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National Trichinae Certification Program

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I. Introduction and Need for the Proposal

The U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), in cooperation with USDA's Food Safety Inspection Service (FSIS) and USDA's Agricultural Marketing Service (AMS), is proposing to administer and implement a national voluntary Trichinae Certification Program. The intent of this program would be to ensure the quality and safety of animal-derived pork products from the farm through slaughter. Under this program, pork production facilities that follow prescribed good production practices that minimize the risk of exposure of swine to the trichinae parasite would be able to market their swine as originating from sites certified to be trichinae-safe or to pose negligible risk to human health from trichinae.

Trichinae is a parasite that constitutes a transmissible disease of swine. It may also be passed on to humans who consume undercooked pork that is infected with the parasite. Historically, the disease control strategy in the United States has been to educate consumers to thoroughly cook pork to inactivate the parasite. Potential hazards of undercooked pork from the zoonotic parasite, *Trichinella spiralis*, are widely recognized by American consumers according to the FSIS Food Safety Hotline and industry-sponsored consumer surveys. This recognition has caused many consumers to overcook pork products to ensure inactivation of trichinae with commensurate decreases in palatability, texture, and nutritional value. Despite this recognition, some consumers continue to undercook pork and run a risk of trichinae infection. However, epidemiological evidence indicates that modern pork production practices have nearly eliminated trichinae from the U.S. domestic swine population. Therefore, the potential risks of contracting trichinae from undercooked pork have diminished dramatically in recent years.

Previous measures regulating the pork industry have been implemented to reduce trichinae in fresh pork products including curing, cooking, freezing, irradiation, and other treatments that are approved by the FSIS Administrator. However, there has been no national program that recognizes and certifies the good production practices employed in pork production that reduce trichinae risk factors. Other countries are considering development of national certification programs. Awareness of the lack of a national trichinae control program in the United States by some countries has diminished demand for exports of fresh domestic pork products due to a perceived risk. This perception of potential risk from United States pork products due to a lack of

regulatory control mechanism could be drastically diminished by establishment of a certification program. Such a program would enhance the marketing of pork and pork products both in the United States and in export markets. The proposed program is needed to provide assurance to the market of the quality and safety of pork-derived food products produced in the United States based upon consideration of potential risks of trichinae infection.

The regulations for USDA participation in voluntary certification programs are specified in subchapter I in 9 Code of Federal Regulations (CFR) Part 156. The Animal Health Protection Act (7 U.S.C. 8301–8317) authorizes the Administrator of APHIS to carry out operations and measures to detect, control, or eradicate any pest or disease of livestock. This includes animals at slaughterhouses, stockyards, or other points of concentration. The Administrator may also cooperate with State authorities, Indian tribal authorities, or other persons in the administration of regulations for the improvement of livestock or livestock products. APHIS' regulations in 9 CFR part 130 provide for user fees to cover costs of inspection and related services. APHIS' regulations for veterinary accreditation under 9 CFR parts 160 to 162 allow APHIS to authorize trained veterinarians to perform certain regulatory tasks to control and prevent the spread of trichinae in this program. In addition, cooperating State agriculture departments have control authorities that permit participation in cooperative disease management programs.

FSIS' involvement in this program is based upon the Federal Meat Inspection Act (FMIA), as amended (21 U.S.C. 1031 *et seq.*). This Act allows FSIS to inspect meat slaughtered or processed at official establishments to ensure the safety, wholesomeness, and proper labeling of meat. In addition to mandatory inspection, FSIS, under the Agricultural Marketing Act of 1946, as amended (7 U.S.C. 1621–1627), is authorized to provide a range of voluntary inspection, certification, and identification services to assist in the orderly marketing of various animal products and byproducts not subject to FMIA. FSIS regulations governing inspection and related activities are found at 9 CFR chapter III.

AMS' involvement in this program is based upon the Agricultural Marketing Act of 1946. This Act authorizes AMS to provide analytical testing services that facilitate marketing and that allow products to obtain grade designations or meet marketing or quality standards. Under this authority, AMS develops and maintains laboratory certification and accreditation programs as needed by the agricultural industry to support domestic and international marketing of U.S. products.

II. Alternatives

Potential alternatives analyzed for this program include no action, slaughter testing of each carcass, irradiation treatment of each carcass, and establishment and implementation of a National Trichinae Certification Program (preferred alternative). Descriptions of each alternative are provided in this section with a brief discussion of the various agency and producer responsibilities under each alternative. Certain quality control issues, such as good accountability through verification of records and audits, can affect program performance and these issues will be addressed to the extent that they pose any potential risks to the human environment.

One alternative was considered by program officials but has been ruled out due to potential logistical and implementation difficulties. This alternative involved certification of the swine herd by region rather than production site. The basis for a regional approach is described in Part 2, Article 2.2.9.3 of the Office International des Epizooties (OIE) International Animal Health Code. The OIE Code considers the domestic swine, in a country or part of a country (region), to be free from trichinae based upon the following requirements: (1) trichinellosis in humans and animals must be reported, (2) there must be an effective disease reporting system in place that has proven to be capable of detecting the occurrence of cases, and (3) trichinae infection has been shown to not exist in the domestic swine population based upon regular testing of a statistically significant sample of the population or trichinellosis has not been reported in 5 years and a surveillance program shows that the disease is absent from wild populations. Although the first two requirements may be readily fulfilled, the third is more problematic. Wildlife provides a natural reservoir for possible trichinae infections of slaughter animals. This is particularly a problem with rodents (Leiby *et al.*, 1990; Pozio, 2001). Results of a surveillance program of wildlife would only indicate locations of positive findings, not origin or potential movement of these animals. The detection and delimitation of areas with infected wildlife would vary over time and would vary with the extent of sampling. Delineating the borders between endemic regions and *Trichinella*-free regions would be difficult because a pork production site may be in an adjacent area and movement of wildlife (particularly rodents) is not hindered by property borders. Some production sites provide natural pastures for the swine that are readily accessed by wildlife. A meaningful surveillance for trichinae occurrence in a systematic manner for the large number of potential wildlife indicator-animals even in a small “region” would be difficult, expensive, and could involve considerable delay from the time of outcome publication to the

time of acceptance by the industry. For these reasons, certification by region is not considered to be a reasonable alternative for the trichinae program.

Another program alternative that was considered was to establish trichinae safe status based upon freezing of the pork for a specific length of time to eliminate viable trichinae. This approach would result in pork products that are not fresh (as is true for some other potential treatments) and would require individual verification of treatment. Since the intent of this program is to certify fresh pork as trichinae safe, this approach would actually be certifying frozen pork (rather than fresh pork) as trichinae safe. Therefore, This treatment does not meet the intent of certifying fresh pork as trichinae safe. This treatment is already allowed under FSIS regulations and would not provide new or more efficient regulation. Freezing of pork involves negligible adverse environmental impacts and this option could be incorporated into other regulations of pork products to verify trichinae safety of those commodities.

A. No Federal Action

Under no Federal action, USDA would take no new action to control or voluntarily certify pork production sites in the United States. The State agriculture departments, producer groups, and marketing groups could take whatever steps they deem necessary to control trichinae in swine or certify compliance with good production practices and principles of a Hazard Analysis and Critical Control Points (HACCP) system. The information and experience gained from the pilot testing and certification programs would not apply to any future agency actions. The lack of Federal certification for pork production facilities under this alternative would place any decisions to apply good management practices on the industry. This could limit future markets for U.S. pork products, in that, the markets in some countries are anticipated to stipulate production facility certification as a requirement for entry of pork products. The potential advertisement of pork or pork products as originating from a certified production facility to promote sales would not be possible with the lack of a national certification program. Most pork slaughter facilities in the United States already adhere to many of the good production practices and principles of a HACCP system. As a result, the current incidence of trichinae in swine is extremely low. This low incidence is not expected to change, whether a certification program is implemented or not. However, the good practices of the industry to eliminate trichinae would not be recognized in the absence of a certification program to identify those producers and the quality of their products.

B. Slaughter Testing Program

Under the slaughter testing program alternative, the trichinae-safe status of pork products would be based upon testing of each carcass. Testing of all carcasses is currently done in some countries and is largely a continuation of measures implemented at a time when trichinae was a prevalent and serious problem. Slaughter inspection programs are required in some countries, but the costs of such efforts are high. For example, countries in the European Union (E.U.) spent \$572 million in 1997 for trichinae inspection. The relative cost of this program compared to the other alternatives is likely to be considerably greater.

The slaughter testing program would involve no new action to certify pork production sites in the United States. The information and experience gained from the pilot testing and certification programs would not apply to any future agency actions under this alternative. Unlike the proposed program, certification of trichinae-safe pork products would be based upon individual tests of each carcass rather than good manufacturing processes and statistical verification testing. This program alternative would be expected to be more labor intensive than the other alternatives.

There are three approved slaughter testing methods that are recognized for effectively detecting trichinae infection in swine. These are the same methods that would be required for process verification testing under the proposed National Trichinae Certification Program alternative. Two of the methods are pooled sample digestion methods. These methods involve sampling of specific animal tissues, preparation of those tissues for analysis, and observation for trichinae larvae under a microscope. The specific requirements for these methods are given in the FSIS regulations in 9 CFR § 318.10(e). The third testing method involves checking swine sera, plasma, whole blood, tissue fluid, or meat juice for antibodies to the parasites using the enzyme-linked immunosorbent assay (ELISA). The ELISA has been used extensively for testing in both pre- and post-slaughter applications and is also a useful tool for monitoring herds for trichinae infection. The ELISA test for swine is licensed by APHIS. The lower cost of the ELISA test relative to the pooled diaphragm digestion tests (Cummings and Koprak, 1998) make it likely that this test would be used by most slaughter facilities for basic screening. However, if an ELISA test is used and the results are positive, then those findings would have to be confirmed using a pooled diaphragm digestion test. All three methods are effective at detecting trichinae infection in swine if conducted properly.

A slaughter testing program for all carcasses would involve a very large program. If one considers the low prevalence of trichinae in the national swine herds and the rare occurrence of transmission to the human population, there is limited justification for this approach from a public health perspective and a swine health perspective. However, this method is effective as a practice to certify meat as trichinae-safe and could serve to open markets for pork products. This program could be useful for trade with some countries that require testing of all carcasses for imported pork products.

C. Irradiation Treatment Program

Under the irradiation treatment program alternative, pork products could be certified as trichinae-safe if the product was subject to an irradiation treatment that has been demonstrated to control any *Trichinella spiralis* present in the meat. The dose requirements for control in pork carcasses or fresh, non-heated processed cuts of pork carcasses are given in 21 CFR 179. The minimum acceptable dose is 300 Gray (or 30 krad). The maximum allowable dose is not to exceed 1,000 Gray (or 100 krad). This dose range is designed to control trichinae, but not ruin the pork product. This alternative would involve no new action to certify pork production sites in the United States. The State agriculture departments, producer groups, and marketing groups could take whatever steps they deem necessary to control trichinae in swine or certify compliance with good production practices and principles of the HACCP system. The information and experience gained from the pilot testing and certification programs would not apply to any future agency actions under this alternative. The lack of certification for pork production facilities would place any decisions to apply good management practices on the industry.

Although the irradiation treatments may not produce any unique radiolytic substances in the pork products, irradiation treatment may not be acceptable to some consumers who choose to avoid the purchase and consumption of irradiated food products. This alternative, as a basis for demonstrating trichinae-safe certification, could limit future markets for U.S. pork products in that personal preferences and the market constraints in some countries might not facilitate the entry of these pork products.

The processing at most pork slaughter facilities in the United States already adheres to many of the good production practices that eliminate trichinae concerns. The application of irradiation is unlikely to affect the low prevalence of trichinae in swine and pork products. The public health benefit would be negligible considering that this alternative which would only eliminate the small

number of human cases of trichinae infection each year from pork products (generally less than a dozen). These benefits of the good production practices of the industry to eliminate trichinae risks would not be recognized by markets in the absence of need for a certification program if all pork products were irradiated.

D. National Trichinae Certification Program (preferred alternative)

Under this alternative APHIS, in cooperation with FSIS and AMS, would administer and implement a national voluntary Trichinae Certification Program. The program would provide for the certification of pork production facilities that follow certain prescribed management practices that prevent or minimize the risk of exposure to *Trichinella spiralis*.

A production site could seek enrollment in the proposed program by evidence of compliance with good production practices, as evidenced by an initial site audit, and adherence to other record keeping and program requirements. Complete certification is a 3-stage process. A site is classified as Stage I, enrolled when the APHIS Administrator approves the outcome of the initial site audit. A certified production site is a facility that has attained Stage II or III. A Stage II certified facility is a site that has achieved a favorable site audit by APHIS when classified as Stage I enrolled. Stage III certification would signify that the production site has adhered to good production practices as evidenced by favorable site audits when the facility was Stage I enrolled and Stage II certified. The primary difference between Stage II and Stage III certified sites is the frequency of site audits to maintain certification. A site awarded Stage II certified status would have to undergo another site audit 8 to 10 months later to continue in the program as a Stage III certified site. However, once a site is awarded Stage III certified status, it would not be required to undergo another site audit, for purposes of recertification, for another 14 to 16 months. The audits involve review of good production practices, waste feeding logbook, animal movement records, origin verification, rodent control logbook, animal disposal plan and records, and feed mill quality assurance affidavit. In addition to the scheduled audits, there would be USDA spot audits to verify that compliance is continual and consistent. Should a facility fail to meet the requirements of any audit, have a positive test result from process verification testing, or request withdrawal from the certification program; that site would be decertified.

These site audits would be conducted by a qualified accredited veterinarian (QAV) or a qualified veterinary medical officer (QVMO). The accreditation specialization for these auditors is granted upon successful completion of an APHIS-approved orientation or training program.

None of the auditing procedures generate adverse environmental effects and are subject to categorical exclusion under APHIS NEPA implementing regulations. However, thorough audits to ensure adherence to good production practices are critical to excluding trichinae from the swine in the production facilities and from the human environment which can pose important environmental impacts. In addition, the collection of the required data for audits involves the collecting of samples for testing and the disposal of carcasses, which are processes that can pose various adverse environmental effects. Although routine sampling may be subject to categorical exclusion, disease risk and animal disposal require an environmental assessment. The sanitation and rodent control methods may also pose certain environmental effects. All of these impact-generating issues are discussed in the chapter 3, Environmental Consequences.

Process-verification testing would be conducted using a USDA-approved tissue or blood-based postmortem test completed at an approved laboratory that is accredited for trichinae testing by AMS. The approved tests include either a pooled sample digestion method, as described in FSIS regulations in 9 CFR § 318.10(e), or an ELISA test licensed by APHIS. Basic information about these methods was described in the slaughter testing program alternative. The number of samples to test would be determined from the Program Standards by FSIS. The program standards for sample size are based upon statistical application of the 1995 data for trichinae in swine from the National Animal Health Monitoring System. This data is used to design the sampling size necessary for statistical confidence (Martin et al., 1987) that verifies negative test results of swine from facilities that adhere to the good production practices of the National Trichinae Certification Program. This verification serves to both confirm the effectiveness of the good production practices at certified facilities and to indicate the ongoing program effectiveness at ensuring safety of fresh pork from these facilities. Routine laboratory testing of this type is generally subject to categorical exclusion under APHIS NEPA implementing regulations, but sample and animal disposal are subject to good laboratory practices and may pose some environmental effects.

III. Environmental Consequences

Each of the alternatives were determined to have the potential to pose certain adverse environmental consequences. This section presents those potential impacts by alternative.

A. No Action

Trichinae infection has a long standing association with pork products in the United States and around the world. It is a concept in which people believe that the need to cook pork thoroughly is based on the risk of becoming infected with the parasite. In 1900, greater than 2.5% of the swine tested in the U.S. were found to be infected with trichinae. The infection rate declined to about 0.95% in the 1930's, 0.63% in 1952, 0.16% in 1965, and 0.12% in 1970. The National Animal Health Monitoring Swine survey conducted in 1995 reported 1.3 per ten thousand (0.013%) of 7,987 seropositive samples tested (Pyburn, *et al.* 2001). The detection and presence of trichinae in U.S. swine has substantially declined because of changes in the pork industry over the years. As part of many disease control or eradication programs, entire herds are tested to determine if a specific disease is present, or, conversely, to ensure that the disease is absent. Since testing of an entire herd is extremely expensive to actually prove 100% certain that a disease is absent from the population, the sample testing of most programs is designed to provide statistical confidence that the tested herd is free of the disease. Unlike the lack of testing required under the no action alternative, the verification testing required under the National Trichinae Certification Program is designed to provide a 99% confidence that the National Trichinae Certified Herd is free of trichinae as confirmed by lack of positive test results.

Despite these difficulties in testing entire herds, sampling can provide valid insight into the health status of the population, given that only one animal in the herd may have the disease of interest. The sampling strategy is designed to detect disease if more than a specified number or percentage (>0) of animals have the disease. The actual number or percentage of diseased animals to specify when making the sample size calculations should be based on knowledge of the biology of the disease (Martin, *et al.*, 1987). In modern pork production sites and slaughter facilities, there is essentially no risk of swine becoming infected with trichinae because of modern swine production practices.

Trichinellosis is primarily a disease of concern because of its public health significance. It is transmitted by eating or ingesting infected meat that has not been sufficiently cooked. *Trichinella spiralis* is a parasitic nematode (roundworm) and can be found in humans, swine, rats, and many other warm-blooded mammals. Infection was once very common; however, the infection rate now is relatively rare. In 1986, 51 cases of trichinosis were reported to the Center for Disease Control (CDC) from 12 States and the District of Columbia. Thirty-six (71%) of these cases occurred in the following states: New Hampshire, Hawaii, Massachusetts, and Pennsylvania. During that same year only three of the 51 isolated cases of trichinosis were caused by commercial pork products. The other cases of trichinosis caused by pork products were from wild boar or uninspected meat purchased from a farm. From 1993 through 1999, an annual average of 19 cases per year was reported in the United States. In 2000, 16 cases of trichinosis were reported from eight states and marked the fifth consecutive year in which less than 20 cases were reported from each State (Groseclose *et al.*, 2000). The low incidence is attributed primarily to an aggressive program of meat inspection and improved swine production practices such that it is unlikely that pork products purchased in your local supermarket will be infected. Most recent outbreaks discovered in the United States have been traced back to feral animal meats and meats not having been inspected. Game meats should always be considered a potential source of infection, and therefore should be tested or cooked thoroughly.

B. Slaughter Testing Program

A slaughter testing program would involve the postmortem inspection of every carcass for trichinae infection. For pork exported to the European Union, U.S. packers test carcasses using the same methods employed by European meat inspectors. Despite the low prevalence of trichinae in swine, considerable energy and cost goes into preventing human exposure.

It is necessary to perform one of several possible laboratory tests to detect trichinae because it is not possible to see trichinae cysts within the tissue by macroscopic examination. The parasitological methods currently recognized for effectively detecting trichinae infection in swine are the pooled sample digestion methods and the ELISA. These detection methods would be acceptable under the proposed Trichinae Certification program alternative.

The pooled sample digestion methods involves the collection of tissues from sites where parasites concentrate, such as the diaphragm, masseters, or tongue and are subjected to digestion in acidified pepsin. Larvae, which are freed from the

muscle cell cysts by this process are recovered by a series of settling steps, then visualized and counted under a microscope. This direct method of testing is generally limited to post-mortem inspection .

The use of ELISA to detect the presence of parasite-specific antibodies provides a rapid method that can be performed on blood or serum collected before or after slaughter. Serological testing has an advantage of increased sensitivity for detecting trichinellosis in lightly infected animals. A disadvantage of ELISA testing is the occurrence of a low rate of false-negative results in the case of infected swine. The Enzyme Immunoassay Method cannot reliably detect infections between 21 and 35 days after infection. Tests conducted more than 35 days after infection are highly reliable. Despite its time limitations on reliability of detection, the use of ELISA remains a highly effective tool for detecting ongoing transmission of trichinae infection on swine farms.

With the testing of each carcass comes the additional responsibility and added cost of disposing of tissue samples and chemicals according to standard operating procedures. Using the pooled sample digestion methods for *Trichinella* testing, samples must be trimmed free from all fat and fascia. Even though *Trichinella* larvae do not congregate in these tissues, facilities must ensure that tissue samples are disposed of and placed in such a manner that neither rodents nor swine will have access to or be attracted to the waste.

Methods of disposition include burial, incineration, composting (on farm), and rendering. There is no carcass disposal method that is universally preferred. The method chosen in a particular site-specific case will be dependent upon the type of animal, size of the herd or flock, the disease pathogen, and the characteristics of the site relative to potential negative environmental impacts. The disposition of carcasses is more important under the Slaughter Testing Program alternative than under the proposed National Trichinae Certification Program because the Slaughter Testing Program involves disposition of tissues from all carcasses rather than from only a representative statistical sample.

Since every carcass is tested after slaughter under this alternative, statistical sampling is not used to ascertain if a disease is absent or present in a population. Sampling methods can provide valid insight into the health status of the population because it is rare for only one animal in a herd to have the disease of interest. Infectious diseases tend to spread, and even infrequent noninfectious diseases would be expected to cluster somewhat within a herd. The sampling strategy used by the proposed National Trichinae Certification Program is designed to detect disease if more than a specified number or percentage (>0) of

animals have the disease. Pork processing facilities in the certification program are directed to what sample size is required to be tested in order to maintain confidence that the National Trichinae Certified Herd is trichinae safe without going through the costly expense of testing entire herds (Martin *et al.*, 1987).

The Slaughter Testing Program does not rely on good production practices (GPPs) or site audits to account for those management practices that affect the risk of exposure of swine to trichinae. Despite the relatively rare occurrence of *Trichinella* infection in U.S. swine, most pork production sites currently have some degree of risk for potential exposure from known sources of infection, such as cannibalism among swine, within an infected herd or exposure to living or dead rodents or other wildlife infected with trichinae. By not adhering to GPPs, production sites not only run the risk of exposing herds to known sources of infection but also the loss of profits due to infection and the added expense and time of disposing of infected carcasses.

The Slaughter Testing Program is designed to prevent transmission of trichinae to humans and not designed to prevent infection entirely. Since carcasses that test positive for the infection would not be made available for human consumption as fresh pork, the risk of human infections in the United States would be expected to remain at the same low levels. However, pork production sites that went through the expense and effort to meet the pilot Trichinae Certification Program requirements for certification would forego any benefits associated with the certification program and any potential for increased exports or domestic consumption would not be realized if this program is implemented.

C. Irradiation Treatment Program

The Food and Drug Administration (FDA) is responsible for the regulatory actions and ensuring the safe use of irradiation as a treatment on all foods. Food irradiation is a process that destroys harmful bacteria and pathogens by treating foods with ionizing radiation. Gamma rays, electron beams, and x-rays are three types of ionizing radiation used for food irradiation in approved amounts by FDA. Worker and environmental safety issues, particularly in respect to the use of cobalt-60 or cesium-137 (gamma rays) as a radiation source, have raised concerns. To decrease the risk of any accidental exposure, all irradiation facilities are built with layers of redundant safety systems of protection and subject to strict Federal and State regulations. Irradiation treatments are conducted in approved facilities. This type of treatment method is limited to certain approved meats that are compatible with approved limits of radiation exposure (<1,000 Gray). The range of acceptable irradiation exposures of

pork is from 300 to 1,000 Gray to ensure control of *Trichinella spiralis* (21 CFR 179.26). The irradiation equipment is designed to release radiation to the product only. The equipment has shielding to avoid direct exposure of the operator to the radiation source. Monitoring of radiation at facilities has demonstrated low ambient background radiation levels at plant boundaries. Personnel working at approved irradiation facilities are monitored for exposure to any radiation by dosimeters. All dosimeter readings at facilities monitored by FSIS have yielded negative results for the last five years. The standards set by the Nuclear Regulatory Commission now allow monitoring to be eliminated at facilities where no exposure has been consistently demonstrated. FSIS intends to require dosimeter readings for their lead inspectors during the first two years of operation of new plants. Negative results would be expected to result in a decision to forego further monitoring at these locations. Most facilities are expected to use electronic beam accelerator technology rather than radioactive isotopes to irradiate fresh pork products. Therefore, the use of irradiation treatment is expected to have negligible impact on the physical environment and on the health of irradiation facility workers.

Food irradiation has been shown to be highly effective in destroying bacteria and parasites in food products. Extensive research has proven that irradiation is a safe and reliable process and it has been approved by FDA (21 CFR 179), the American Medical Association, and the World Health Organization (WHO). Safeguards in the facility prevent food products that have been irradiated from picking up radioactive particles, but irradiation does result in the creation of chemicals called radiolytic products, some which have potential harmful effects. In regards to the quality of food, these effects have been shown to be minimal. With regard to toxicity, the evidence indicates that the compounds formed in irradiated foods are similar to the same as those produced during normal cooking, outdoor grilling, canning, pasteurization, and other forms of food preparation with risk to the consumer. An expert committee of the WHO determined that most of the radiolytic products were found at low concentrations (parts per billion) and most were also present in food treated by conventional processes (FAO/IAEA/WHO, 1977). This committee determined that the health hazard from these radiolytic products is negligible. The formation of free radicals and hydrogen peroxide in irradiated foods pose very low genetic risks. The genetic risk from consumption of irradiated food was found to be 10,000 times lower than the natural probability of genetic error (Fernandez *et al.*, 1984). The cumulative evidence from over four decades of research carried out in laboratories in the United States, Europe, and other countries worldwide indicates that irradiated food is safe to eat. The food is not radioactive, there is no evidence of toxic substances as a result of irradiation, and there is no

evidence or reason to expect that irradiation produces more virulent pathogens among those that survive irradiation treatment (U.S. General Accounting Office, 2000). Food irradiation causes no toxicological, microbiological, or nutritional problems, that adversely affect human health.

D. National Trichinae Certification Program

The proposed national program is characterized as a pre-harvest pork safety program that will provide documentation of swine management practices which minimize risk of exposure of swine to the zoonotic parasite *Trichinella spiralis*. This program establishes a set of criteria that enable producers to market swine which are not considered a risk to human health due to the reduction, minimization or avoidance of exposure to this parasite.

Once the producers have implemented the standards outlined in the pre-audit package, a QAV performs a site audit. If the audit is approved, the appropriate status for the site will be established as discussed in the alternatives section. Approval of the initial site audit for a production facility by the APHIS Administrator indicates the attainment of Stage I in the 3 stage process of certification. The producer is expected to maintain these standards and GPPs between audits. To ensure the integrity of the auditing process, spot audits would be conducted by a qualified State or Federal veterinary medical officer (QVMO). As previously mentioned, failure to adhere to the GPPs or other requirements of an audit or a positive test result from process verification testing are grounds for decertification of the production facility.

The purpose of an audit is to document implementation of and adherence to GPPs which are designed to eliminate the possibility for swine to become trichinae infected, and certain key elements for trichinae certification will be observed by the QAV during an audit. GPPs ensure that all non-breeding swine entering the site either originate from a Certified Production Site or are less than 5 weeks old. The Trichinae Identification Number (TIN) is a unique number assigned to a site by the APHIS administrator. The source herd TIN must be documented in an animal movement record. This ensures that all such swine moved into or from the site can be subsequently traced back to that site.

Slaughter facilities processing swine from Stage II or Stage III trichinae certified sites are responsible for testing a statistical sample (Martin *et al.*, 1987), of the certified herd using pooled sample digestion or ELISA, as discussed in the

Slaughter Testing Program alternative, to verify that on-farm controls are working.

Sources of feed or feed ingredients have to meet Good Manufacturing Practices (GMP) or quality assurance standards recognized by the feed industry. A letter from the feed suppliers shall be maintained on file and available for review by the auditor. Since it is illegal to feed raw garbage in commercial establishments, this source of infection should never be an issue. However, feeding of any raw or undercooked meat scrapes, including table waste could pose a risk. All waste products fed to swine must come from a state licensed garbage feeder and cooking times and temperature must be consistent with state and federal regulation.

Rodents and wildlife pose a significant risk to swine. Rodents, and rats in particular serve as both a reservoir host and as a bystander host for trichinae infection. When rat populations are in close contact with swine, it is possible that either live or dead rats will be caught and eaten. Under this proposed program producers must implement and maintain an effective rodent control program. Biosecurity, maintaining perimeters, baiting, and trapping are all part of the program. All production sites need to have in place and document, an Animal Disposal plan, a procedure for the prompt removal and disposal of swine carcasses found in pens to prevent cannibalism and the attraction of rodents and wildlife. General hygiene of the facility is also instrumental in not attracting rodents and wildlife. The containment and regular removal of solid waste and spilled feed from the facility will greatly help reduce the risk of exposure.

Production sites are required to exclude and control rodents and wildlife to a level such that fresh signs of activity of these animals are not observed in swine production or feed preparation and storage areas. Swine will not have access to wildlife harborage or wildlife carcasses at the site nor will wildlife carcasses be intentionally fed to swine. Since producers in the program must create barriers which do not allow swine free range to browse outdoors and with the possibility to encounter and eat wildlife carcasses, a wildlife surveillance program is not necessary.

Under the standards established by the National Trichinae Certification Program it defines a rodent control logbook as a written record which documents the activities of a rodent control program for a production site. Rodents, and rats in particular serve as both reservoir host and as a bystander host for trichinae infection. Rodents are the reservoirs of a large number of infectious organisms many of which, if transmitted to human and domestic animal populations, may

cause outbreaks of diseases often with high mortality (Buckle et.al 1994). They can pick up infection from landfills, carrion, or even dead swine from a production site.

In an effort to control rodent populations, production sites and slaughter facilities would implement and maintain an effective rodent control program. At a minimum it includes: (1) a rodent control diagram of the site indicating the location of all rodent bait stations and traps, (2) document the number of rodent traps set and how often bait is refreshed, (3) document the disposal method for all unused bait, (4) document the brand name and active ingredients as well as the quantity of bait used, (5) the number of rodents caught or killed and indicate whether they are mice or rats, (6) and if possible, document the number of rodents sighted monthly.

All pesticides or rodenticides used in such rodent control programs must be registered for use by the Environmental Protection Agency (EPA). Most rodent control rodenticides are formulated as pelletized baits. In general, rodenticides have similar environmental fate characteristics, in part because they are most commonly used as bait formulations. The potential for rodenticides to reach groundwater level is low because of their relative low solubility in water and immobility in soil. Rodenticides, however are highly toxic to birds, domestic animals, and mammals. Small pellets and whole grain baits are attractive to birds and other non-target vertebrates. In addition to direct toxicity, rodenticides may also pose a secondary hazard to predators feeding on poisoned rodents. Some rodenticides are not persistent in animal tissues and must be eaten over a period of several days to cause mortality. Other rodenticides are more persistent and a single dose may pose a greater risk when poisoned rodents or other animals are consumed.

Occupational exposure to rodenticides may occur during manufacture, formulation, and bait application. Of special concern are potential dermal exposures to handlers during the loading and applications of these bait formulations. Certified applicators should only use approved USEPA labeled products and in accordance with their direction. Training in the safe handling, use, and application of rodenticides is essential for personnel who use them.

As mentioned in the Slaughter Testing Program alternative section there are several methods of carcass disposition and determining which method to use is based upon numerous factors and considerations. The Trichinae Certification Program is considering the following disposition methods: burial, incineration, composting (on farm), and rendering. All these methods ensure that carcasses

are disposed of in such a way as to destroy the pathogen and eliminate, to the greatest extent possible, the spread of disease and risk of transmission to other swine, wildlife, and humans. Any emissions or possible ground or surface water contamination from incineration, composting, and burial should pose little if any environmental risks. Disposal sites are placed in secure locations where access is restricted to facility personnel and designed to keep out wildlife and other animals. With the extremely low prevalence of trichinae in the pork supply, disposing of carcasses due to a positive finding of the parasite should be very minimal. The low sampling rate under the proposed National Trichinae Certification Program would involve less disposition of samples than would the Slaughter Testing Program alternative.

The risk of trichinae infection is primarily perception since the infection is so rare in today's product. With the advent of modern swine management practices the incidence of trichinosis in swine in the United States has been virtually eliminated. The Centers for Disease Control and Prevention reported that cases of human trichinellosis have declined to below 25 annually over the past several years. Many of the cases in the last few years or so were the result of eating bear and other game meats. Recent outbreaks of trichinosis from swine in the U.S. have been traced to pork products from pigs that have not been inspected and that have been slaughtered privately.

The use of good production/management practices proposed in the Trichinae Certification Program will preclude most risks for exposure to trichinae in the environment. Educational efforts to change the public's perception about the parasite would now be supported by a process which validates the absence of the parasite from the pork supply. Implementation of the program would also serve as a model with which to approach other food borne pathogens where systematic production practices could be identified in order to reduce or eliminate the threat of infection.

The number of swine producers that will actually participate in the National Trichinae Certification Program will depend upon economic and competitive market considerations. The possibility of increased sales of pork to consumers would benefit pork producers and slaughter facilities. Some producers may be driven by slaughter facilities that only accept pork from certified sites. However, most producers, especially the larger ones, are likely to participate in the program due to the expanding marketability of their product. It is estimated that 90 to 95 percent of pork production sites could meet the proposed requirements for site certification with only minimal facility changes (i.e. those costing approximately \$500.00 over a 5-year period.) In a worst case scenario, only

moderate facility changes (i.e. those that cost \$2,500 over 5 Years) would be required. Although not certain, having a voluntary trichinae certification program could increase participating producers and slaughter facilities ability to export pork to countries that are considered trichinae free.

E. Additional Considerations

1. Environmental Justice

Executive Order 12898, “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations,” requires each Federal agency to make achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low-income populations in the United States and its territories and possessions. None of the alternatives for trichinae control were found to have disproportionate adverse effects on any minority or low-income populations.

2. Protection of Children

Executive Order 13045, “Protection of Children From Environmental Health Risks and Safety Factors,” requires each Federal agency to address disproportionate environmental health risks or safety risks to children from implementation of proposed policies, programs, activities, and standards. The proposed National Trichinae Certification Program changes does not pose greater risks to children than to other parts of the affected population. No disproportionate adverse effects to the health or safety of children are anticipated from this program.

3. Endangered and Threatened Species

Section 7 of the Endangered Species Act (ESA) and the ESA's implementing regulations require Federal agencies to consult with the U.S. Fish and Wildlife Service (FWS) and/or the National Marine Fisheries Service to ensure that their actions are not likely to jeopardize the continued existence of endangered or threatened species or result in the destruction or adverse modification of critical habitat. APHIS has considered the potential effects on endangered and threatened species and their habitats from the proposed program. This program involves actions relating to the functioning and testing of commercial pork production facilities. Other than occasional entry of rodents or birds into these secure facilities, most wildlife are excluded. The isolation of the swine from

exposure to wildlife in these facilities is designed to prevent potential disease exposure, but this also precludes any effects to endangered and threatened species or their habitats as well.

IV. Listing of Agencies, Organizations, and Individuals Consulted

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FAO/IAEA/WHO—See Joint Food and Agriculture Organization/International Atomic Energy Agency/World Health Organization Expert Committee

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