCR and ELISA testing for use with additional matrices, including
  - milk (such as from bulk milk tanks)
  - oral fluids (such as from saliva-drenched ropes)
  - meat juice
  - air and environmental samples
  - blood (especially for testing for FMD virus)
- Validate pooling of samples to test for foreign animal diseases, including
  - optimal pooling of swabs or similar specimens for key high consequence poultry diseases
  - optimal pooling of animal blood and/or swab samples, especially for FMD detection
- Develop simple, low-cost, field-deployable devices for nucleic acid extraction and/or amplification.
- Develop and validate serological tests for "disease free" testing and develop associated policies for using those tests.

Workshop participants discussed several other critical needs to support the use of agricultural screening tools. Particularly, they identified a need to conduct a methods comparison for existing chemistries and platforms. The goal would be to identify how existing chemistries and platforms can be used for additional matrices and tests during an outbreak, especially if laboratory resources are in short supply.

Another critical need is an information technology (IT) infrastructure to provide communications and links between databases for reporting laboratory test results. This same recommendation has risen out of other forums, such as recent tabletop exercises for the

NAHLN and NVSL. At the agricultural screening tools workshop, participants noted that the current IT systems do not support linking the test results that are reported from state and federal laboratories. Agricultural screening tools would present another layer of results that need to be reported in a timely manner and linked with identification codes for both the animals/premises being tested and the laboratory providing confirmatory results. Thus, a robust IT infrastructure is also critical for the full, efficient, and effective use of agricultural screening tools.

The results from this workshop will be presented to DHS for consideration. DHS managers will assess the amount of funding to allocate for development and validation of agricultural screening tools. The FAZD Center plans to host additional workshops in the coming year to bring together subject matter experts, industry leaders, and policy makers to discuss pressing needs and gaps in foreign animal and zoonotic disease defense. Continued input from all of these groups will enhance the resiliency of production agriculture in the event of a foreign animal disease outbreak.

Appendix: Workshop participants

Table 2. Alphabetical list of workshop participants

Name	Organization
Tammy Beckham	Director, FAZD Center and Texas Veterinary Medical Diagnostic Laboratory (TVMDL)
David Brake	Scientific Consultant, Plum Island Animal Disease Center (PIADC), DHS
Rusty Cawley	Communications Director, FAZD Center and Communications Manager, TVMDL
Matthew Coats	Program Manager, Office of University Programs, DHS
William Edmiston, Jr.	Veterinarian and Texas Animal Health Commissioner
Larry Elsken	Global Vaccine Manager, USDA-APHIS Center for Veterinary Biologics (CVB)
Betsy Flores	Director of Regulatory Affairs, National Milk Producers Federation
Michael Gallagher	Commercial Responders Specialist, USDA-APHIS
Bruce Harper	Director of Science, PIADC, DHS
Melissa Hefferin	Program Coordinator, Office of University Programs, DHS
Dick Hesse	Director, Diagnostic Virology, Center of Excellence for Emerging and Zoonotic Animal Diseases (CEEZAD), Kansas State University
Sharon Hietala	California Animal Health and Food Safety Laboratory System
Anna Higgins	Business Administrator, FAZD Center
Pam Hullinger	University of California, Davis
Jamie Jonker	Director of Regulatory Affairs, National Milk Producers Federation
Barb Kamicker	Scientific Consultant, PIADC, DHS
Donald King	Research Leader, Pirbright Institute for Animal Health, United Kingdom
John Korslund	Centers for Epidemiology and Animal Health (CEAH), USDA-APHIS

Tom Latta	Veterinary Research Associates
Elizabeth Lautner	Director, National Veterinary Services Laboratories, USDA-APHIS
Luther Lindler	Science Advisor, DHS
Barb Martin	Coordinator, National Animal Health Laboratory Network (NAHLN), USDA-APHIS
Mike McIntosh	Foreign Animal Disease Diagnostic Laboratory (FADDL), USDA-APHIS
Stacy Morris	Chief of Staff, FAZD Center and TVMDL
Roger Parker	Deputy Director, TVMDL
Elizabeth Parker	National Cattlemen's Beef Association
Jennifer Rinderknecht	Research Associate, FAZD Center
Don Ritter	Director of Health Services, Mountaire Farms
Gary Ross	CEAH, USDA-APHIS
Beverly Schmitt	Director, Diagnostic Virology Laboratory, NVSL, USDA-APHIS
Harry Snelson	American Association of Swine Veterinarians
Rosemary Speers	Research Analyst / Project Director, CNA
Marty Stokes	Fellow, American Association for the Advancement of Science (AAA), DHS
Kynan Sturgess	Veterinary Research Associates
Patrick Webb	National Pork Board
Bill White	Director, FADDL, USDA-APHIS
Ross Wilson	Texas Cattle Feeders Association
Jon Zack	National Center for Animal Health Emergency Management (NCAHEM), USDA-APHIS
Anne Marie Zaudtke	Consultant, Booz Allen Hamilton