significant economic effect upon a substantial number of small entities. Accordingly, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

Unfunded Mandates

OSM determined and certifies under the Unfunded Mandates Reform Act (2 U.S.C. 1502 *et seq.*) that this rule will not impose a cost of $100 million or more in any given year on local, state, or tribal governments or private entities.

List of Subjects in 30 CFR Part 904

Intergovernmental relations, Surface mining, Underground mining.

Dated: September 3, 1998.

Charles E. Sandberg,

Acting Regional Director, Mid-Continent Regional Coordinating Center.

[FR Doc. 98–24380 Filed 9–10–98; 8:45 am]

BILLING CODE 4310–05–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 86

[FRL–6159–9]

Optional Certification Streamlining Procedures for Light-Duty Vehicles, Light-Duty Trucks, and Heavy-Duty Engines for Original Equipment Manufacturers and for Aftermarket Conversion Manufacturers

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; extension of public comment period.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is extending the public comment period on the Notice of Proposed Rulemaking (NPRM), which proposes optional certification procedures for light-duty vehicles, light duty trucks, and heavy-duty engines that meet Clean-Fuel Vehicle requirements as well as for certain gaseous-fueled vehicles certified to EPA's Tier 1 standards. The NPRM was published in the **Federal Register** on July 20, 1998 (63 FR 38767). The purpose of this document is to extend the comment period from August 19, 1998 to October 13, 1998, to allow commenters additional time to respond to the NPRM.

The document provided an opportunity for a public hearing, if requested by August 19, 1998. No request for a hearing was made and, therefore, no public hearing will be scheduled for this proposal.

DATES: EPA will accept comments on the NPRM until October 13, 1998.

ADDRESSES: Comments should be submitted in duplicate to the EPA Air & Radiation Docket #A–97–27, Room 1500–M (Mail Code 6102), 401 M Street SW., Washington, D.C. 20460. Copies of information relevant to this NPRM are available for inspection in public docket A–97–27 at the above address, between the hours of 8:00 a.m. to 5:30 p.m. Monday through Friday.

FOR FURTHER INFORMATION CONTACT: For information concerning the NPRM, contact Clifford Tyree, Sr. Project Manager, Vehicle Programs and Compliance Division, U.S. Environmental Protection Agency, 2000 Traverwood, Ann Arbor, MI 48105, Phone (734) 214–4310, E-mail: tyree.clifford@epa.gov.

Dated: September 4, 1998.

Robert Perciasepe,

Assistant Administrator, Air and Radiation.

[FR Doc. 98–24476 Filed 9–10–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300710; FRL–6026–8]

RIN 2070–AB78

Azoxystrobin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This is a proposed regulation to establish a temporary tolerance for 1 year for the combined residues of azoxystrobin [methyl (E)-2-{2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate)] and its Z isomer in or on potatoes. This action is in response to Wisconsin potato growers and University extension specialists, Zeneca Ag Products and EPA's combined efforts to generate the information necessary for registration of the reduced risk pesticide, azoxystrobin, on late blight and early blight of potatoes. This proposed temporary tolerance supports a non-crop destruct experimental use permit (EUP) under section 5 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of azoxystrobin on potatoes in Wisconsin. This regulation proposes to establish a maximum permissible level for residues of azoxystrobin in this food commodity pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: Comments must be received on or before September 28, 1998.

ADDRESSES: By mail, submit written comments in triplicate to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, deliver comments to: Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically to: opp-docket@epamail.epa.gov. Follow the instructions under Unit VII. of this document. No Confidential Business Information (CBI) should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential 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. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential will be included in the public docket by EPA without prior notice. The public docket is available for public inspection in Rm. 119 at the Virginia address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: John Bazuin, Registration Division 7505C, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–7381, e-mail: bazuin.john@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, in cooperation with Wisconsin potato growers, University extension specialists, and Zeneca Ag Products, Inc., and pursuant to section 408(e) and (r) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (r), is proposing to establish a temporary tolerance for 1 year for the combined residues of the fungicide azoxystrobin and its Z isomer, in or on potatoes at 0.03 parts per million (ppm).

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq*. The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. These activities are described below and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 FR 58135, November 13, 1996) (FRL–5572–9).

New section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Section 5 of FIFRA authorizes EPA to issue an experimental use permit for a pesticide. This provision was not amended by FQPA. EPA has established regulations governing such experimental use permits in 40 CFR part 172. Section 408(r) of FFDCA authorizes EPA to issue temporary tolerances for pesticide residues resulting from FIFRA experimental use permits.

II. Risk Assessment and Statutory Findings

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings. The Agency has determined that azoxystrobin is a reduced risk pesticide for use on potatoes.

A. Toxicity

1. *Threshold and non-threshold effects*. For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no observed adverse effect level'' or ''NOAEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOAEL from the study with the lowest NOAEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100% or less of the RfD) is generally considered acceptable by EPA. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOAEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This 100–fold MOE is based on the same rationale as the 100–fold uncertainty factor.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short-term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or MOE calculation based on the appropriate NOAEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

2. *Differences in toxic effect due to exposure duration*. The toxicological effects of a pesticide can vary with different exposure durations. EPA considers the entire toxicity data base, and based on the effects seen for different durations and routes of exposure, determines which risk assessments should be done to assure that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include ''acute,'' ''short-term,'' ''intermediate term,'' and ''chronic'' risks. These assessments are defined by the Agency as follows.

Acute risk, by the Agency's definition, results from 1 day consumption of food and water, and reflects toxicity which could be expressed following a single oral exposure to the pesticide residues. High end exposure to food and water residues is typically assumed.

Short-term risk results from exposure to the pesticide for a period of 1 to 7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enaction of FQPA, this assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In this assessment, risks from average food and water exposure, and high-end residential exposure, are aggregated. High-end exposures from all three sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in

this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1 to 7 days exposure, and the toxicological endpoint/NOAEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

Intermediate-term risk results from exposure for 7 days to several months. This assessment is handled in a manner similar to the short-term risk assessment.

Chronic risk assessment describes risk which could result from several months to a lifetime of exposure. For this assessment, risks are aggregated considering average exposure from all sources for representative population subgroups including infants and children.

B. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in ground water or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Dietary exposure to residues of a pesticide in a food commodity is estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children. The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

Percent of crop treated estimates are derived from Federal and private market survey data. Typically, a range of estimates is supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of percent of crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups, to pesticide residues. For this pesticide, the most highly exposed population subgroup (non-nursing infants (<1 year old)) was not regionally based.

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action, EPA has sufficient data to assess the hazards of azoxystrobin and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a temporary tolerance for 1 year for combined residues of azoxystrobin and its Z isomer) on potatoes at 0.03 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects and the Agency's selection of toxicological endpoints upon which to assess risk caused by azoxystrobin are discussed below.

1. *Acute toxicity*. The Agency evaluated the existing toxicology data base for azoxystrobin. No acute dietary endpoint was identified, no developmental toxicity was observed in the rabbit and rat studies reviewed, and no primary neurotoxicity was seen in the acute neurotoxicity study. Therefore, no risk has been identified for this scenario and a risk assessment is not needed.

2. *Short - and intermediate-term toxicity*. The Agency evaluated the existing toxicology data base for short- and intermediate-term dermal and inhalation exposure and determined that this risk assessment is also not required. In a 21–day dermal toxicity study the NOAEL was 1,000 milligrams/kilograms/day (mg/kg/day) at the highest dose tested (acute inhalation toxicity category III).

3. *Chronic toxicity*. EPA has established the RfD for azoxystrobin at 0.18 mg/kg/day. This RfD is based on a chronic toxicity study in rats with a NOAEL of 18.2 mg/kg/day. The endpoint effects were reduced body weights and bile duct lesions at the lowest effect level (LEL) of 34 mg/kg/day. An Uncertainty Factor (UF) of 100 was used to account for both the interspecies extrapolation and the intraspecies variability.

4. *Carcinogenicity*. Carcinogenicity testing of azoxystrobin in two appropriate species of mammals revealed no evidence that this fungicide is carcinogenic. Therefore, EPA classifies azoxystrobin as ''not likely'' to be a human carcinogen in line with the proposed revised cancer guidelines.

B. Exposures and Risks

1. *From food and feed uses*. Permanent tolerances have been established (40 CFR 180.507(a)) for the combined residues of azoxystrobin and its Z isomer, in or on a variety of raw agricultural commodities at levels ranging from 0.01 ppm in pecans to 1.0 ppm in grapes. In addition, time-limited tolerances have been established (40 CFR 180.507(b) at levels ranging from 0.006 ppm in milk to 20 ppm in rice hulls) in conjunction with section 18 requests. Risk assessments were conducted by EPA to assess dietary exposures and risks from azoxystrobin as follows:

i. *Acute exposure and risk*. Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1 day or single exposure. The Agency did not conduct an acute risk assessment because no toxicological endpoint of concern was identified during review of available data.

ii. *Chronic exposure and risk*. In conducting this chronic dietary risk assessment, the Agency has made very conservative assumptions—100% of potatoes and all other commodities having azoxystrobin tolerances will contain azoxystrobin residues and those residues would be at the level of the tolerance—which result in an overestimation of human dietary exposure. Thus, in making a safety determination for this tolerance, EPA is taking into account this conservative

exposure assessment. The existing azoxystrobin tolerances (published, pending, and including the necessary section 18 tolerance(s)) result in a Theoretical Maximum Residue Contribution (TMRC) that is equivalent to the following percentages of the RfD:

Population Sub-Group	TMRC (mg/kg/day)	% RFD
U.S. Population (48 States)	0.003	1.8%
Nursing Infants (<1 year old)	0.004	2%
Non-Nursing Infants (<1 year old)	0.011	8%
Children (1-6 years old)	0.007	4%
Children (7-12 years old)	0.004	2%
Hispanics	0.004	2%
Non-Hispanics Others	0.005	3%
U.S. Population (summer season)	0.003	2%
U.S. Population (Northeast region)	0.003	2%
U.S. Population (Western region)	0.003	2%
U.S. Population (Pacific region)	0.003	2%
Females (13+, nursing)	0.003	2%
Females (13-19, not pregnant or nursing)	0.002	1%

Neither the U.S. population as a whole nor any of the subgroups whose food consumption patterns were analyzed for dietary exposure and risk to azoxystrobin reached even one-twelfth of the RfD under these assumed theoretical maximum exposures to azoxystrobin for all published, pending, and proposed tolerances. Moreover, real-world exposure is likely to be substantially lower than this.

2. *From drinking water.* There is no established Maximum Contaminant Level for residues of azoxystrobin in drinking water. No health advisory levels for azoxystrobin in drinking water have been established.

i. *Acute exposure and risk.* An acute risk assessment was not appropriate since no toxicological endpoint of concern was identified for this scenario during review of the available data.

ii. *Chronic exposure and risk.* Based on the chronic dietary (food) exposure estimates, chronic drinking water levels of concern (DWLOC) for azoxystrobin were calculated and are summarized in the following table. Estimated environmental concentrations (EECs) using GENEEC for azoxystrobin on bananas, grapes, peaches, peanuts, pecans, tomatoes, and wheat are listed in SWAT Team Second Interim Report (June 20, 1997). The highest EEC for azoxystrobin in surface water is from the application of azoxystrobin on grapes (39 µg/L) and is substantially lower than the DWLOCs calculated. Therefore, chronic exposure to azoxystrobin residues in drinking water do not exceed the Agency's level of concern.

	RfD (mg/kg/day)	TMRC [Food Exposure] (mg/kg/day)	Maximum Water Exposure[1] (mg/kg/day)	DWLOC[2,3,4] (µg/L)
U.S. Population (48 States)	0.18	0.0027	0.178	6,200
Females (13 + years old, not pregnant or nursing)	0.18	0.0019	0.178	5,300
Non-nursing Infants (<1 year old)	0.18	0.0113	0.169	1,680

[1] Maximum water exposure (mg/kg/day) = RfD (mg/kg/day) - TMRC from DRES (mg/kg/day)
[2] DWLOC (µg/L) = Max water exposure (mg/kg/day) * body wt (kg)/[(10^{-3} mg/µg)*water consumed daily (L/day)]
[3] HED default body wts for males, females, and children are 70 kg, 60 kg, and 10 kg respectively
[4] HED default daily drinking rates are 2 L/day for adults and 1 L/day for children

3. *From non-dietary exposure.* Azoxystrobin is not currently registered for use on residential non-food sites.

4. *Cumulative exposure to substances with common mechanism of toxicity.* Azoxystrobin is related to the naturally occurring strobilurins. There are no other members of this class of fungicides registered with the Agency. Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

EPA does not have, at this time, available data to determine whether azoxystrobin has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative

risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, azoxystrobin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that azoxystrobin has a common mechanism of toxicity with other substances.

C. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk*. This risk assessment is not necessary since no acute toxicological end-point of concern was identified for this exposure scenario during review of the available data.

2. *Chronic risk*. Using the conservative TMRC exposure assumptions described above, and taking into account the completeness and reliability of the toxicity data, the Agency has estimated that exposure to azoxystrobin from food will utilize 2% of the RfD for the U.S. population as a whole. The Agency generally is not concerned about 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. Despite the potential for exposure to azoxystrobin in drinking water, the Agency does not expect the aggregate exposure to exceed 100% of the RfD. Under current Agency guidelines, the registered non-dietary uses of azoxystrobin do not constitute a chronic exposure scenario and EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to currently registered azoxystrobin residues.

3. *Short- and intermediate-term risk*. Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. This risk assessment is not needed because no dermal or systemic effects were seen in the repeated dose dermal study at the limit dose. Additionally, no indoor or outdoor residential exposure uses are currently registered for azoxystrobin.

D. Aggregate Cancer Risk for U.S. Population

This risk assessment is also not needed. Azoxystrobin is classified as ''not likely'' to be a carcinogen under the proposed revised carcinogenicity guidelines because carcinogenicity testing was performed on two appropriate species and no evidence of carcinogenicity was found.

E. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children— i. In general*. In assessing the potential for additional sensitivity of infants and children to residues of azoxystrobin, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the data base unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for combined inter- and intra-species variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. *Developmental toxicity studies*—a. *Rabbit*. In the developmental toxicity study in rabbits, developmental NOAEL was 500 mg/kg/day, at the highest dose tested (HDT). Because there were no treatment-related effects, the developmental LEL was ≥500 mg/kg/day. The maternal NOAEL was 150 mg/kg/day. The maternal LEL of 500 mg/kg/day was based on decreased body weight gain during dosing.

b. *Rat*. In the developmental toxicity study in rats, the maternal (systemic) NOAEL was not established. The maternal LEL of 25 mg/kg/day at the lowest dose tested (LDT) was based on increased salivation. The developmental (fetal) NOAEL was 100 mg/kg/day (HDT).

iii. *Reproductive toxicity study*—a. *Rat*. In the reproductive toxicity study (MRID No. 43678144) in rats, the parental (systemic) NOAEL was 32.3 mg/kg/day. The parental LEL of 165.4 mg/kg/day was based on decreased body weights in males and females, decreased food consumption and increased adjusted liver weights in females, and cholangitis. The reproductive NOAEL was 32.3 mg/kg/day. The reproductive LEL of 165.4 mg/kg/day was based on increased weanling liver weights and decreased body weights for pups of both generations.

iv. *Conclusion*. The pre- and post-natal toxicology data base for azoxystrobin is complete with respect to current toxicological data requirements. The results of these studies indicate that infants and children are no more sensitive to exposure to azoxystrobin than are adults, based on the results of the rat and rabbit developmental toxicity studies and the 2-generation reproductive toxicity study in rats. Accordingly, EPA has determined that the standard margin of safety will protect the safety of infants and children and the additional tenfold safety factor can therefore be removed.

2. *Chronic risk*. Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to azoxystrobin from food will utilize 2 to 8% of the RfD for infants and children. 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. Despite the potential for exposure to azoxystrobin in drinking water and from non-dietary, non-occupational exposure, EPA does not expect the aggregate exposure to exceed 100% of the RfD. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to azoxystrobin residues.

IV. Other Considerations

A. Metabolism in Plants and Animals

a. *The metabolism of azoxystrobin as well as the nature of the residues is adequately understood for purposes of the temporary tolerance*. Plant metabolism has been evaluated in three diverse crops; grapes, wheat, and peanuts, which is required to define similar metabolism of azoxystrobin in a wide range of crops. Parent azoxystrobin is the major component found in crops. Azoxystrobin does not accumulate in crop seeds or fruits. Metabolism of azoxystrobin in plants is complex, with more than 15 metabolites identified. These metabolites are present at low

levels, typically much less than 5% of the total radioactive residue level.

b. *The qualitative nature of the residue in animals is adequately understood for the purposes of this proposed 1 year temporary tolerance.* Establishment of a temporary tolerance of 0.03 ppm for azoxystrobin in/on potatoes is not expected to lead to detectable azoxystrobin residues in animal commodities.

B. Analytical Enforcement Methodology

An analytical method, gas chromatography with nitrogen-phosphorus detection (GC-NDP) or, in mobile phase, by high performance liquid chromatography with ultraviolet detection (HPLC-UV), is available for enforcement purposes with a limit of detection that allows monitoring of food with residues at or above the level proposed for this temporary tolerance. The Agency has concluded that the method is adequate for enforcement of tolerances in/on other non-oily raw agricultural commodities. The Agency concludes this method is adequate for enforcement of the proposed temporary tolerance in/on potatoes.

C. Magnitude of Residues

Residues of azoxystrobin and its Z isomer are not expected to exceed 0.03 ppm in/on potatoes as a result of the EUP use. A temporary tolerance should be established at this level.

D. International Residue Limits

There are no CODEX, Canadian, or Mexican Maximum Residue Limits for azoxystrobin in/on potatoes.

E. Rotational Crop Restrictions

Rotational crop data were previously submitted. Based on this information, a 45–day plantback interval is appropriate for all crops other than those with azoxystrobin tolerances.

V. Conclusion

A 15–day comment period is being allowed for this proposed rule because of the speed of growth and of resistance development of early and late blight, and because these fungal diseases are so devastating to potato crops once they become established. The Agency desires to be supportive of efforts by potato growers to combat these diseases and to protect their crops. The Agency also desires to be supportive of efforts by researchers to find control methods for the pests early and late blight. Additionally, the Agency feels that there is strong evidence in support of the safety of this proposed action.

Therefore, a temporary tolerance is proposed for 1 year for the combined residues of azoxystrobin and its Z isomer in/on potatoes at 0.03 ppm.

VI. Public Record and Electronic Submissions

The official record for this rulemaking, as well as the public version, has been established for this rulemaking under docket control number ''OPP–300710'' (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 official rulemaking record is located at the Virginia address in ''ADDRESSES'' at the beginning of this document.

Electronic comments can be sent directly to EPA at:

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. Comment and data will also be accepted on disks in Wordperfect 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket control number ''OPP–300710.'' Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries.

VII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This document proposes establishing a temporary tolerance under FFDCA section 408(d). EPA is proposing this regulation in cooperation with Wisconsin potato growers, University extension specialists, and Zeneca Ag Products, Inc. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4). Nor does it require any special considerations as required by Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997).

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601–612), the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, ''entitled Enhancing Intergovernmental Partnerships (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to the Office of Management and Budget (OMB) a description of the extent of EPA's prior consultation with representatives of affected State, local and Tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local and Tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's proposed rule does not create an unfunded Federal mandate on State, local or Tribal governments. The proposed rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this proposed rule.

C. Executive Order 13084

Under Executive Order 13084, entitled ''Consultation and Coordination with Indian Tribal Governments'' (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal

governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the Tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected Tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's proposed rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this proposed rule.

List of Subjects in 40 CFR Part 180

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

Dated: September 2, 1998.

Stephen L. Johnson,

Acting Director, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. Section 180.507(a) is amended by redesignating the existing text as paragraph (a)(1) and adding paragraph (a)(2) to read as follows:

§ 180.507 Azoxystrobin; tolerances for residues.

(a)(1) * * *

(2) *Temporary tolerance*. A tolerance to expire on September 13, 1999 is established for the combined residues of azoxystrobin [methyl (E)-2-{2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate)] and its Z isomer in or on potatoes at 0.03 parts per million (ppm) .

* * * * *

[FR Doc. 98–24338 Filed 9–10–98; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 229

[Docket No. 970129015–8157–07; I.D. 042597B]

RIN 0648–AI84

Taking of Marine Mammals Incidental to Commercial Fishing Operations; Harbor Porpoise Take Reduction Plan Regulations

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; notice of availability of proposed take reduction plan.

SUMMARY: NMFS announces the availability of a proposed harbor porpoise take reduction plan (HPTRP) to reduce the bycatch of harbor porpoise (*Phocoena phocoena*) in gillnet fisheries throughout the stock's U.S. range. NMFS also proposes regulations to implement the HPTRP. The proposed plan, including a discussion of the recommendations of the Gulf of Maine Take Reduction Team (GOMTRT) and the Mid-Atlantic Take Reduction Team (MATRT), is contained in the HPTRP/Environmental Assessment/Initial Regulatory Flexibility Analysis (HPTRP/EA/IRFA), available upon request (see addresses below). Changes to the recommendations of the GOMTRT and the MATRT are described within this document. This action replaces the proposed rule issued on August 13, 1997 (62 FR 43302).

The potential biological removal (PBR) level for Gulf of Maine harbor porpoise throughout their range is 483 animals (62 FR 3005, January 21, 1997). The incidental bycatch of harbor porpoise in the Gulf of Maine (GOM) and Mid-Atlantic gillnet fisheries exceeds the PBR level. The proposed HPTRP would use a wide range of management measures to reduce the bycatch and mortality of harbor porpoise. In the GOM, the HPTRP proposes time and area closures and time/area periods during which pinger use would be required in the Northeast, Mid-coast, Massachusetts Bay, Cape Cod South and Offshore Closure Areas. In the Mid-Atlantic area, the HPTRP proposes time/area closures and modifications to gear characteristics, including floatline length, twine size, tie downs, and number of nets, in the large mesh and small mesh fisheries. NMFS seeks comment on the proposed HPTRP/EA/IRFA, and the proposed regulations to implement the plan.

DATES: Comments due October 13, 1998.

ADDRESSES: Copies of the draft plan prepared by the GOMTRT, the final report from the MATRT and the HPTRP/EA/IRFA may be obtained from Donna Wieting, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910–3226.

FOR FURTHER INFORMATION CONTACT: Donna Wieting, NMFS, 301–713–2322 or Laurie Allen, NMFS, Northeast Region, 978–281–9291.

SUPPLEMENTARY INFORMATION: The 1994 amendments to the Marine Mammal Protection Act (MMPA) require the preparation and implementation of TRPs for strategic marine mammal stocks that interact with Category I or II fisheries. A Category I fishery is a fishery that has frequent incidental mortality and serious injury of marine mammals. A Category II fishery is a fishery that has occasional incidental mortality and serious injury of marine mammals. A Category III fishery is a fishery that has a remote likelihood of causing incidental mortality or serious injury of marine mammals.

This proposed rule addresses preparation and implementation of a take reduction plan (TRP) for harbor porpoise, a strategic marine mammal stock, that interacts with the NE multispecies gillnet fishery and with the Mid-Atlantic coastal gillnet fisheries. The 1996 Stock Assessment Report (SAR) (Waring et al., 1997) states that harbor porpoise bycatch has been observed by the NMFS Sea Sampling program in the following fisheries: (1) the Northeast (NE) multispecies sink gillnet, (2) the mid-Atlantic coastal gillnet, (3) the Atlantic drift gillnet, (4) the North Atlantic bottom trawl fisheries, and (5) the Canadian Bay of Fundy sink gillnet fishery. The fisheries of greatest concern, and the subject of this TRP, are the NE multispecies sink gillnet fishery (Category I), and the Mid-Atlantic coastal gillnet fishery (Category II).

The Atlantic drift gillnet fishery, a Category I fishery, is being addressed by the Atlantic Offshore Cetacean Take Reduction Team (AOCTRT). The North Atlantic bottom trawl fishery is a Category III fishery and is not the subject of take reduction efforts at this time. The Canadian sink gillnet fishery