I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA’s tolerance regulations at 40 CFR part 180 through the Government Printing Office’s eCFR site at http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&htpl=ecfrbrowse/Title40/40tab_02.tpl. To access the OCSPP test guidelines referenced in this document electronically, please go to http://www.epa.gov/ocspp and select “Test Methods and Guidelines.”

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2012–0177 in the subject line on your objection or hearing request with the Hearing Clerk for the OCSPP docket. EPA will consider objections or hearing requests received before August 20, 2013.

II. Summary of Petitioned-for Tolerance

In the Federal Register of May 23, 2012 (77 FR 30481) (FRL–9347–8), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 17956) by Syngenta Crop Protection, LLC., P.O. Box 18300, Greensboro, NC 27419. The petition requested that 40 CFR 180.485 be amended by establishing tolerances for residues of the fungicide cyproconazole, in or on peanut, hay, and peanut, nutmeat; peanut, meal; peanut, butter; and peanut, refined oil at 0.03 ppm. That document referenced a summary of the petition prepared by Syngenta Crop Protection, the registrant, which is available in the docket, http://www.regulations.gov. There were no substantive comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has modified the requested tolerance levels and crops for which tolerances were needed. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

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) of FFDCA 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) of FFDCA requires EPA to give special consideration to the potential exposure of infants and children to the pesticide chemical residue in establishing a...
tollertance 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. . . .”

Consistent with FFDCA section 408(b)(2)(ID), and the factors specified in FFDCA section 408(b)(2)(ID), 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 and to make a determination on aggregate exposure for cyproconazole including exposure resulting from the tolerances established by this action. EPA’s assessment of exposures and risks associated with cyproconazole 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 acute studies demonstrate that cyproconazole is moderately toxic by the oral, dermal, and inhalation routes. It is neither an eye nor dermal irritant. Cyproconazole did not cause dermal sensitization. Consistent with similar anti-fungal pesticide active ingredients in this class (e.g., tetraconazole), the critical toxicological effects for cyproconazole in mammals appear to be indicative of hepatotoxicity. These effects include elevated levels of the liver enzymes lactate dehydrogenase (LDH) and aspartate aminotransferase, increased liver weight (relative and absolute), vacuolization, fatty changes, hepatocytomegaly, hypertrophy, and single-cell necrosis. For both subchronic and chronic durations, hepatotoxicity was observed in rats, mice and dogs, and all of these species appeared to be equally sensitive to cyproconazole toxicity with regards to the range of the doses tested (0.5 to 130 milligrams/kilogram/day (mg/kg/day)). Other notable effects seen in rat subchronic oral feeding studies included increased macrophages in the lung, increased white blood cell counts and globulins, decreased spleen weights, histiocytosis of the spleen, and spleen micropathology.

There are two dermal toxicity studies submitted for cyproconazole, both showing effects similar to the oral studies. In the 21-day study, dermal exposure to cyproconazole resulted in decreased body-weight gain and food consumption (males), increased aspartate aminotransferase (males), increased creatinine (females), and increased cholesterol in both sexes at the highest dose tested (1,250 mg/kg/day). In the 28-day study, toxicity occurred at the mid-dose (100 mg/kg/day). These effects included increased plasma globulin, protein and cholesterol, and hemosiderin deposition in the spleen in females (1,000 mg/kg/day in males), hypertrophy of the thyroid follicular epithelium in both males and females, and increased incidences of centilobular hepatocellular hypertrophy in males (1,000 mg/kg/day in females).

The developmental studies indicate that cyproconazole causes developmental toxicity. There are two developmental toxicity studies in rabbits, which were more sensitive for developmental effects than the rat. In the older study using chinchilla rabbits, the pups showed increased susceptibility with toxicity occurring at the lowest dose tested (2 mg/kg/day, the developmental no observed adverse effect level (NOAEL) was not established). These effects included increased incidences of hydrocephalus internus (abnormal accumulation of cerebral spinal fluid in the ventricles of the brain). The maternal lowest observed adverse effect level (LOAEL) was 10 mg/kg/day. This developmental toxicity study was classified unacceptable and does not satisfy the guideline requirement for a developmental toxicity study (OPPTS Guideline 870.3700; OECD 414) in the rabbit because the concentrations of test material were not within the acceptable range (±15% of nominal concentration) for the mid- and high-dose suspensions immediately after preparation. In the most recent study using New Zealand white rabbits, cyproconazole produced increased incidences of malformed fetuses and litters with malformed fetuses (hydrocephalus and kidney agenesis) at doses lower than the doses that produced maternal toxicity (50 mg/kg/day for dams and 10 mg/kg/day for fetuses). In rats, cyproconazole increased the incidences of supernumerary ribs at the same doses at which maternal adverse effects (decreased body-weight gain) were observed (12 mg/kg/day). There was no evidence of reproductive toxicity in the 2-generation reproduction toxicity study. The parental toxicity in the 2-generation reproduction study was manifested as increased lipid storage and relative liver weights in males and increased relative liver weights in females (8.29 mg/kg/day). No offspring toxicity was observed at any of the doses tested.

Although there was evidence of carcinogenicity found in a mouse study, EPA has determined that cyproconazole is “not likely to be carcinogenic to humans” at doses that do not cause a mitogenic response in the liver (Ref. 1). In contrast to rodent cells, there are some limited data to suggest that constitutive androstane receptor (CAR) activation does not stimulate cell proliferation or inhibit apoptosis in human cells. However, the literature does not yet support the conclusion that CAR activation is not biologically plausible in humans. This conclusion is based on the weight of evidence that supports a non-genotoxic mitogenic mode of action for cyproconazole. The activation of the CAR receptor, the required initiating event, leads to a cascade of key events resulting in liver tumor development in mice. The data did not support: (1) Peroxisome proliferation, (2) mutagenesis, or (3) cytotoxicity followed by sustained regenerative proliferation as alternative modes of action. The quantification of carcinogenic potential is not required. The current reference dose (RfD) of 0.01 mg/kg/day is based on a 1-year dog study in which hepatotoxicity and organ weight changes were seen at 3.2 mg/kg/day and no adverse effects were observed at 1 mg/kg/day (NOAEL). This RfD would be protective of any liver effects caused by cyproconazole in the mouse toxicity studies or mode of action studies at higher doses.

There is no evidence of targeted neurotoxicity in the toxicity database. There were no central nervous system (CNS) malformations present in the developmental toxicity studies in rats and rabbits. In a 2-generation reproduction study in rats, there were no findings in pups that were suggestive of changes in neurological development. Additionally, there was no evidence of neurotoxicity in other studies.

Finally, there is no evidence that cyproconazole is an immunotoxin. Although there is no immunotoxicity study currently available for cyproconazole, the available data indicate that cyproconazole does not have immunotoxic effects. This is consistent with the fact that the target organ is the liver, which is similar to the other triazole fungicides, which do not have immunotoxic effects.

Specific information on the studies received and the nature of the adverse effects caused by cyproconazole as well as the NOAEL and the LOAEL from the toxicity studies can be found at http://www.regulations.gov in document “Cyproconazole, Tolerance Petition for
TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR CYPROCONAZOLE FOR USE IN HUMAN HEALTH RISK ASSESSMENT

<table>
<thead>
<tr>
<th>Exposure scenario</th>
<th>POD</th>
<th>Uncertainty/FQPA SF</th>
<th>RID, PAD, LOC for risk assessment</th>
<th>Study and toxicological effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Dietary (General population, including infants and children).</td>
<td>NOAEL = 2 mg/kg/day</td>
<td>UF_A = 10X, UF_H = 10X, FQPA SF = 1X</td>
<td>aPAD = aRfD = 0.02 mg/kg/day.</td>
<td>A dose and endpoint attributable to a single dose were not identified in the database including the developmental toxicity studies.</td>
</tr>
<tr>
<td>Acute Dietary (Females 13–49 years of age).</td>
<td>NOAEL = 1.0 mg/kg/day</td>
<td>UF_A = 10X, UF_H = 10X, FQPA SF = 1X</td>
<td>cPAD = cRfD = 0.01 mg/kg/day.</td>
<td>Prenatal Developmental toxicity Study—New Zealand white rabbits</td>
</tr>
<tr>
<td>Chronic Dietary (All populations).</td>
<td>NOAEL = 10 mg/kg/day</td>
<td>UF_A = 10X, UF_H = 10X, FQPA SF = 1X</td>
<td>Residential LOC for MOE = 100.</td>
<td>Developmental LOAEL = 10 mg/kg/day based on increased incidence of malformed fetuses and litters with malformed fetuses.</td>
</tr>
<tr>
<td>Short (1–30 days)-and Intermediate (1–6 months)-Term Dermal.</td>
<td>NOAEL = 10 mg/kg/day</td>
<td>UF_A = 10X, UF_H = 10X, FQPA SF = 1X</td>
<td></td>
<td>Chronic oral toxicity study—dog</td>
</tr>
<tr>
<td>Cancer (oral, dermal, inhalation).</td>
<td>EPA has classified cyproconazole as “not likely to be carcinogenic to humans”, according to EPA Proposed Guidelines for Carcinogen Risk Assessment (April 10, 1996).</td>
<td></td>
<td></td>
<td>LOAEL = 3.2 mg/kg/day based on liver effects (P450 induction in females and histopathology, lamellar eosinophilic intrahepatocytic bodies in males).</td>
</tr>
</tbody>
</table>

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligrams/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RID = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. Dietary exposure from food and feed uses. In evaluating dietary exposure to cyproconazole, EPA considered exposure under the petitioned-for tolerances as well as all existing cyproconazole tolerances in 40 CFR 180.485. EPA assessed dietary exposures from cyproconazole in food as follows:
   i. Acute exposure. Quantitative acute dietary exposure and 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. In conducting the acute dietary exposure assessment, EPA used the food consumption data from the U.S. Department of Agriculture’s (USDA) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). This dietary survey was conducted from 2003 to 2008. As to residue levels in food, an unrefined acute dietary exposure and risk analysis was performed assuming tolerance-level residues, 100% crop treated, DEEM (ver. 7.81) default processing factors.
   ii. Chronic exposure. In conducting the chronic dietary exposure assessment, EPA used the food consumption data from the USDA’s NHANES/WWEIA. This dietary survey was conducted from 2003 to 2008. An unrefined chronic dietary exposure and risk analysis was performed assuming tolerance-level residues, 100% crop treated, DEEM (ver. 7.81) default processing factors.
   iii. Cancer. Based on the data summarized in Unit III.A., EPA has concluded that cyproconazole does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.
   iv. Anticipated residue and percent crop treated (PCT) information. EPA did not use anticipated residue and/or PCT information in the dietary assessment for cyproconazole. Tolerance-level


B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see http://www.epa.gov/pesticides/factsheets/riskassess.htm.

A summary of the toxicological endpoints for cyproconazole used for human health risk assessment is shown in Table 1 of this unit.
residues and 100% crop treated was assumed for all food commodities.

2. Dietary exposure from drinking water. The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for cyproconazole in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of cyproconazole. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at http://www.epa.gov/pesticides/science/edwc/index.htm.

Based on the First Index Reservoir Screening Tool (FIRST) and Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of cyproconazole for acute exposures are estimated to be 113 parts per billion (ppb) for surface water and 1.52 ppb for ground water. For chronic exposures for non-cancer assessments are estimated to be 43 ppb for surface water and 1.52 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. Since the EDWC estimates from surface water were higher than those from ground water, EDWC estimates in surface water were used in both acute and chronic dietary risk assessments.

3. From non-dietary exposure. The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiteicides, and flea and tick control on pets).

Cyproconazole is not registered for any specific use patterns that would result in residential handler exposure. Cyproconazole is proposed for use on golf course turf, which may result in post-application dermal exposure to golfers (both adults and children). No chemical-specific data were available to assess potential short-term dermal post-application exposures to adult and youth golfers. Therefore, a series of assumptions and exposure factors served as the basis for completing the residential post-application risk assessment. Each assumption and factor is detailed in the 2012 Residential SOPs (http://www.epa.gov/pesticides/science/residential-exposure-sop.html). Post-application oral and inhalation exposures, as well as residential handler exposures, are not expected based on the current use patterns for cyproconazole. Further information regarding assumptions and generic inputs for residential exposures may be found at http://www.epa.gov/pesticides/trac/science/trac6a05.pdf.

4. Cumulative effects from substances with a common mechanism of toxicity. Section 408(b)(2)(D)(v) of FFDCA 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.”

Cyproconazole is a member of the triazole-containing class of pesticides. Although conazoles act similarly in plants by inhibiting ergosterol biosynthesis, there is not necessarily a relationship between their pesticidal activity and their mechanism of toxicity in mammals. Structural similarities do not constitute a common mechanism of toxicity. Evidence is needed to establish that the chemicals operate by the same, or essentially the same, sequence of major biochemical events (Ref. 2). In conazoles, however, a variable pattern of toxicological responses is found; some are hepatotoxic and hepatocarcinogenic in mice. Some induce thyroid tumors in rats. Some induce developmental, reproductive, and neurological effects in rodents. Furthermore, the conazoles produce a diverse range of biochemical events including altered cholesterol levels, stress responses, and altered DNA methylation. It is not clearly understood whether these biochemical events are directly connected to their toxicological outcomes. Thus, there is currently no evidence to indicate that conazoles share common mechanisms of toxicity and EPA is not following a cumulative risk approach based on a common mechanism of toxicity for the conazoles. For information regarding EPA’s procedures for cumulating effects from substances found to have a common mechanism of toxicity, see EPA’s Web site at http://www.epa.gov/pesticides/cumulative.

Cyproconazole is a triazole-derived pesticide. This class of compounds can form the common metabolite 1,2,4-triazole and two triazole conjugates (triazylolylanine and triazolylacetic acid). To support existing tolerances and to establish new tolerances for triazole-derived pesticides, including cyproconazole, EPA conducted a human health risk assessment for exposure to 1,2,4-triazole, triazolylalanine, and triazolylacetic acid resulting from the use of all current and pending uses of any triazole-derived fungicide. The risk assessment is conservative, screening-level evaluation in terms of hazards associated with common metabolites (e.g., use of a maximum combination of uncertainty factors) and potential dietary and non-dietary exposures (i.e., high end estimates of both dietary and non-dietary exposures). In addition, the Agency retained the additional 10X FQPA Safety Factor for the protection of infants and children. The assessment includes evaluations of risks for various subgroups, including those comprised of infants and children. The Agency’s complete risk assessment is found in the propiconazole registration docket at http://www.regulations.gov, docket identification (ID) number EPA–HQ–OPP–2005–0497.

An updated dietary exposure and risk analysis for the common triazole metabolites 1,2,4-triazole (T), triazolylalanine (TA), triazolylacetic acid (TAA), and triazolylpyruvic acid (TP) was conducted and completed in August 2012, in association with a registration request for the triazole fungicide, propiconazole. Residue data demonstrated that there was no increase in exposure to the common triazole metabolites with the proposed use. The tolerances for cyproconazole in/on peanuts covered by this action are not expected to change the risk of exposure to the triazoles determined in that risk analysis. The document, titled “Common Triazole Metabolites: Updated Aggregate Human Health Risk Assessment to Address the Amended Propiconazole Section 3 Registration to Add Use on Sugarcane” may be found in docket ID number EPA–HQ–OPP–2012–0427.

D. Safety Factor for Infants and Children

1. In general. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. Prenatal and postnatal sensitivity. There are no residual uncertainties with regard to prenatal and postnatal toxicity, and the database is complete for purposes of assessing maternal and postnatal toxicity. There is evidence that cyproconazole is a developmental
toxicant; however, the LOC is low since:
(1) The effects in fetuses are well-characterized with a clear NOAEL and
(2) the developmental toxicity study where increased susceptibility was
observed is being used for the acute dietary endpoint (females 13–49 years),
which will be protective of effects in infants and children. There is no
evidence of reproductive toxicity or neurotoxicity in the cyproconazole
database.

3. Conclusion. EPA has determined that reliable data show the safety of
infants and children would be adequately protected if the FQPA SF
were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for
cyproconazole is complete, except for
an immunotoxicity study. As noted in
Unit III.A., the concern for the lack of this study is low because there is no
evidence that cyproconazole causes
immunotoxic effects. EPA does not
believe that an immunotoxicity study
will result in a lower point of departure
(POD) than that which is currently in
use for overall risk assessment. As such, a
database uncertainty factor is not
necessary to account for the lack of an
immunotoxicity study.

ii. There is no indication that
cyproconazole is a neurotoxic chemical and there is no need for a
developmental neurotoxicity study or additional UF to account for
neurotoxicity.

iii. While there is evidence that exposure to cyproconazole results in
increased susceptibility in in utero rabbits, EPA does not believe that the
FQPA safety factor of 10X is necessary to protect infants and children for the
reasons stated in Unit III.D.2. above.

iv. There are no residual uncertainties
identified in the exposure databases.
EPA made conservative (protective)
assumptions in the ground water and
surface water modeling used to assess exposure to cyproconazole in drinking
dwater. These assessments will not
underestimate the exposure and risks
posed by cyproconazole.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and
chronic dietary pesticide exposures are
safe by comparing aggregate exposure
estimates to the acute PAD (aPAD) and
chronic PAD (cPAD). For linear cancer
risks, EPA calculates the lifetime
probability of acquiring cancer given the
estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are
estimated by comparing the estimated aggregate food, water, and
residential exposure to the appropriate
PODs to ensure that an adequate MOE
exists.

1. Acute risk. Using the exposure assumptions discussed in this unit for
acute exposure, the acute dietary exposure from food and water to
cyproconazole will occupy 32% of the
aPAD for females 13–49 years old. The
acute dietary exposure and risk analysis
was conducted only for females 13–49
years old since an endpoint of concern attributable to a single dose for the
general population was not identified.

2. Chronic risk. Using the exposure assumptions described in this unit for
chronic exposure, EPA has concluded that chronic exposure to cyproconazole
from food and water will utilize 28% of the
cPAD for infants (<1 years old), the
population group receiving the greatest
exposure. There are no residential uses for cyproconazole.

3. Short-term risk. Short-term
aggregate exposure is calculated by
aggregating short-term residential
exposure plus chronic exposure to food
and water (considered to be a
background exposure level). A short-
term adverse effect was identified; however, cyproconazole is not currently
registered for any use patterns that
would result in short-term residential
exposure. In consideration of a pending
turf use for cyproconazole, a short-term
aggregate assessment was completed.
The pending golf course use is the only
use that may result in residential
exposure. The golfer exposure (dermal)
represents the highest residential
exposure of all potential adult exposure
scenarios. Therefore, the short-term
assessment is protective of all potential
exposures resulting from the pending
golf course use. For the short-term
aggregate assessment, the short-term
oral NOAEL of 1.5 mg/kg/day (from the
90-day oral rat study) is compared to the
total (dietary + residential) exposure to
calculate risk. Since the aggregate MOE
are greater than 100, the calculated risks
do not exceed the Agency’s LOCs.

takes into account intermediate-term
residential exposure plus chronic
exposure to food and water (considered
to be a background exposure level). There
are no residential scenarios that
result in intermediate-term exposure;
therefore, an intermediate-term
aggregate exposure and risk assessment
is not required.

5. Aggregate cancer risk for U.S.
population. Although there was
evidence of carcinogenicity found in a
mouse study, EPA has determined that
cyproconazole is not likely to be
carcinogenic to humans” at doses that
do not cause a mitogenic response in the
liver (Ref. 1). As a result, an aggregate
cancer exposure and risk assessment is
not required, as cyproconazole is not
expected to pose a cancer risk to
humans.

6. Determination of safety. Based on
these risk assessments, EPA concludes
that there is a reasonable certainty that
no harm will result to the general
population or to infants and children
from aggregate exposure to
cyproconazole residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adapate enforcement methodology
(gas chromatograph/nitrogen-
phosphorus detection) is available to
enforce the tolerance expression. The
method may be requested from: Chief,
Analytical Chemistry Branch,
Environmental Science Center, 701
Maps Rd., Ft. Meade, MD 20755–5350;
telephone number: (410) 305–2905;
email address: residuemethods@epa.gov.

B. International Residue Limits

In making its tolerance decisions, EPA
seeks to harmonize U.S. tolerances with
international standards whenever
possible, consistent with U.S. food
safety standards and agricultural
practices. EPA considers the
international maximum residue limits
(MRLs) established by the Codex
Alimentarius Commission (Codex), as
required by FFDCA section 408(b)(4).
The Codex Alimentarius is a joint
United Nations Food and Agriculture
Organization/World Health
Organization food standards program,
and it is recognized as an international
food safety standards-setting
organization in trade agreements to
which the United States is a party. EPA
may establish a tolerance that is
different from a Codex MRL; however,
FFDCA section 408(b)(4) requires that
EPA explain the reasons for departing
from the Codex level. The Codex has not
established a MRL for cyproconazole.

C. Revisions to Petitioned-for Tolerances

The Agency is correcting the
commodity terminology for peanut by
establishing a tolerance for peanut,
rather than peanut, nutmeat. In
addition, the Agency has modified the
levels for which tolerances are being
established for peanut (0.03 to 0.01
ppm). Based on an analysis of the
residue data using the OECD tolerance
calculation procedures, the tolerance for
peanut is based on the limit of
quantitation (0.01 ppm). Following
exaggerated-rate applications of
cyproconazole, average residues of
cyproconazole were below the limit of quantitation in/on peanut, meal, refined oil, and butter; therefore, processing factors could not be calculated. Accordingly, separate tolerances for residues of cyproconazole are not required for peanut, meal, refined oil, and peanut butter.

Also, EPA has revised the tolerance expression for cyproconazole 40 CFR 180.485 to clarify:

1. That as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of cyproconazole.

2. That compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

V. Conclusion

Therefore, tolerances are established for residues of cyproconazole, in or on peanut and peanut, hay at 0.01 and 6.0 ppm, respectively.

VI. References

The following is a listing of the documents that are specifically referenced in this rule.


VII. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. 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). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 et seq.), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1994).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 3727 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 et seq.), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the Federal Register. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping.

Dated: June 11, 2013.

Lois Rossi, Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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


2. Section 180.485 is amended as follows:

   a. Revise paragraph (a)(1) introductory text.
   b. Add alphabetically the entries “peanut” and “peanut, hay” to the table in paragraph (a)(1).
   c. Revise paragraph (a)(2) introductory text.
   d. Revise paragraph (a)(3) introductory text.

The amendments read as follows:

§ 180.485 Cyproconazole; tolerances for residues.

(a) * * *(1) Tolerances are established for residues of the free and conjugated forms of the fungicide cyproconazole, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the proposed tolerance levels specified below is to be determined by measuring only cyproconazole (α-(4-chlorophenyl)-α-(1-cyclopropylethyl)-1H-1,2,4-triazole-1-ethanol) in or on the following commodities:

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Parts per million</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peanut</td>
<td>0.01</td>
</tr>
<tr>
<td>Peanut, hay</td>
<td>6.0</td>
</tr>
</tbody>
</table>

(2) A tolerance is established for the combined residues of the free and conjugated forms of the fungicide cyproconazole, including its metabolites and degradates, in or on the commodity in the table below. Compliance with the tolerance level specified below is to be determined by measuring only the sum of cyproconazole (α-(4-chlorophenyl)-α-(1-cyclopropylethyl)-1H-1,2,4-triazole-1-ethanol) and its metabolite β-(4-chlorophenyl)-β,δ-dihydroxy-γ-methyl-1H-1,2,4-triazole-1-hexenoic acid, calculated as the stoichiometric equivalent of cyproconazole, in or on the following commodity:

* * * * * *
Tolerances are established for the combined residues of the free and conjugated forms of the fungicide cyproconazole, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance level specified below is to be determined by measuring only the sum of cyproconazole (α-(4-chlorophenyl)-α-(1-cyclopropylethyl)-11F-1,2,4-triazole-1-ethanol) and its metabolite 2-(4-chlorophenyl)-3-cyclopropyl-1-[1,2,4]triazol-1-yl-butane-2,3-diol, calculated as the stoichiometric equivalent of cyproconazole, in or on the following commodities:

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Tolerance Level</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ppm</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

For further information, contact:

Marlene H. Dortch,
Secretary.

Effective July 22, 2013.

FOR FURTHER INFORMATION CONTACT:
Deborah Dupont, Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This document announces that on June 7, 2013 OMB approved, for a period of three years, the information collection requirements contained in the Commission's Report and Order, FCC 13–4, published at 78 FR 23150, April 18, 2013. The OMB Control Number is 3060–0537. The Commission publishes this notice as an announcement of such approval.

**Synopsis**

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), the FCC is notifying the public that on June 7, 2013 it received OMB approval for the information collection requirements contained in the modifications to the Commission's rules found in 47 CFR 13.9, 13.13(c), 13.17(b), 13.211(e) and 13.217.

Under 5 CFR 13.20, an agency may not conduct or sponsor a collection of information unless it displays a current, valid OMB Control Number.

No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act that does not display a current, valid OMB Control Number. The OMB Control Number is 3060–0537.


The total annual reporting burdens and costs for the respondents are as follows:

<table>
<thead>
<tr>
<th>OMB Control Number</th>
<th>Burden Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>3060–0537</td>
<td>14,796 hours</td>
</tr>
</tbody>
</table>

There is no need for confidentiality.

As required by the Paperwork Reduction Act of 1995, the FCC obtains or retains benefits. Statutory authority for this information collection is contained in 47 U.S.C. 154 and 303 of the Communications Act of 1934, as amended.

**Total Annual Burden:** 14,796 hours

**Total Annual Cost:** N/A

**Privacy Impact Assessment:** N/A

**Nature and Extent of Confidentiality:** There is no need for confidentiality.

**Needs and Uses:** Each COLEM recovering fees from examinees must maintain records of expenses and revenues, frequency of examinations administered, and examination pass rates. Records must cover from January to December 31 of the preceding year and must be submitted as directed by the FCC. Each COLEM must retain records for three years and the records must be made available to the FCC upon request.

The records are journal entries showing revenues collected and expenses incurred. The records may be inspected by FCC field investigators.

The records will provide a vehicle for the FCC to cancel the designation of a person or organization as an examination manager. If the information were not collected, it is conceivable that fraud and abuse could occur in the commercial operator examination program.

Federal Communications Commission.

Marlene H. Dortch,
Secretary.

Effective July 22, 2013.

FOR FURTHER INFORMATION CONTACT:
Deborah Dupont, Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission’s Report and Order, MB Docket No. 12–352, adopted February 28, 2013, and released March 1, 2013. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Information Center, Portals II, 445 12th Street SW., Room CY–A257, Washington, DC 20554. The complete text of this decision also may be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street SW., Room CY–B402, Washington, DC 20554, (800) 378–3160, or via the company's Web site, www.bcpiweb.com. This document does...