encoding this protein and its regulatory regions. ''Regulatory regions'' are the genetic material that control the expression of the genetic material encoding the protein, such as promoters, terminators and enhancers. DNA is common to all forms of plant and animal life and the Agency has previously stated that they are not aware of an instance where these nucleic acids have been associated with toxic effects related to their consumption as a component of food. These ubiquitous nucleic acids, as they appear in the subject inert ingredient, have been adequately characterized. Therefore, no mammalian toxicity is anticipated from dietary exposure to the genetic material necessary for the production of the subject inert plant pesticidal ingredient.

D. Aggregate Exposure

1. *Dietary exposure—i. Food.* The functional activity of the GUS protein has been thoroughly studied and the protein is present in a number of animals, plants and microbes. Considering that GUS is already present in both the environment and food, the presence of the GUS protein in transgenic plants is unlikely to pose additional health concerns for humans or animals. Additionally, the *in vitro* digestive fate data demonstrate that the protein is likely degraded by stomach digestion prior to passage to the intestinal tract. Finally, the GUS protein is degraded upon heating and looses its functional activity.

ii. *Drinking water.* Transfer of the GUS protein to drinking water from genetically modified crops is highly unlikely given containment of the protein in plant cells and natural degradation upon plant senescence. However, if it were to occur, the levels would be insignificant compared to the levels of GUS protein produced by bacteria known to inhabit natural waters.

2. *Non-dietary exposure.* Occupational exposure is anticipated to be minimal during handling, storage, transportation or disposal of transgenic plants containing the GUS protein, since the protein is contained within the cells of the plant. This containment also results in a lack of volatilization or movement.

E. Cumulative Exposure

GUS belongs to a category of non-toxic proteinaceous substances that are not known to produce toxicological effects. The presence of the GUS protein in animals, plants and bacteria demonstrated a history of safe consumption of the protein in human food and animal feed supplies. Because there is no indication of mammalian toxicity caused by the GUS protein, there are no cumulative effects expected.

F. Safety Determination

1. *U.S. population.* The toxicity profile for the GUS protein indicates essentially no risk from exposure to the overall U.S. population. Therefore, there is a reasonable certainty that no harm will result from aggregate exposure of the U.S. population, including infants and children, to the GUS protein and the genetic material necessary for its production. This includes all anticipated dietary exposures and all other exposures for which there is reliable information.

2. *Infants and children.* The functional activity of this protein has been thoroughly studied and the protein is present in plants, animals and microbes. Considering the widespread exposure to GUS, additional food sources containing the GUS protein are unlikely to pose health concerns for humans or animals, including infants and children. This is supported by a history of safe consumption of the GUS protein naturally occurring in food and confirmed by the lack of toxic effects in an acute mouse gavage study.

G. Effects on the Immune and Endocrine Systems

No instances are known or reported of adverse reproductive or developmental effects to humans, domestic animals or wildlife as a result of exposure to the GUS protein or the microbial source of the *uidA gene*, *Escherichia coli*. The functional activity of this protein has been thoroughly studied and there is no known toxicological activity associated with this protein. Enzyme proteins are not known to interact or bind directly with the estrogen receptor, which would be necessary to produce endocrine effects. Further, there is little opportunity for systematic absorption of the GUS protein due to degradation upon heating and by digestive enzymes.

H. Existing Tolerances

The registrant is not aware of any tolerances established for residues of GUS in raw agricultural commodities and or processed food/feed.

I. International Tolerances

The registrant is not aware of any Maximum Residue Levels (MRLs) established for GUS by the Codex Alimentarius Commission (CODEX).

[FR Doc. 00–11033 Filed 5–2–00; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–939; FRL–6555–9]

Notice of Filing a Pesticide Petition to Establish a Tolerance for Certain Pesticide Chemicals in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of certain pesticide chemicals in or on various food commodities.

DATES: Comments, identified by docket control number PF–939, must be received on or before June 2, 2000.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the ''SUPPLEMENTARY INFORMATION.'' To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–939 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: William G. Sproat, Jr., Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–8587; e-mail address: Sproat.william@epamail.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American

Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under ''FOR FURTHER INFORMATION CONTACT.''

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person.* The Agency has established an official record for this action under docket control number PF–939. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–939 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3.*Electronically.* You may submit your comments electronically by e-mail to: *''opp-docket@epa.gov,''* or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF–939. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under ''FOR FURTHER INFORMATION CONTACT.''

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Make sure to submit your comments by the deadline in this notice.

7. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 24, 2000.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the view of the petitioner. EPA is publishing the petition summary verbatim without editing it in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

I. Elanco Animal Health, a Division of Eli Lilly and Company

OF6115

EPA has received a pesticide petition OF6115 from Elanco Animal Health, a Division of Eli Lilly and Company, 2001 W. Main Street, Greenfield, IN 46140 proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of spinosad in or on the raw agricultural commodity cattle meat, cattle meat by-products, cattle fat, milk, and milk fat at 0.45, 2.25, 5.75, 0.75, and 8.0 parts per million (ppm), respectively. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Analytical method*. There are two practical methods immunoassay, high performance liquid chromotography (HPLC), for detecting (0.005 ppm) and measuring (0.01 ppm) levels of spinosad in or on food with a limit of detection that allows for monitoring of food with residues at or above the levels set for these tolerances. The methods have had successful method tryout in EPA's laboratories.

2. *Magnitude of residues*. A magnitude of the residue study was conducted in lactating dairy cattle after dermal application of spinosad, where spinosad residues were most concentrated in fat (approx 1.3 ppm) and were much lower in the other edible tissues and milk (<0/75 ppm).

B. Toxicological Profile

1. *Acute toxicity*. Spinosad has low acute toxicity. The rat oral LD_{50} is 3,738 milligrams/kilograms (mg/kg) for males and >5,000 mg/kg for females, whereas the mouse oral LD_{50} is >5,000 mg/kg. The rabbit dermal LD_{50} is >5,000 mg/kg and the rat inhalation LC_{50} is >5.18 milligrams/liter (mg/L) air. In addition, spinosad is not a skin sensitizer in guinea pigs and does not produce significant dermal or ocular irritation in rabbits. End use formulations of spinosad that are water based suspension concentrates have similar low acute toxicity profiles.

2. *Genotoxicity*. Short-term assays for genotoxicity consisting of a bacterial reverse mutation assay (Ames test), an *in vitro* assay for cytogenetic damage using the Chinese hamster ovary (CHO) cells, an *in vitro* mammalian gene mutation assay using mouse lymphoma cells, an *in vitro* assay for DNA damage and repair in rat hepatocytes, and an *in vivo* cytogenetic assay in the mouse bone marrow (micronucleus test) have been conducted with spinosad. These studies show a lack of genotoxicity.

3. *Reproductive and developmental toxicity*. Spinosad caused decreased body weights in maternal rats given 200 mg/kg/day by gavage (highest dose tested (HDT)). This was not accompanied by either embryo toxicity, fetal toxicity, or teratogenicity. The no observed adverse effect levels (NOAELs) for maternal and fetal toxicity in rats were 50 and 200 mg/kg/day, respectively. A teratology study in rabbits showed that spinosad caused decreased body weight gain and a few abortions in maternal rabbits given 50 mg/kg/day (HDT). Maternal toxicity was not accompanied by either embryo toxicity, fetal toxicity, or teratogenicity. The NOAELs for maternal and fetal toxicity in rabbits were 10 and 50 mg/kg/day, respectively. In a 2–generation reproduction study in rats, parental toxicity was observed in both males and females given 100 mg/kg/day. Perinatal effects (decreased litter size and pup weight) at 100 mg/kg/day were attributed to maternal toxicity. The NOAEL for maternal and pup effects was 10 mg/kg/day.

4. *Subchronic toxicity*. Spinosad was evaluated in 13–week dietary studies and showed NOAELs of 4.89 and 5.38 mg/kg/day in male and female dogs, respectively; 6 and 8 mg/kg/day in male and female mice, respectively; and 33.9 and 38.8 mg/kg/day in male and female rats, respectively. No dermal irritation or systemic toxicity occurred in a 21–day repeated dose dermal toxicity study in rabbits given 1,000 mg/kg/day.

5. *Chronic toxicity*. Based on chronic testing with spinosad in the dog and the rat, EPA has set a reference dose (RfD) of 0.0268 mg/kg/day for spinosad. The RfD has incorporated a 100–fold safety factor to the NOAELs found in the chronic dog study to account for interspecies and intraspecies variation. The NOAELs shown in the dog chronic study were 2.68 and 2.72 mg/kg/day for male and female dogs, respectively. The NOAELs (systemic) shown in the rat chronic/carcinogenicity/neurotoxicity study were 9.5 and 12.0 mg/kg/day for male and female rats, respectively. Using the Guidelines for Carcinogen Risk Assessment published September 24, 1986 (51 FR 33992), it is proposed that spinosad be classified as Group E for carcinogenicity (no evidence of carcinogenicity) based on the results of carcinogenicity studies in two species. There was no evidence of carcinogenicity in an 18–month mouse feeding study and a 24–month rat feeding study at all dosages tested. The NOAELs shown in the mouse oncogenicity study were 11.4 and 13.8 mg/kg/day for male and female mice, respectively. A maximum tolerated dose was achieved at the top dosage level tested in both of these studies based on excessive mortality. Thus, the doses tested are adequate for identifying a cancer risk. Accordingly, a cancer risk assessment is not needed.

6. *Animal metabolism*. There were no major differences in the bioavailability, routes or rates of excretion, or metabolism of spinosyn A and spinosyn D following oral administration in rats. Urine and fecal excretions were almost completed in 48–hours post-dosing. In addition, the routes and rates of excretion were not affected by repeated administration.

7. *Metabolite toxicology*. The residue of concern for tolerance setting purposes is the parent material (spinosyn A and spinosyn D). Thus, there is no need to address metabolite toxicity.

8. *Endocrine disruption*. There is no evidence to suggest that spinosad has an effect on any endocrine system.

C. Aggregate Exposure

1. *Dietary exposure*. For purposes of assessing the potential dietary exposure from the use of spinosad on cattle, and existing registered uses on cotton, fruit, and vegetable crops, a conservative estimate of aggregate exposure is determined by basing the theoretical maximum residue concentration (TMRC) on the proposed tolerance levels for spinosad and assuming that 100% of the proposed and registered uses on cattle and crops raised or grown in the U.S. were treated with spinosad. The TMRC is obtained by multiplying the tolerance residue levels by the consumption data which estimates the amount of meat, crops and related foodstuffs consumed by various population subgroups. This conservative use of a tolerance level and 100% of the cattle and crops are treated with spinosad clearly results in an over estimation of human exposure.

Using a more realistic analysis anticipated residues can be evaluated under a Tier II risk assessment taking into account a conservative percent of market share expected for the dermally applied spinosad to cattle (Extinosad). Assuming residues of spinosad in food commodities at the tolerance levels for commodities based on existing crop uses, and a 35% market share for the portion of the tolerance increasing in

commodities due to the new dermal application of spinosad to cattle, a Tier II dietary risk assessment can be calculated.

2. *Drinking water*. Another potential source of dietary exposure are residues in drinking water. Based on the available environmental studies conducted with spinosad which shows little or no mobility in soil, there is no anticipated exposure to residues of spinosad in drinking water. In addition, there is no established maximum concentration level for residues of spinosad in drinking water.

3. *Non-dietary exposure*. Spinosad is being submitted in this application for control of ectoparasites on cattle and agricultural premises. Spinosad is currently registered for use on a number of crops including cotton and various fruits and vegetables, all of which involve applications of spinosad in an agriculture environment. Spinosad is also currently registered for outdoor use on turf and ornamentals at low rates of application (0.04 to 0.54 lb active ingredent per acre) and indoor use for drywood termite control extremely low application rates with no occupant exposure expected. Thus, the potential for non-occupational exposure to the general population is considered negligible.

D. Cumulative Effects

The potential for cumulative effects of spinosad and other substances that have a common mechanism of toxicity is also considered. In terms of insect control, spinosad causes excitation of the insect nervous system, leading to involuntary muscle contractions, prostration with tremors, and finally paralysis. These effects are consistent with the activation of nicotinic acetylcholine receptors by a mechanism that is clearly novel and unique among known insecticidal compounds. Spinosad also has effects on the gamma aminobatopic acid (GABA) receptor function that may contribute further to its insecticidal activity. Based on results found in tests with various mammalian species, spinosad appears to have a mechanism of toxicity like that of many amphiphilic cationic compounds. There is no reliable information to indicate that toxic effects produced by spinosad would be cumulative with those of any other pesticide chemical. Thus it is appropriate to consider only the potential risks of spinosad in an aggregate exposure assessment.

E. Safety Determination

1. *U.S. population*. Using the conservative exposure assumptions and the proposed RfD described above, the aggregate exposure (based on food and feed wherein potable water and non-occupational exposure is expected to be negligible) to spinosad use on cattle as well as existing registered crop uses will utilize 41.8% of the RfD for the U.S. population. A more realistic estimate of dietary exposure and risk relative to a chronic toxicity endpoint is obtained if market share percentage is applied to the tolerance levels to yield anticipated residue values. Inserting the anticipated residue values as a result of the percent market share, in place of tolerance residue levels produces a more realistic, but still conservative risk assessment. Based on anticipated residues which considers percent of market share in a dietary risk analysis, the use of spinosad on cattle and premises as well as existing registered crop uses will utilize 36.9% of the RfD for the U.S. population. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Thus, it is clear that there is reasonable certainty that no harm will result from aggregate exposure to spinosad residues on all existing crop uses and the pending animal uses.

2. *Infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of spinosad, data from developmental toxicity studies in rats and rabbits and a 2–generation reproduction study in rats are considered. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability and potential systemic toxicity of mating animals and on various parameters associated with the well-being of pups.

FFDCA section 408 provides that EPA may apply an additional safety factor for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base. Based on the current toxicological data requirements, the data base for spinosad relative to prenatal and postnatal effects for children is complete. Further, for spinosad, the NOAEL in the chronic feeding study which was used to calculate the RfD (0.027 mg/kg/day) is already lower than the NOAELs from the developmental studies in rats and rabbits by a factor of more than 10–fold. Concerning the reproduction study in rats, the pup effects shown at the highest dose tested were attributed to maternal toxicity. Therefore, it is concluded that an additional uncertainty factor is not needed and that the RfD at 0.027 mg/kg/day is appropriate for assessing risk to infants and children. In addition, EPA has determined that the 10x factor to account for enhanced sensitivity of infants and children is not needed because:

i. The data provided no indication of increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to spinosad. In the prenatal developmental toxicity studies in rats and rabbits and 2–generation reproduction in rats, effects in the offspring were observed only at or below treatment levels which resulted in evidence of parental toxicity.

ii. No neurotoxic signs have been observed in any of the standard required studies conducted.

iii. The toxicology data base is complete and there are no data gaps.

Using the conservative exposure assumptions previously described (tolerance level residues), the percent RfD utilized by the use of spinosad on cattle and premises as well as existing registered crop uses is 96.1% for children 1–6 years old, the most sensitive population subgroup. Based on anticipated residues which considers a percent of market share in a dietary risk analysis, the use of spinosad on cattle and premises as well as existing registered crop uses will utilize 81.9% of the RfD for the children 1–6 years old. Thus, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, it is concluded that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to spinosad residues on the proposed crop uses, including all existing crop uses.

F. International Tolerances

There are no Codex maximum residue levels established for residues of spinosad on any commodity.

[FR Doc. 00–10772 Filed 5–2–00; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[OPP–50867; FRL–6552–5]

Issuance of Experimental Use Permits

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has granted experimental use permits (EUPs) to the following