

**Summary of
Tribal Consultation Teleconference on
Chum Salmon Bycatch in the Bering Sea Pollock Fishery
June 1, 2011**

In Attendance

Attending via telephone:

Native Village of Elim/Elim IRA Council

Robert Keith, President

Sheldon Naguruk, Council member

e-mail: jmurray@kawerak.org (Janelle Murray, Tribal Coordinator)

Native Village of Gambell

Iver Campbell, IRA Council President

e-mail: ivercampbell@yahoo.com

Native Village of Savoonga

Ronnie Toolie, President (stoolie@kawerak.org)

Peggy Akeya (peggyakeya@yahoo.com)

Verna Immingan

Native Village of Shishmaref/Shishmaref IRA Council

Donna Barr, Vice-President

Howard Weyiouanna, Sr.

e-mail: knayokpuk@kawerak.org; tc.shh@kawerak.org (tribal coordinators)

Native Village of Teller/Teller Traditional Council

Wesley Okbaok, President

Joe Garnie

e-mail: cisabell@kawerak.org

Mary's Igloo Traditional Council

Albert W. Oquilluk

e-mail: [cablowaluk@kawerak.org](mailto:cablowluk@kawerak.org)

Kawerak, Inc.

Julie Raymond-Yakoubian

e-mail: JRaymond-Yakoubian@kawerak.org

Attending in person, NMFS Alaska Regional Office:

Doug Mecum, Deputy Regional Administrator, NMFS Alaska Region

Glenn Merrill, Assistant Regional Administrator, NMFS, Sustainable Fisheries Division

Sally Bibb, NMFS, Sustainable Fisheries Division (907-586-7389)

Melanie Brown, NMFS Sustainable Fisheries Division

Mary Grady, NMFS Sustainable Fisheries Division

Sarah Ellgen, NMFS Sustainable Fisheries Division

Gabrielle Aberle, NMFS Sustainable Fisheries Division (907-586-7356)

Scott Miller, NMFS, Analytical Team and co-author on chum salmon bycatch analysis

John Lepore, NOAA General Counsel

Demian Schane, NOAA General Counsel

Summary

The six Norton Sound and Bering Strait tribes listed above requested a consultation on chum salmon bycatch in the Bering Sea pollock fishery. Each tribe had submitted to the National Marine Fisheries Service (NMFS) a written resolution stating its position on chum salmon bycatch and a separate resolution requesting a permanent ban of all bottom trawling in the Northern Bering Sea Research Area. The consultation between the NMFS and representatives of the six tribes was conducted under Presidential Executive Order 13175. Julie Raymond-Yakoubian also participated in the consultation.

Sally Bibb opened the meeting by introducing those present at the NMFS Alaska Regional Office, then asked for an introduction from each tribal representative. Sally Bibb asked if any of the representatives had questions, but none did at that time. She then presented an overview of the chum salmon bycatch issue and asked the representatives to share their concerns and questions. The following issues were raised by the tribal representatives.

- All six of the tribes requested the North Pacific Fishery Management Council (Council) adopt a hard cap of 30,000 chum salmon for the Bering Sea pollock fishery. On reaching the hardcap, the pollock fishery should be closed and no sector allocations, sector transfers, or cooperative provisions allowed. This request is in response to the continuing decline of regional salmon stocks, which has severely impacted the tribes' subsistence practices and traditions.
 - Response: In a letter dated June 6, 2011, NMFS provided the Council with a preliminary summary of the issues discussed at the consultation. NMFS requested the Council address the recommendation for a 30,000 hard cap by either including it in the alternatives analyzed or providing an explanation why this suggested cap does not meet the purpose and need for the action, and therefore, will not be included in the alternatives analyzed. A copy of this letter is enclosed with this report.

The Council discussed the tribes' resolutions at its June 2011 meeting and asked for additional information about the reasons that the tribes recommended a 30,000 hard cap. NMFS will schedule a teleconference with interested Norton Sound and Bering Strait tribes in September 2011, or as soon as all interested parties are available to further discuss the tribes' recommendations on chum salmon bycatch.

A summary of the Council's June 2011 action on chum salmon bycatch is enclosed with this report.

A copy of the Council's revised set of alternatives and schedule for future analysis and discussion of chum salmon bycatch will be provided to the tribes as soon as it is available from the Council.

- An agenda for the June Council meeting in Nome was requested.
 - Response: After the consultation, the link to the Council meeting agenda was emailed to representatives of the tribes who participated in the consultation.
- Several representatives requested information about the prohibited species donation program (PSD) program and expressed interest in participation in the program by western Alaska communities.

- Response: The PSD program allows for the distribution of salmon and halibut caught accidentally in the groundfish trawl fisheries to hunger relief organizations. NMFS will provide additional information about the PSD program at its next teleconference with interested Norton Sound and Bering Strait tribes. We can discuss at that time whether any tribes are interested in further follow-up on this program.
- Several representatives noted that salmon have cultural value, not just economic value, and tribes would rather catch fish than acquire them from a food bank. Salmon are nutritionally very important to tribal members. The idea of wasting food is offensive to Alaska Natives. A food bank should not be used to justify salmon bycatch.
 - Response: NMFS appreciates the comments about the cultural significance of salmon. Salmon are prohibited species and are required to be avoided. The purpose of the PSD program is to try to use salmon, which has already been caught and killed, for human consumption, if that salmon has been maintained in the appropriate condition. A relatively small proportion of the salmon bycatch is of the size or quality appropriate for human consumption. Therefore, few salmon are donated to the PSD program. Most salmon are discarded after they have been counted and biological samples have been taken from them.
- Several representatives described environmental changes they have observed in recent years. These include larger fish, more king crabs washing ashore, fish moving north, and a decline in the salinity of some river waters.
 - Response: NMFS notes these observations. We have limited data on the effects of environmental change on salmon and bycatch. Current salmon bycatch data collection and research focuses on using genetics to identify geographic origin of salmon caught as bycatch.
- One representative asked about the effects of radioactive water from Japan's Fukushima Daiichi nuclear power plant on fish off northwest Alaska.
 - Response: Some information from the U.S. Food and Drug Administration is enclosed with this report. This information is available on the internet at: <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm247403.htm>.
- Red salmon returns in Salmon Lake have been insufficient in recent years to provide food for the people.
 - Response: Bering Sea bycatch includes only a small amount of red salmon, pink salmon, and coho salmon. Therefore, it is unlikely that salmon bycatch in the Bering Sea trawl fisheries are impacting red salmon returns to western Alaska. However, NMFS will forward a copy of this report to the Alaska Department of Fish and Game so that they are aware that this issue came up in this tribal consultation.
- One representative asked if hatchery eggs can cause cancer.
 - Response: Doug Mecum responded that he is not aware of cancer resulting from hatchery fish. Hatchery practices are stringent about the use of chemicals. Fish live at the hatchery about a year and spend most of their life in the ocean.

- Multiple factors can lower salmon returns, and some cannot be controlled. Consequences of some industries (e.g., shipping, mining) are not clear, but bycatch can be controlled.
 - Response: The Magnuson-Stevens Fishery Conservation and Management Act requires that bycatch be minimized to the extent practicable. The Council's objective for its Chinook salmon bycatch management measures was to provide incentives to minimize Chinook salmon bycatch while still allowing the pollock fishery to continue. The Council's program does not set as a goal allowing the pollock fishery to harvest up to the hard cap of Chinook salmon.

Thus far in 2011, the first year of the new Chinook salmon bycatch management program, Chinook salmon bycatch is about 7,400 fish. If the Council's chum salmon bycatch management program involves a hard cap, the focus also will be to minimize bycatch rather than establish the hard cap as an acceptable level of bycatch.

- Representatives commented on science and research needs in the area and an interest in collaborative research and funding for the tribes and non-profit corporations. Questions were asked on the cumulative impact of salmon interception in the False Pass salmon fisheries, what information do we get from Russia, and the percent of fisheries taxes that is used for science. Tribes and non-profit corporations should have access to fisheries taxes for their science and research needs.
 - Response: Some of these issues may be addressed in the analysis being prepared by Council and NMFS analysts about chum salmon bycatch in the Bering Sea pollock fishery. NMFS will provide these questions to those analysts and follow-up with the tribes with any further information we obtain.
- Representatives asked how the Council and NMFS are working together to address tribal concerns and what steps NMFS is taking to provide information and education to the tribes on fisheries issues, the Council process, and the agency process.
 - Response: The Council created its Rural Community Outreach Committee to improve communication and outreach to residents of rural Alaska about fisheries conservation and management issues under consideration by the Council. The Council also has conducted extensive outreach efforts over the last three years on salmon bycatch in the Bering Sea pollock fishery. The outreach plans, which include meetings in rural communities, attending regional conferences, and mailings to all villages, tribes, and local government officials, have been developed by and vetted through the committee and several rural stakeholder groups. The outreach plans are presented to the Council and public at multiple meetings, and the results of the outreach are part of the analytical document on which the Council bases its decision. NMFS staff participates in the Council's committee meetings and outreach efforts.

The University of Alaska's Sea Grant College Program has provided short courses in Nome, Kotzebue, and Togiak about the National Environmental Policy Act (NEPA) with particular focus on fisheries management issues and process. These courses were offered, in part, due to the requests from people in rural communities for education and training about NEPA and the fisheries management process. NMFS staff participated in the Nome and Kotzebue courses.

NMFS contacts by letter all tribes, Alaska Native corporations, and local government officials about fisheries management issues and proposed rule that may be of interest to rural Alaskans. These letters specifically notify the tribes of their opportunities to consult under E.O. 13175. When requested to conduct a consultation, NMFS organizes and participates in the tribal consultations and follow-up meetings. NMFS staff also participate in meetings and regional conferences when requested to do so and when time and budget resources allow that participation.

- NMFS should hire a tribal liaison.
 - Response: NMFS acknowledged the tribes request that it hire a tribal liaison. However, at this time, funding for such a position cannot be prioritized over other responsibilities of the Alaska Regional Office.

Other Issues

In mid-June 2011, NMFS received letters and resolutions from:

Darin Douglas, President, Native Village of Koyuk
Shirley Martin, President, Native Village of St. Michael

They requested a tribal consultation on chum salmon bycatch and provided copies of resolutions on bycatch and trawling in the northern Bering Sea.

- Response: NMFS responded by phone and in writing to Mr. Douglas and Ms. Martin to let them know about the June 1 consultation, that we would provide them a copy of the consultation report, and include them in future meetings or consultations on chum salmon bycatch.

NMFS also will identify contact names and e-mail addresses for the following tribes so that they can be sent a copy of the final consultation report and notified of future discussions with Norton Sound or Bering Strait tribes about chum salmon bycatch:

| | |
|------------------------|----------------|
| Brevig Mission Council | Shaktoolik |
| Diomedes | Stebbins |
| Golovin | Unalakleet |
| King Island | Wales |
| Nome Eskimo Community | White Mountain |

Senator Donny Olson wrote to the Secretary of Commerce (June 10, 2011) and requested to be informed of NMFS's future consultations with Native villages in his district and to be kept apprised of the Department of Commerce's actions and recommendations under E.O. 13175.

- Response: NMFS Alaska Region staff contacted Senator Olson's aide Loren Peterson on June 10, 2011, and provided a verbal overview of the June 1 tribal consultation. NMFS will discuss with the tribes what additional information to send to Senator Olson's office in the future and whether to also send copies of tribal consultation information to others in the Alaska Legislature.



UNITED STATES DEPARTMENT OF COMMERCE
National Oceanic and Atmospheric Administration

National Marine Fisheries Service

P.O. Box 21668

Juneau, Alaska 99802-1668

June 6, 2011

Eric Olson, Chairman
North Pacific Fishery Management Council
605 W. Fourth Avenue, Suite 306
Anchorage, Alaska 99501

Dear Chairman Olson:

This letter provides a preliminary summary of the issues discussed at a tribal consultation on June 1, 2011, about chum salmon bycatch in the Bering Sea pollock fishery. The consultation between the National Marine Fisheries Service (NMFS) and representatives of six Norton Sound and Bering Strait area tribes was conducted under Presidential Executive Order (E.O.) 13175. The following tribes participated in the consultation: Native Village of Teller, Native Village of Shishmaref, Native Village of Savoonga, Mary's Igloo Traditional Council, Native Village of Gambell, and the Native Village of Elim. Julie Raymond-Yakoubian with Kawerak, Inc., also participated in the consultation.

Each of these tribes submitted to NMFS a written resolution stating its position on chum salmon bycatch. The North Pacific Fishery Management Council (Council) has received a copy of these resolutions, and they are part of the information you are considering at your June 2011 meeting. The tribes emphasized the cultural and nutritional significance of salmon, the importance of the subsistence use of salmon, and concerns with the status of some chum salmon stocks.

All six of the tribes we consulted with requested that the Council adopt a hard cap for the Bering Sea pollock fishery of 30,000 chum salmon. This cap currently is not within the range of the hard caps that the Council is considering. NMFS is required under E.O. 13175 to prepare a tribal summary impact statement to accompany rulemakings that summarizes the nature of concerns identified by the tribes and extent to which these concerns have been met. In addition, regulations governing the National Environment Policy Act process require NMFS to identify alternatives that were eliminated from detailed study and briefly discuss the reasons why these were eliminated (40 CFR 1502.14(a)). It would greatly help NMFS fulfill these responsibilities if the Council would address the tribes' recommendation for a 30,000 chum salmon cap by either including this recommendation in the alternatives analyzed or providing an explanation why this suggested cap does not meet the purpose and need for the action and, therefore, was not included in the alternatives analyzed.

We also discussed the prohibited species donation (PSD) program. Several tribal representatives requested additional information about this program and expressed interest in participation in the program by western Alaska communities. We will provide additional information to the tribal

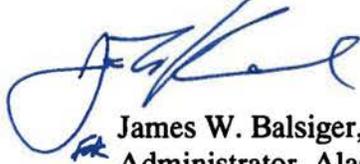


representatives, and we will organize a follow-up meeting between interested tribal representatives and people knowledgeable about the PSD program.

In addition to these two issues, we also discussed environmental changes tribal members have observed in recent years, science and research needs in the area, interest in collaborative research and funding for tribes and regional non-profit corporations to conduct research activities, and the cumulative impact of salmon interception in the False Pass salmon fisheries and salmon bycatch in the pollock fisheries. We also received questions about how NMFS and the Council are working together to ensure that tribal concerns are addressed, what steps NMFS is taking to provide information and education about fisheries issues to the tribes, and the status of the tribes' request that NMFS hire a tribal liaison.

A more detailed report of the consultation is being prepared by NMFS staff and will be sent to the Council when it is completed.

Sincerely,

A handwritten signature in blue ink, appearing to read 'J. Balsiger', with a small blue mark below the signature.

James W. Balsiger, Ph.D.
Administrator, Alaska Region

cc: Representatives of the tribes that
participated in the June 1, 2011, consultation

Julie Raymond-Yakoubian

North Pacific Fishery Management Council
Action Bering Sea Chum Bycatch, June 2011

The Council held its first initial review on an analysis evaluating proposed management measures to minimize non-Chinook salmon bycatch in the Bering Sea pollock fishery. The proposed measures include hard caps on the pollock fishery, triggered time and area closures and participation in the Rolling Hotspot (RHS) Program, a fleet managed program for real-time bycatch area closures on 4-7 day time frames. The Council revised and restructured the suite of alternatives and options, and requested new information. Some of the restructuring includes the following:

- An additional option for a separate hard cap for June and July when western Alaskan chum stocks are more prevalent in the bycatch. If reached this cap would close all fishing for pollock until August 1.
- Removal from consideration complicated monthly area management options and triggers (formerly Alternative 3)
- Include additional provisions to the RHS program for area closures based on historical bycatch proportions (80% and 60%) to which the fleet would be subject regardless of RHS participation
- Include analysis of additional parameters of the RHS system that could be adjusted by the Council to improve program performance

The Council further requested that the analysis be revised per their requests and come back to the Council for another initial review in early 2012. The exact meeting is yet to be determined. This schedule is in part to avoid reviewing the draft analysis at a Council meeting located in a place more difficult for rural western Alaska residents to access (e.g., Dutch Harbor), and in part to avoid review at the December meeting, the months preceding which staff are focused on preparing stock assessments for the groundfish fisheries. This schedule means that the Council will review the analysis two more times prior to making a final decision: initial review in early 2012, and public review/final action at a subsequent meeting. This also provides ample time for the public to provide input on the proposed alternatives and analysis.

The Council plans to convene another Rural Community Outreach Committee meeting this year (timing to be determined), and requested that the committee discuss whether and what type of further community outreach is needed on this issue.

Staff contact for the chum analysis is Diana Stram. Staff contact for rural community outreach is Nicole Kimball.



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News & Events

Radiation Safety

New and Updated Information

- **Updated** - What is FDA doing to ensure the safety of products imported from Japan? FDA's screening at U.S. borders will remain vigilant and will be augmented with radiation screening of shipments [More...](#)
- **New** - What products come to the U.S. from Japan? FDA-regulated products imported from Japan include human and animal foods, medical devices and radiation emitting products, cosmetics, animal and human drugs and biologics, dietary supplements, and animal feeds [More...](#)
- **Updated** - What specific tests is FDA using? FDA has procedures and laboratory techniques for measuring radionuclide levels in food, and can also utilize the Food Emergency Response Network (FERN) [More...](#)
- **New** - What does FDA look for when it tests food for radioactive contamination? When FDA tests food for radioactive contamination, it measures how much radiation is released by radioactive materials that are not expected to be naturally present. [More...](#)
- **New** - What are the principal radionuclides involved in a nuclear reactor accident? Iodine-131 (I-131), Cesium-134 (Cs-134) and Cesium-137 (Cs-137) are the radionuclides of greatest concern to the food supply following a nuclear power plant accident. Along with those three radionuclides, FDA also monitors others as needed – among them, Strontium-90, Ruthenium-103 (Ru-103) and Ruthenium-106 (Ru-106). [More...](#)
- **New** - What are the standards FDA uses to determine the amounts of specific radioactive materials in foods and whether they may cause a safety concern? FDA uses Derived Intervention Levels (DILs) to help determine whether food presents a safety concern. [More...](#)
- **Updated** - What has FDA's screening and testing shown so far? As of Wednesday, June 29, FDA import investigator had performed 21,787 field examinations for radionuclide contamination. FDA had tested 870 samples, 140 of which were seafood or seafood products. 869 samples had no Iodine-131, Cesium-134, Cesium-137, or other gamma-ray emitting radionuclides of concern. 1 sample was found to contain detectable levels of Cesium, but was below the established Derived Intervention Level (DIL) and posed no public health concern. [More...](#)
- **New** - How will water contaminated with radioactive materials affect seafood safety? FDA does not anticipate any public health effect on seafood safety. [More...](#)
- **New** - What about fish that swim from the reactor site into U.S. fishing waters? FDA does not believe that such fish would have levels of radioactive contamination that would be of concern. [More...](#)
- **New** - Where would the seafood be analyzed? FDA's Winchester Engineering and Analytical Center (WEAC) will conduct any needed sample analysis. [More...](#)
- **New** - The U.S. Environmental Protection Agency (EPA) has reported low levels of radionuclides in milk in the U.S. Is this a cause for concern? At this time, there is no radiation safety risk related to milk produced in the U.S. [More...](#)
- **Updated** - What will FDA do if grass or feed crop in the US does become contaminated? FDA's response will depend on the nature of the risk determined to exist. [More...](#)
- **New** - What are other Federal agencies doing to protect the food supply? Information about the U.S. Government's comprehensive efforts to protect the food supply can be found in this joint fact sheet⁸ from the U.S. Department of Agriculture (USDA) and the National Oceanic and Atmospheric Administration (NOAA). [More...](#)
- **New** - What is the FDA doing to ensure the safety of drugs coming from Japan? FDA's screening procedures will remain vigilant and will be augmented with screening of all Japanese shipments entering the United States. [More...](#)
- **New** - Why is FDA paying special attention to injectable and inhalable drugs? Injectable and inhalable drugs will be subject to physical examination and testing regardless of their place of origin within Japan because these drugs more directly enter into the bloodstream. [More...](#)
- **New** - How long will FDA maintain this heightened level of scrutiny for drugs coming from Japan? FDA will adjust the evaluation and testing procedures based upon additional information about conditions in Japan, and the results of testing procedures of drugs originating from Japan. [More...](#)

- **New** - Has FDA taken any action on these types of products thus far? FDA has issued Warning Letters to firms promoting a variety of fraudulent products that claim to prevent or treat the harmful effects of radiation exposure from the nuclear power plant incident in Japan as a consequence of the earthquake and tsunami. [More...](#)
- **Updated** - How can consumers identify products that may be violative? Consumers should be wary of the following [More...](#)
- [Questions about Food Safety](#)
- [Questions about Medical Products](#)
- [EPA-FDA Statement on Monitoring of Milk, Precipitation, Milk and Milk Products](#)¹
- [NOAA-EPA-FDA Statement on U.S. Seafood: Safe and Unaffected by Japan Radiation Contamination](#)²
- [Donating Drugs to International Humanitarian Relief Efforts \(PDF\) 64 KB](#)³

Updated May 19, 2011, 10:00 a.m. EDT

Questions about Food Safety

What systems does FDA have in place to protect the U.S. food supply?

The U.S. enjoys one of the world's safest food supplies. FDA has systems in place to help assure that our food supply is wholesome, safe to eat, and produced under sanitary conditions.

FDA has a team of more than 900 investigators and 450 analysts in the Foods program who conduct inspections and collect and analyze product samples. FDA oversees the importation of the full range of regulated products, including food and animal feed, among other responsibilities.

Altogether, FDA electronically screens all import entries and performs multiple analyses on about 31,000 import product samples annually. During Fiscal Year (FY) 2010, the Agency performed more than 175,000 food and feed field exams and conducted more than 350 foreign food and feed inspections.

FDA works to inspect the right imports—those that may pose a significant public health threat – by carrying out targeted risk-based analyses of imports at the points of entry.

If unsafe products reach our ports, FDA's imports entry reviews, inspections, and sampling at the border help prevent these products from entering our food supply. FDA also works cooperatively with U.S. Customs and Border Protection and other agencies to help identify shipments that may pose a threat. If radiation levels in any food reach the FDA intervention level, FDA will take action to remove the food from distribution.

We will continue to keep you updated about this situation. For more information about milk and other food screening, please visit www.usa.gov/japan2011⁴.

What is FDA doing to ensure the safety of products imported from Japan?

FDA's screening at U.S. borders will remain vigilant and will be augmented with radiation screening of shipments. On March 22, 2011, in order to complement the measures taken by the Government of Japan and to strengthen the global food safety net regarding certain products, FDA issued Import Alert 99-33

(http://www.accessdata.fda.gov/cms_ia/importalert_621.html)⁵ regarding the importation of all milk and milk products and fresh vegetables and fruits produced or manufactured from the four Japanese prefectures of Fukushima, Ibaraki, Tochigi and Gunma. As of May 17, FDA has reduce the area of concern to three prefectures: Fukushima, Ibaraki, and Tochigi. This import alert was revised on March 25, April 12, April 15 and April 20, April 21, and May 17.

FDA is processing all food products from Japan in four categories:

- Category 1 consists of products that the Government of Japan has restricted for sale or export. Authorities will prevent these products from entering the U.S. These products cannot gain entry by providing sample results. As of May 17, 2011, these include:
 - Spinach, lettuce, celery, cress, endive, escarole, chard, collards, and other head-type leafy vegetables from the Fukushima Prefecture.

- Turnips and other non-head type leafy vegetables, as well as broccoli, cauliflower, flower head brassicas (i.e. broccoli and cauliflower), mushrooms bamboo shoots, and Ostrich fern from the Fukushima Prefecture.
 - Sand lance from Fukushima Prefecture
 - Milk from the Fukushima and Ibaraki Prefectures.
 - Spinach and kakina from the Fukushima and Ibaraki Prefectures.
- Category 2 consists of products from the Fukushima, Ibaraki, and Tochigi Prefectures that the Government of Japan has not currently banned for sale or export. These specific products include dairy products and fresh produce. Under Import Alert 99-33, authorities may detain these products when they arrive in the U.S. Authorities will release these products from detention if the importer can show the products are compliant.
 - Category 3 consists of food and feed products not covered by FDA's Import Alert that come from these three Japanese prefectures:
 - Fukushima
 - Ibaraki
 - Tochigi

FDA will examine these products, sampling and testing as needed, to determine if they are safe to enter the U.S.

- Category 4 consists of all other FDA-regulated food products from Japan that are not listed in the Import Alert and do not belong to one of the other categories. Authorities will review these products using standard procedures, and as part of this may monitor and sample products as resources permit.

FDA may adjust this strategy based on additional information received from monitoring results in Japan. FDA may also further evaluate this strategy if the Government of Japan makes changes to its list of prohibited exports.

FDA's import tracking system has been programmed to automatically flag all shipments of FDA-regulated products from Japan, and the Agency maintains a registry of companies that prepare, pack, manufacture, or hold food for intended consumption in the U.S. The Agency will be paying special attention to shipments from those companies in the affected area.

Standard operating procedure requires shippers to submit and FDA to receive prior notice of a shipment before the arrival of any shipments of FDA-regulated food/feed products. FDA's Prior Notice Center (PNC) enables the agency to stop these products upon arrival at the U.S. border or before they are distributed in U.S. commerce if a credible threat is identified for any shipment.

United States Customs and Border Protection (CBP) agents routinely use radiation detection equipment to screen food imports, cargo, and travelers. This screening helps identify and resolve potential safety or security risks. FDA is working with CBP to determine if their Automated Targeting System can assist in identifying shipments of FDA-regulated products, other than food or feed, originating from Japan before they arrive so that these shipments can be better targeted for examination. FDA's import staff will review each shipment of regulated goods originating from Japan and determine if it should be examined and sampled or released.

What products come to the U.S. from Japan?

FDA-regulated products imported from Japan include human and animal foods, medical devices and radiation emitting products, cosmetics, animal and human drugs and biologics, dietary supplements, and animal feeds. Foods imported from Japan make up less than 4 percent of foods imported from all sources. (Food products from Canada and Mexico each make up about 29 percent of all imported foods.) Almost 60 percent of all products imported from Japan are foods. The most common food products imported include seafood, snack foods and processed fruits and vegetables.

What specific tests is FDA using?

FDA has procedures and laboratory techniques for measuring radionuclide levels in food, and can also utilize the **Food Emergency Response Network (FERN)**⁶. FERN integrates the nation's food-testing laboratories at the local, state, and federal levels into a network that is able to respond to emergencies involving biological, chemical, or radiological contamination of food. FDA is working with Customs and Border Protection (CPB) to share resources and techniques for measuring contamination. FDA has the ability to measure contamination in products and issued guidance in 1998 regarding safe levels.

For those food and feed imports from the areas in proximity to the reactor but not covered by the import alert, FDA will:

- Conduct a field examination, including time/temperature changes, water damage.
- Collect a sample for radionuclide analysis at FDA laboratories.

For food and feed imports from Japan that originate outside the area of concern, FDA will:

- Collect a sample for any radiation pager reading significantly above background.
- As additional surveillance and as resources allow, collect other samples for radionuclide analysis as resources permit, for readings of 0 on the radionuclide pager.

[Click here for FDA's methodology used in radionuclide analysis](#)⁷

What does FDA look for when it tests food for radioactive contamination?

When FDA tests food for radioactive contamination, it measures how much radiation is released by radioactive materials that are not expected to be naturally present.

Radioactive materials are substances that release high energy particles or electromagnetic radiation. These high energy particles or electromagnetic radiation are emitted by unstable atoms as they go through transition to a more stable state. The energy that is released from radioactive materials is called radiation. Radioactive materials can be natural (for example, some rocks in the earth are radioactive) or man-made.

What are the principal radionuclides involved in a nuclear reactor accident?

Iodine-131 (I-131), Cesium-134 (Cs-134) and Cesium-137 (Cs-137) are the radionuclides of greatest concern to the food supply following a nuclear power plant accident. Along with those three radionuclides, FDA also monitors others as needed – among them, Strontium-90, Ruthenium-103 (Ru-103) and Ruthenium-106 (Ru-106).

Since the Fukushima nuclear accident, FDA has screened incoming food items for these radionuclides and others as needed. FDA also continually evaluates data and information from the accident and adjusts monitoring activities as needed.

What are the standards FDA uses to determine the amounts of specific radioactive materials in foods and whether they may cause a safety concern?

FDA uses **Derived Intervention Levels (PDF)**⁸ (DILs) to help determine whether food presents a safety concern. The criteria used to set DILs include:

- the percentage of potentially contaminated foods in a person's diet
- the amount of food typically eaten
- the length of time that a person may be expected to eat contaminated food
- the potential exposure to contaminated foods of different members of the population, including infants and children

In general, DILs apply to all foods. FDA does not have different DILs for different types of food, though DILs may be adjusted based on, for example, whether a food must be rehydrated before being ready to eat.

For more information about the DILs, please see the following links:

- **[CPG Sec. 560.750 Radionuclides in Imported Foods - Levels of Concern](#)**⁹
- **[Accidental Radioactive Contamination of Human Food and Animal Feeds: Recommendations for State and Local Agencies \(PDF\)](#)**¹⁰

What has FDA's screening and testing shown so far?

As of Wednesday, June 29, FDA import investigators had performed 21,787 field examinations for radionuclide contamination. FDA had tested 870 samples, 140 of which were seafood or seafood products. 869 samples had no Iodine-131, Cesium-134, Cesium-137, or other gamma-ray emitting radionuclides of concern. 1 sample was found to contain

detectable levels of Cesium, but was below the established Derived Intervention Level (DIL) and posed no public health concern. MS Excel Data File¹¹

How will water contaminated with radioactive materials affect seafood safety?

FDA does not anticipate any public health effect on seafood safety. This is due to a number of factors:

- **Little or no harvesting of fish is taking place in the area around the reactor.** The initial earthquake and tsunami caused significant damage to fishing vessels and dock areas prior to the release of radiation. Additionally, many of the remaining ocean-worthy vessels are being used for recovery missions. Because of this, fishing is not a priority at this time.
- **Water acts as both a shield and a diluent.** Airborne radioactive particles settle on the surface of the water. The volume of water between particles and fish absorbs radiation, "shielding" the fish. In the case of a direct release into the sea, the amount of water in the ocean rapidly dilutes and disperses the radiation to negligible levels.
- **Some radioactive isotopes rapidly decay.** The half life of I-131 is about eight days. That means that the level of radiation drops by half every eight days. This process is called "radioactive decay." This drop in the level of radiation means that the level does not stay constant through the lifetime of the fish. While Cesium isotopes have longer half lives (Cs-134 has a half-life of about two years, Cs-137 a longer half-life of about 30 years), the radionuclides also undergo biological excretion and do not continue to build up in fish forever.
- **FDA and Customs and Border Protection (CBP) are screening all imported food from Japan.** Fish harvested in Japan undergo the same screening for radiation when they arrive in the U.S. as other food products from Japan. This means that whole shipping containers are screened by CBP. FDA field staff also conduct field examinations. They carry hand-held equipment that detects radiation. If the detectors indicate radiation above background levels, FDA samples and tests the shipment to determine the amount of radiation.

What about fish that swim from the reactor site into U.S. fishing waters?

Japan to U.S. waters would take several days under the best of circumstances. Vessels fishing in waters far off U.S. shore must also travel several days to return to port. It is unlikely that a fish exposed to significant levels of radionuclides near the reactor could travel to U.S. waters and be caught and harvested. If this improbable trip did occur, the level of short-lived radionuclides such as I-131 would drop significantly through natural radioactive decay during the time needed to make the journey. At this time, Japanese tests have detected longer-lived radionuclides such as Cs-137 in only a few samples and at levels below FDA DILs. FDA's testing of fish imported from Japan has not detected the presence of Cs-137

In the unlikely scenario that pollutants could affect fish that have traveled to the U.S., FDA will work with the National Oceanic and Atmospheric Administration (NOAA) to test seafood caught in those areas. Together FDA and NOAA will also inspect facilities that process and sell seafood from those areas.

Where would the seafood be analyzed?

FDA's Winchester Engineering and Analytical Center (WEAC) will conduct any needed sample analysis. WEAC can also reach out to the Food Emergency Response Network (FERN) laboratories that are able to perform this analytical testing for assistance if needed.

Is FDA looking at products that might have traveled through Japan at the time of the explosion?

FDA will be examining both food products labeled as having originated in Japan or having passed through Japan in transit. The same is true for raw ingredients.

Are there dairy products that come from Japan?

Foods imported from Japan constitute less than 4 percent of foods imported from all sources. Dairy products make up only one-tenth of one percent of all FDA-regulated products imported from Japan. Most dairy products in the U.S. market are produced domestically.

The U.S. Environmental Protection Agency (EPA) has reported low levels of radionuclides in milk in the U.S. Is this a cause for concern?

At this time, there is no radiation safety risk related to milk produced in the U.S.

EPA monitors milk for radiation under its RADNET program, and has reported extremely low levels of I-131 and Cesium in some milk samples. These results are expected and are far below FDA's Derived Intervention Levels. Even for a person who drinks a lot of milk, it would be virtually impossible to consume enough milk to approach the level of concern.

As federal and state agencies test milk samples, low levels of I-131 may be found in different samples, and the levels may vary slightly. However these low levels are not expected to cause adverse health effects, even for the developing fetus, babies, or children.

At this time, there is no public health threat in the U.S. related to radiation exposure. FDA, together with other agencies, carefully monitoring any possibility for distribution of radiation to the United States. At this time, theoretical models do not indicate that significant amounts of radiation will reach the U.S. Please see www.epa.gov¹² for more information about monitoring efforts.

What will FDA do if grass or feed crop in the US does become contaminated?

FDA's response will depend on the nature of the risk determined to exist. If the grass or feed crop in the U.S. becomes contaminated, FDA will evaluate the risk based on:

- A. the extent/type of contamination in terms of radionuclides and their levels
- B. the area contaminated and whether it is used for food production
- C. if used for food production, what types of foods or crops produced and whether those foods or crops would be further processed and if so, what foods would ultimately result from that further processing.

What are other Federal agencies doing to protect the food supply?

Information about the U.S. Government's comprehensive efforts to protect the food supply can be found in this joint fact sheet¹³ from the U.S. Department of Agriculture (USDA) and the National Oceanic and Atmospheric Administration (NOAA).

Additionally FDA continues to work with its fellow member of the Federal Advisory Team for Environment Food and Health including EPA, USDA and CDC. The Advisory Team is a radiological emergency response group of technical experts tasked with providing protective action recommendations to state and local governments on behalf of its member agencies.

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Questions about Medical Products**What is the FDA doing to ensure the safety of drugs coming from Japan?**

FDA's screening procedures will remain vigilant and will be augmented with screening of all Japanese shipments entering the United States. The agency has established special procedures to evaluate drugs originating from the ten prefectures in closest proximity to the Fukushima Daiichi nuclear plant.

FDA will physically examine for radiation all drugs originating from these ten prefectures. Based on the results of those physical examinations, FDA may also test products to determine if they are safe to admit into the U.S. FDA will also physically examine and test all injectable and inhalable drugs regardless of their place of origin within Japan.

Why is FDA paying special attention to injectable and inhalable drugs?

Injectable and inhalable drugs will be subject to physical examination and testing regardless of their place of origin within Japan because these drugs more directly enter into the bloodstream. All other drugs originating from outside of the ten prefectures in closest proximity to the Fukushima Daiichi nuclear plant will be subject to normal processing for examination, sampling, and testing.

How long will FDA maintain this heightened level of scrutiny for drugs coming from Japan?

FDA will adjust the evaluation and testing procedures based upon additional information about conditions in Japan, and the results of testing procedures of drugs originating from Japan.

Hypothetically, if they were needed, what are the FDA-approved products for treatment of internal contamination with radioactive iodine?

There are three FDA-approved potassium iodide (KI) products for use as an adjunct to other public health protective measures in the event that radioactive iodine is released into the environment. The three over-the-counter products are:

- Iosat Tablets (130 mg), Anbex, Inc., Williamsburg, Va., <http://www.anbex.com>¹⁵ ¹⁶
- ThyroSafe Tablets (65 mg), Recipharm AB, Jordbro, Sweden, <http://www.thyrosafe.com>¹⁷ ¹⁸
- ThyroShield Solution (65 mg/mL), Fleming & Company Pharmaceuticals, Fenton, Mo.
<http://www.thyroshield.com>¹⁹ ²⁰

When administered at the recommended dose, KI is effective in reducing the risk of thyroid cancer in people at risk for inhalation or ingestion of radioactive iodine. KI floods the thyroid with non-radioactive iodine and prevents the uptake of the radioactive molecules. Potassium iodide works only to prevent the thyroid from uptaking radioactive iodine. It is not a general radioprotective agent.

Is potassium iodide the only medication available for radiation exposure?

Potassium iodide is the only FDA-approved medication available to treat contamination with radioactive iodine. There are FDA-approved products available that increase the rate of elimination of other radioactive elements. They include:

- **Calcium-DTPA and Zinc DTPA, Hameln Pharmaceuticals.** Approved to treat known or suspected internal contamination with plutonium, americium, or curium to increase the rates of elimination.
- **Radiogardase (Prussian blue insoluble capsules), HEYL Chemisch-Pharmazeutische Fabrik GmbH & Co. KG.** Approved to treat known or suspected internal contamination with radioactive cesium and/or radioactive or non-radioactive thallium to increase their rates of elimination.

We have heard that potassium iodide is in short supply. Is that correct?

FDA daily evaluates the pharmaceutical supply for a wide variety of drugs to assess shortage issues.

Despite the fact that there is no public health event in the U.S. requiring KI, FDA is aware of an increased demand for KI products. FDA is working with these companies to facilitate increased production. FDA can't provide an exact date on when that might happen but it will occur as quickly as possible.

Due to public concern related to the nuclear incident in Japan, there is an increased demand for drugs used to prevent and treat harmful effects caused by radiation exposure or contamination with radioactive materials. At this time, however, the U.S. Government is not recommending that residents of the United States or its territories take potassium iodide, even as a preventative measure. According to the Nuclear Regulatory Commission, all the available information continues to indicate that the U.S. Territories and the U.S. West Coast are not expected to experience any harmful levels of radioactivity. Based on this, it is not expected that U.S. citizens will need potassium iodide. Nonetheless, the FDA is working with manufacturers to facilitate increased production of this medicine as quickly as possible.

Does FDA recommend that consumers purchase potassium iodide as a protective step?

No. There is no public health event requiring anyone in the U.S. to take KI because of the ongoing situation in Japan.

With exports from Japan disrupted, is there any possibility that some medical products could be in short supply?

FDA has been contacted by a few companies who receive product from Japan and the Agency is working with them on their supply issues.

Have U.S. manufacturers of potassium iodide been asked to ship any products to Japan?

At this time, the FDA is not aware of any request from Japan to the U.S. manufacturers of FDA -approved potassium iodide. In addition, there is not a public health event requiring anyone in the U.S. to be taking KI because of the ongoing situation in Japan.

Drugs shipped to a foreign country, including as part of a humanitarian relief effort, are considered exports, and therefore need to meet certain legal requirements under the Federal Food, Drug, and Cosmetic Act (FFDCA). If a drug is approved and is otherwise in compliance with the FFDCA's requirements, there are no additional restrictions by FDA on its exportation. Drugs that are not approved or that otherwise are not in compliance with the FFDCA's requirements may be exported if the exportation meets certain conditions and requirements.

Can a sponsor of an investigational new drug export its product to Japan? Does FDA have to authorize such an export?

The sponsor of an investigational new drug can export its product to Japan. The FDA regulations, found at 21 CFR 312.110(b)²¹, outline several ways for the sponsor to export its investigational new drug provided the new drug satisfies the terms listed. For exports most relevant to the current situation, prior FDA authorization is not required for the sponsor to export an investigational new drug under this section of the regulations.

If I see web sites advertising potassium iodide or alternative cures, should I buy the products?

Due to public concern related to the nuclear incident in Japan, there is an increased demand for drugs used to prevent and treat harmful effects caused by radiation exposure or contamination with radioactive materials. One drug, potassium iodide (KI), has been approved by the FDA to prevent thyroid cancer in people internally contaminated with radioactive iodine.

At this time, the U.S. Government is not recommending that residents of the United States or its territories take KI, even as a preventative measure. According to the Nuclear Regulatory Commission, all the available information continues to indicate that Hawaii, Alaska, the U.S. Territories, and the U.S. West Coast are not expected to experience any harmful levels of radioactivity.

The FDA is alerting consumers to be wary of internet sites and other retail outlets promoting products making false claims to prevent or treat effects of radiation or products that are not FDA-approved. These fraudulent products come in all varieties and could include dietary supplements, food items, or products purporting to be drugs, devices or vaccines.

Has FDA taken any action on these types of products thus far?

FDA has issued Warning Letters to firms promoting a variety of fraudulent products that claim to prevent or treat the harmful effects of radiation exposure from the nuclear power plant incident in Japan as a consequence of the earthquake and tsunami. The firms that received the letters, along with the radiation protection products they market, are:

- KT Botanicals, LLC: - "Acute Radiation Exposure Support Formula" - <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm251311.htm>²²
- Eidon, Inc. - "Liquid Iodine" - <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm251793.htm>²³
- Premier Micronutrient Corporation - "Bioshield Radiation® R1", "Bioshield Radiation® R2" - <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm253423.htm>²⁴

How can consumers identify products that may be violative?

Consumers should be wary of the following:

- claims that a product not approved by FDA can prevent or treat the harmful effects of radiation exposure related to a nuclear incident (i.e., meltdown of a nuclear power plant);

- suggestions that a potassium iodide product will treat conditions other than those for which it is approved, i.e., KI floods the thyroid with non-radioactive iodine and prevents the uptake of the radioactive molecules, which are subsequently excreted in the urine;
- promotions using words such as "scientific breakthrough," "new products," "miraculous cure," "secret ingredient," and "ancient remedy";
- testimonials by consumers or doctors claiming amazing results;
- limited availability and advance payment requirements;
- promises of no-risk, money-back guarantees;
- promises of an "easy" fix; and,
- claims that the product is "natural" or has fewer side effects than approved drugs.
- claims that kelp, seaweed, and other food products contain enough iodine to protect against radioactive iodine. These products contain very little iodine when compared to the approved drug products. There are no foods or dietary supplements approved by FDA for protection against radioactive iodine

Don't be fooled by professional-looking Web sites. Avoid Web sites that fail to list the company's name, physical address, phone number, or other contact information. For more tips for online buying, visit [Buying Medicines and Medical Products Online](#)²⁵. To determine if a particular drug is FDA approved, check [The Orange Book](#)²⁶ or [Drugs@FDA](#)²⁷. Consumers and health care professionals are encouraged to report adverse side effects or medication errors from the use of both approved and unapproved radiation exposure products to the FDA's MedWatch Adverse Event Reporting program at www.fda.gov/MedWatch²⁸ or by calling 800-332-1088.

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