this requirement Oregon amended their existing certification plan. This amendment establishes a 1080 LPC subcategory under their existing regulatory pest control category.

Oregon will only be certifying employees of the U.S. Department of Agriculture, Animal Damage Control (ADC), as 1080 LPC applicators. Certification granted ADC employees will permit them to utilize 1080 LPC in performance of their official duties. ADC estimates that approximately 34 employees of ADC will seek certification under the 1080 LPC subcategory. The only registrant of 1080 LPC in Oregon is the ADC. Therefore, the ADC will be the source of 1080 LPC collars.

The Oregon 1080 Livestock Protection Collar Plan is more restrictive than the federal requirements in the following areas: use is limited to ADC agents, and monitoring and tracking of collars must be done twice per week rather than once per week.

The amendment to the Oregon certification plan contains a draft Memorandum of Agreement between the Oregon Department of Agriculture (ODA) and the ADC addressing their respective roles and responsibilities. The ODA will oversee the activities of the ADC in its roles both as registrant and as employer/supervisor of 1080 LPC applicators. In addition to its responsibilities as registrant, the ADC will provide training and supervision to its 1080 LPC applicators. Certification and recertification will be based upon a written examination administered by the ODA. Recertification will be required every 5 years.

II. Discussion of Comments

Approximately 190 commenters responded with a few commenters submitting multiple comments. Of the comments received approximately 50 favored approval of the amendment establishing a 1080 Livestock Protection Collar Certification Plan. The remaining approximately 140 commenters opposed approval of the amendment. The comments on both sides of the approval question focused on the need for the 1080 LPC, its effectiveness, the effectiveness and availability of alternative means of control, and its safety to man, animals and the environment.

The notice of intent to approve the amendment to Oregon Certification Plan asked for comments on the proposed amendments to the Oregon Certification Plan. None of the comments in opposition specifically addressed the provisions of the Oregon plan. The opposing comments addressed registration of the 1080 LPC with the most common comment being that the 1080 LPC should not be registered because of its toxicity. The comments directed at the registration of the 1080 LPC are outside the scope of the Notice of Intent to Approve the Oregon 1080 LPC Plan; these comments could not be addressed. Information on the registration of 1080 however, is addressed in the Reregistration Eligibility Decision (RED) that was published in 1995 on sodium fluoroacetate (Compound 1080). The document number is (EPA 738-R95-025). The sodium fluoroacetate RED contains the Agency's evaluation of the data base of this chemical, its conclusions of the potential human health and environmental risks of the current product's use, and its decisions and conditions under which this use and products will be eligible for reregistration. The RED has been included in the docket accompanied by the October 31, 1983 final decision, concerning registration applications to use sodium fluoroacetate to control predators. Both documents along with comments received on the Notice of Intent to Approve the Oregon 1080 LPC Plan can be reviewed at any time during normal business hours at the addresses noted at the end of this notice. The RED can also be obtained through the National Technical Information Service (NTIS). Orders may be placed to NTIS by telephone at the following number: (703) 487-4650, or by mail to the following address: National Technical Information Service, ATTN: Order Desk, 52854 Port Royal Road, Springfield, Virginia 22161.

Most of those commenting in favor of the proposal also confined their comments to the general question of 1080 LPC use. However, some of those commenting in favor of the proposed amendment addressed the administrative controls contained in the proposed 1080 LPC amendment. These comments generally addressed the fact that only ADC officials would be certified to use 1080 LPC and the control of access to 1080 LPC provided by this provision.

No comments were received that addressed or demonstrated how the Oregon proposed 1080 LPC amendment failed to meet the requirement for approval contained in FIFRA, the regulations at 40 CFR part 171, the labeling, and the Administrator's final decision. EPA continues to monitor the registration and use of the 1080 LPC to assure restrictions are adequate for minimizing risks to human health and the environment. EPA and the ODA plan to closely monitor the use of 1080 LPC's by the ADC to ensure compliance with the Plan and label requirements. Reports of misuse or problems connected with the use of 1080 LPC should be directed to the EPA or the ODA. Address and phone numbers can be found below.

The amendment to the Oregon Certification Plan for the certification of 1080 LPC applicators is approved.

Copies of the Oregon approved plan amendment and comments are available for review at the following locations during normal business hours:

1. U.S. Environmental Protection Agency, Region 10, Pesticides Unit, 1200 Sixth Avenue, Eighth Floor, Seattle, Washington 98101. Telephone (206) 553-1980.

2. U.S. Environmental Protection Agency, Office of Pesticide Programs, Crystal Mall #2, 1921 Jefferson Davis Highway, Room 1121, Arlington, VA 22202. Telephone (703) 305-7370.

3. Oregon Department of Agriculture, Plant Division, 635 Capitol Street N.E., Salem, Oregon 97310. Telephone (503) 986-4635.

Dated: December 3, 1996.

Charles Clarke,

Regional Administrator, Region 10.

[FR Doc. 96–32526 Filed 12–23–96; 8:45 am]

BILLING CODE 6560–50–F

[PF–684; FRL 5578–2]

DowElanco; Pesticide Tolerance Petition Filing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Filing.

SUMMARY: This notice is a summary of pesticide petitions proposing the establishment of a regulation for residues of spinosad in or on apples, brassica leafy vegetables, and fruiting vegetables (except cucurbits).

DATES: Comments, identified by the docket number [PF–684], must be received on or before, January 23, 1997.

ADDRESSES: By mail, submit written comments to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M Street S.W., Washington, DC 20460. In person, bring comments to: Room 1132, Crystal Mall #2 , 1921 Jefferson Davis Highway Arlington, VA.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Electronic comments must be submitted as an

ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file formate. All comments and data on this notice may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

Information submitted as comments concerning this document may be claimed confidential by marking any part or all of that information as Confidential Business Information (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Room 1132 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: George LaRocca, Product Manager (PM) 13, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 204, CM#2, 1921 Jefferson Davis Highway, Arlington, VA, (703) 305–6100; e-mail: larocca.george@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received pesticide petition (PP) 7F4797 from DowElanco, 9330 Zionsville Road, Indianapolis, IN 46254, proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. section 346a(d), to amend 40 CFR part 180 by establishing tolerances for residues of the insecticide spinosad in or on the raw agricultural commodities apples at 0.2 parts per million (ppm), apple pomace (wet) at 0.5 ppm, head and stem brassica vegetables at 2.0 ppm, leafy brassica vegetables at 15 ppm, and fruiting vegetables (except cucurbits) at 0.4 ppm. Because of the amount of spinosad residue found in wet apple pomace and the amount of apple pomace potentially included in cattle and dairy cow rations, the following meat and milk tolerances for residues of spinosad are also being proposed: meat at 0.05 ppm, kidney and liver at 0.2 ppm, fat at 1.0 ppm, milk at 0.02 ppm, and milk fat at 0.5 ppm. Spinosad is a fermentation derived tetracyclic macrolide product produced by the actinomycete, Saccharopolyspora spinosa and consists of two structurally related compounds, namely spinosyn A and spinosyn D which provide the insect control activity for this new product. The two spinosyns only differ from each other in the substitution of a hydrogen by a methyl group and have structures consisting of a basic amine group, two sugars, and a larger complex hydrophobic ring. This new active ingredient that has been accepted by the EPA as a reduced risk product is being proposed for registration for insect control on apples, brassica leafy vegetables, and fruiting vegetables (except cucurbits). The proposed analytical method is based on high performance liquid chromatography (HPLC) with ultraviolet (UV) detection.

Pursuant to the section 408(d) (2) (A) (i) of the FFDCA, as amended, DowElanco has submitted the following summary of information, data and arguments in support of their pesticide petitions. This summary was prepared by DowElanco and EPA has not fully evaluated the merits of these petitions. EPA edited the summary to clarify that the conclusions and arguments were the petitioner's and not necessarily EPA's and to remove certain extraneous material.

I. Petition Summary

A. Residue Chemistry

The metabolism of spinosad in plants (apples, cabbage, cotton, tomato, and turnip) and animals (goats and poultry) is adequately understood for the purposes of these tolerances. A rotational crop study showed no carry-over of measurable spinosad related residues in representative test crops. Magnitude of residue studies were conducted for apples, brassica leafy vegetables, and fruiting vegetables (except cucurbits). Residues of spinosad did not concentrate in tomato process fractions; however, there was a concentration of spinosad residues in wet apple pomace, an animal feed process fraction. There is a practical method (HPLC with UV detection) for detecting (0.004 ppm) and measuring (0.01 ppm) levels of spinosad in or on food with a limit of detection that allows monitoring of food with residues at or above the levels set for this tolerance. The method has had a successful method tryout in the EPA's laboratories.

B. Toxicological Profile

1. *Acute toxicity*. Spinosad has low acute toxicity. The rat oral LD_{50} is 3,738 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 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 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). This was not accompanied by either embryo toxicity, fetal toxicity, or teratogenicity. The no observed effect levels (NOELs) for maternal and fetal effects 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 (highest dose tested). Maternal toxicity was not accompanied by either embryo toxicity, fetal toxicity, or teratogenicity. The NOELs for maternal and fetal effects in rabbits were 10 and 50 mg/kg/day, respectively. The NOEL found for maternal and pup effects in a rat reproduction study was 10 mg/kg/day. Neonatal effects at 100 mg/kg/day (highest dose tested in the rat reproduction study) were attributed to maternal toxicity.

4. *Subchronic toxicity*. Spinosad was evaluated in 13-week dietary studies and showed NOELs of 4.9 mg/kg/day in dogs, 6 mg/kg/day in mice, and 8.6 mg/kg/day in rats. 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, a reference dose (RfD) of 0.025 mg/kg/day is proposed for spinosad. The RfD has incorporated a 100-fold safety factor to the NOELs found in these two chronic tests. The NOELs shown in the dog chronic study were 2.68 and 2.72 mg/kg/day, respectively for male and female dogs. The NOELs shown in the rat chronic study were 2.4 and 3.0 mg/kg/day, respectively for male and female rats.

6. *Carcinogenicity*. Using the Guidelines for Carcinogen Risk Assessment published in the Federal Register of 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 NOELs shown in the mouse oncogenicity study were 11.4 and 13.8 mg/kg/day, respectively for male and female mice. The NOELs shown in the rat chronic/oncogenicity study were 2.4 and 3.0 mg/kg/day, respectively for male and female rats. 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.

7. *Neurotoxicity*. Spinosad did not cause neurotoxicity in rats in acute, subchronic, or chronic toxicity studies.

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

9. *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. In addition, the routes and rates of excretion were not affected by repeated administration.

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

C. Aggregate Exposure

1. *Dietary exposure*. For purposes of assessing the potential dietary exposure from use of spinosad on apples, brassica leafy vegetables, fruiting vegetables (except cucurbits), meat, and milk, as well as cottonseed (included in a previous submission under pesticide petition (PP) 6F4735), a conservative estimate of aggregate exposure is determined by basing the theoretical maximum residue contribution (TMRC) on the proposed tolerance levels for spinosad and assuming that 100 percent of the cotton, apples, brassica leafy vegetables, and fruiting vegetables (except cucurbits) 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 crops and related food stuffs consumed by various population subgroups. There are no other established U.S. tolerances for spinosad and no other registered uses for spinosad on food or feed crops in the United States. The use of a tolerance level and 100 percent of crop treated clearly results in an over-estimate of human exposure and a safety determination for the use of spinosad on crops cited in this summary that is based on a conservative exposure assessment. Another potential source of dietary exposure are residues in drinking water. Based on the available environmental studies conducted with spinosad wherein it's properties show little or no mobility in soil DowElanco concludes, 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.

2. *Non-dietary exposure*. There are no other uses currently registered for spinosad. The proposed use on apples, brassica leafy vegetables, and fruiting vegetables (except cucurbits), as well as a pending use on cotton involve application of spinosad to crops grown in an agriculture environment. Thus, the potential for non-occupational exposure to the general population is not expected to be significant.

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 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 DowElanco believes it is appropriate to consider only the potential risks of spinosad in an aggregate exposure assessment.

E. Safety Determinations

1. *U.S. population in general*. Using the conservative exposure assumptions and the proposed RfD described above, the aggregate exposure to spinosad use on apples, brassica leafy vegetables, cotton, and fruiting vegetables (except cucurbits) will utilize 9.1 percent 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 average (anticipated) residue values from field trials are used. Inserting the average residue values in place of tolerance residue levels produces a more realistic, but still conservative risk assessment. Based on average or anticipated residues in a dietary risk analysis, the use of spinosad on apples, brassica leafy vegetables, cotton, and fruiting vegetables (except cucurbits) will utilize 2.1 percent of the RfD for the U.S. population. EPA generally has no concern for exposures below 100 perecnt 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, DowElanco concludes that there is reasonable certainty that no harm will result from aggregate exposure to spinosad residues on apples, brassica leafy vegetables, cotton, and fruiting vegetables (except cucurbits).

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 the rat 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 pre- and post-natal toxicity and the completeness of the database. Based on the current toxicological data requirements, the database for spinosad relative to pre- and post-natal effects for children is complete. Further, for spinosad, the NOELs in the chronic feeding studies which were used to calculate the RfD (0.025 mg/kg/day) are already lower than the NOELs 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, DowElanco

concludes that an additional uncertainty factor is not needed and that the RfD at 0.025 mg/kg/day is appropriate for assessing risk to infants and children.

Using the conservative exposure assumptions previously described (tolerance level residues), the percent RfD utilized by the aggregate exposure to residues of spinosad on apples, brassica leafy vegetables, cotton, and fruiting vegetables (except cucurbits) is 20.6 percent for children 1 to 6 years old, the most sensitive population subgroup. If average or anticipated residues are used in the dietary risk analysis, the use of spinosad on these crops will utilize 5.1 percent of the RfD for children 1 to 6 years old. Thus, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, DowElanco concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to spinosad residues on apples, brassica leafy vegetables, cotton, and fruiting vegetables (except cucurbits).

F. International Tolerances

There are no codex maximum residue levels established for residues of spinosad on apples, brassica leafy vegetables, cotton, fruiting vegetables (except cucurbits) or any other food or feed crop.

II. Administrative Matters

Interested persons are invited to submit comments on this notice of filing. Comments must bear a notation indicating the document control number, [PF–684]. All written comments filed in response to this petition will be available in the Public Response and Program Resources Branch, at the address given above from 8:30 a.m. to 4 p.m., Monday through Friday, except legal holidays.

A record has been established for this notice under docket number [PF–684], including comments and data submitted electronically as described below. A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency Room 1132 , Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

Electronic comments can be sent directly to EPA at:

opp=docket@epamail.epa.gov

Electronic comments must be submitted as ASCII file avoiding the use of special characters and any for encryption. The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the address in ADDRESSES at the beginning of this document.

List of Subjects

Environmental Protection Agency, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 13, 1996.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 96–32528 Filed 12–23–96; 8:45 am]
BILLING CODE 6560–50–F

[PF–679; FRL–5576–6]

Monsanto; Pesticide Tolerance Petition Filing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Filing.

SUMMARY: This notice is a summary of the pesticide petitions which proposes to establish time-limited tolerances for residues of the herbicide glyphosate [*N*-phosphonomethyl)glycine] in or on the raw agricultural commodities (RACs) field corn grain at 1.0 parts per million (ppm), field corn forage at 1.0 ppm, field corn fodder at 100 ppm, aspirated grain fractions at 200 ppm, grain sorghum at 15 ppm, grain sorghum fodder at 40 ppm, and oats at 20 ppm. The residues from treatment of field corn include residues from field corn varieties which have been genetically modified to be tolerant of glyphosate. Because additional time is needed for the petitioner to submit additional details on residue and processing data, the Agency is proposing to grant these tolerances with a 3–year expiration date. Monsanto Company requested these tolerances in petitions submitted to EPA pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA). A summary of the petition prepared by Monsanto is being included in this notice.

DATES: Comments, identified by the docket control numbers [PF–679] must be received on or before January 23, 1997.

ADDRESSES: By mail, submit written comments to Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. In person, bring comments to RM 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202. Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

Comments and data will also be accepted on disks in Word Perfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the Docket number [PF–679]. Electronic comments on this notice may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as Confidential Business Information'' (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Robert J. Taylor, Product Manager (PM) 23, Registration Division, (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 241, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, 703–305–6027, e-mail: taylor.robert@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: Pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. section 346 a(d), EPA has received several pesticide petitions (PP 8F3672, PP 8F3673, PP 6E4645 and PP