

occurs commonly in the environment. In fact, this mode of rapid degradation in the environment is one of the proposed criteria for including a harpin protein in the exemption from the requirement of a tolerance. Specifically, the proposed criterion is "no protein fragments >3.5 kD after 15 minutes degradation with SubtilisinA." Residue studies submitted to support the existing exemption from tolerance demonstrate that harpin protein is not detectable at the time of harvest. In these studies, no harpin protein residues could be detected in samples taken immediately after harpin protein was applied at the maximum application rate. Because there is no detectable residue at harvest, an analytical method is not relevant.

3. *A statement of why an analytical method for detecting and measuring the levels of the pesticide residue are not needed.* No analytical method to detect and measure residues of harpin protein is needed because harpin protein poses no hazard to humans. Results of mammalian toxicology studies conducted at the limit dose indicate no observed adverse effects associated with harpin protein. Moreover, no residues of harpin protein are expected to occur at the time of harvest because harpin protein is rapidly degraded by environmental factors such as microbial digestion and UV irradiation.

#### C. Mammalian Toxicological Profile

Products containing harpin proteins exhibit little or no mammalian toxicity. To qualify for exemption, a harpin protein must exhibit a rat acute oral toxicity lethal dose (LD<sub>50</sub>) of greater than 5,000 mg product/kg body weight Toxicity Category IV. The source(s) of genetic material that encode the harpin protein(s) is limited to bacterial plant pathogens that are not known to be pathogenic to mammals. Harpin proteins must be readily degraded by a proteinase that is representative of environmental conditions. Specifically, there must be no protein fragments of a size greater than 3.5 kD after 15 minutes degradation with SubtilisinA, a proteinase that is common and widespread in the environment. Further, harpin proteins have a nontoxic mode of action; they activate the treated plant's own growth and defense systems. EDEN Bioscience Corporation has concluded that harpin proteins pose no unique or additional risk to children or infants, and proposes an exemption from the requirement of a tolerance for all harpin proteins that meet the following specifications:

1. Consists of a protein <100 kD in size that is acidic pI <7.0, glycine rich

>10% and contains no more than one cystine residue.

2. The source(s) of genetic material encoding the protein are bacterial plant pathogens that are not known to be mammalian pathogens.

3. Elicits the hypersensitive response (HR) which is characterized as rapid, localized cell death in plant tissue after infiltration of harpin into the intercellular spaces of plant leaves.

4. Possesses a common secondary structure consisting of alpha and beta units that form an HR domain.

5. Is heat stable (retains HR activity when heated to 65 °C for 20 minutes).

6. Is readily degraded by a proteinase representative of environmental conditions (no protein fragments >3.5 kDa after 15 minutes degradation with SubtilisinA).

7. Exhibits a rat acute oral toxicity LD<sub>50</sub> of >5,000 mg product/kg body weight.

#### D. Aggregate Exposure

1. *Dietary exposure*—i. *Food.* Because harpin proteins are rapidly degraded in the environment by common proteinases, UV irradiation, and oxidizing agents, no active ingredient residues are detectable, using available methods, on treated crops even immediately after application. Dietary exposure to harpin via consumption of treated food or feed is negligible, if any at all.

ii. *Drinking water.* Harpin proteins readily degraded by common proteinases and UV irradiation, and are highly sensitive to very small amounts of chlorine or similar oxidizing agents as contained in many municipal water systems. Therefore, residues of harpin are unlikely to occur in drinking water or food, given its rapid degradation in soil and water.

2. *Non-dietary exposure.* The company believes that the potential for non-dietary exposure to the general population including infants and children is unlikely as the proposed use sites are primarily commercial, agricultural and horticultural settings and that non-dietary exposures would not be expected to pose any quantifiable risks due to lack of residues of toxicological concern. Increased nondietary exposure of harpin via home and garden use, etc., is not considered likely because of the typically low use rates and volumes, and the lack of persistence of the active ingredient in the environment.

#### E. Cumulative Exposure

Consideration of a common mode of toxicity is not appropriate, given that there is no indication of mammalian

toxicity of harpin protein and no information that indicates that toxic effects would be cumulative with any other compounds. Moreover, harpin proteins do not exhibit a toxic mode of action in its target pests or diseases.

#### F. Safety Determination

1. *U.S. population.* Harpin's lack of toxicity is demonstrated by the results of acute toxicity testing in mammals in which harpin causes no adverse effects when dosed orally at the limit dose for the study. Thus, the aggregate exposure to harpin over a lifetime should pose negligible risks to human health.

2. *Infants and children.* Based on the lack of toxicity and low exposure, there is a reasonable certainty that no harm to infants, children, or adults will result from aggregate exposure to harpin residues. Exempting harpin proteins that meet the specified criteria from the requirement of a tolerance should pose no significant risk to humans or the environment.

#### G. Effects on the Immune and Endocrine Systems

EDEN Bioscience Corporation has no information to suggest that harpin proteins will adversely affect the immune or endocrine systems.

#### H. Existing Tolerances

An existing exemption from tolerance has been established for harpin protein in the United States, 40 CFR 180.1204.

#### I. International Tolerances

EDEN Bioscience Corporation is not aware of any tolerances, exemptions from tolerance or maximum residue levels issued for harpin protein outside of the United States.

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## FEDERAL COMMUNICATIONS COMMISSION

### Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission, Comments Requested

January 16, 2004.

**SUMMARY:** The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act (PRA) of 1995, Public Law 104-13. An agency may not conduct or sponsor a collection of information unless it

displays a currently valid 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 valid control number.

Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

**DATES:** Written Paperwork Reduction Act (PRA) comments should be submitted on or before March 29, 2004. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

**ADDRESSES:** Direct all Paperwork Reduction Act (PRA) comments to Judith B. Herman, Federal Communications Commission, Room 1-C804, 445 12th Street, SW., Washington, DC 20554 or via the Internet to *Judith-B.Herman@fcc.gov*.

**FOR FURTHER INFORMATION CONTACT:** For additional information or copies of the information collection(s), contact Judith B. Herman at 202-418-0214 or via the Internet at *Judith-B.Herman@fcc.gov*.

**SUPPLEMENTARY INFORMATION:** OMB Control No.: 3060-0624.

**Title:** Section 24.103(f), Amendment of the Commission's Rules to Establish New Personal Communications Services.

**Form No.:** N/A.

**Type of Review:** Revision of a currently approved collection.

**Respondents:** Individuals or households, business or other for-profit, not-for-profit institutions, and State, local or tribal government.

**Number of Respondents:** 8.

**Estimated Time Per Response:** 250 hours for nationwide licensees, 50 hours for each regional licensee and 25 hours for each MTA licensee.

**Frequency of Response:** Recordkeeping requirement and every 10 year, 5 years and 1 year reporting requirement (depending upon the license requirement).

**Total Annual Burden:** 770 hours.

**Total Annual Cost:** N/A.

**Needs and Uses:** Section 24.103 requires certain narrowband PCS

licensees to notify the Commission at specific benchmarks that they are in compliance with construction requirements in order to ensure that licensees quickly construct their systems and provide substantial service to licensed areas. Further the reporting and recordkeeping requirements under Section 24.103 will be used to determine whether the proposed partitionee or disaggregate is an entity qualified to obtain a partitioned license or disaggregated spectrum. The Commission is revising this collection because we are planning to combine this information collection with 3060-0625, Amendment of the Commission's Rules to Establish New Personal Communications Services under part 24. Without this information, the Commission would not be able to carry out its statutory responsibilities.

Federal Communications Commission.

**Marlene H. Dortch,**

*Secretary.*

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**BILLING CODE 6712-01-P**

## FEDERAL COMMUNICATIONS COMMISSION

### Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission for Extension Under Delegated Authority

January 16, 2004.

**SUMMARY:** The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act of 1995, Public Law 104-13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid 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 (PRA) that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents,

including the use of automated collection techniques or other forms of information technology.

**DATES:** Persons wishing to comment on this information collection should submit comments March 29, 2004. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

**ADDRESSES:** Direct all Paperwork Reduction Act (PRA) comments to Judith B. Herman, Federal Communications Commission, 445 12th Street, SW., Room 1-C804, Washington, DC 20554 or via the Internet to *Judith-B.Herman@fcc.gov*.

**FOR FURTHER INFORMATION CONTACT:** For additional information or copies of the information collections contact Judith B. Herman at 202-418-0214 or via the Internet at *Judith-B.Herman@fcc.gov*.

**SUPPLEMENTARY INFORMATION:**

**OMB Control No.:** 3060-0702.

**Title:** Amendment of Parts 20 and 24 of the Commission's Rules —Broadband PCS Competitive Bidding and the Commercial Mobile Radio Service Spectrum Cap, Amendment of the Commission's Cellular PCS Cross-Ownership Rule.

**Form No.:** N/A.

**Type of Review:** Extension of a currently approved collection.

**Respondents:** Business or other for profit, not-for-profit institutions, and State, local, or tribal government.

**Number of Respondents:** 150.

**Estimated Time Per Response:** 2.5 hours.

**Frequency of Response:** On occasion reporting requirement, recordkeeping requirement and third party disclosure requirement.

**Total Annual Burden:** 2,251 hours.

**Annual Cost Burden:** \$1,079,000.

**Needs and Uses:** The Universal Licensing System (ULS) establishes streamlined set of rules that minimize filing requirements, eliminates redundant or unnecessary submission requirements; and assures ongoing collection of reliable licensing and ownership data. The recordkeeping and third party disclosure requirements contained in this collection are a result of the elimination of a number of filing requirements. The information collection requirement will enable the Commission to ensure that no bidder gains unfair advantage over other bidders in its spectrum auctions and thus enhance the competitiveness and fairness of its auctions. The information collected will be reviewed and, if warranted, referred to the Commission's