ENVIRONMENTAL PROTECTION AGENCY

[OPP–300407; FRL–4992–4]

RIN 2070–AC54

Pesticides; Status of Dried Commodities as Raw Agricultural Commodities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; Interpretive ruling.

SUMMARY: This notice describes EPA's interpretation of the term ''raw agricultural commodity'' as applied to dried commodities under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.). The statutory definition is not clear, and EPA's current regulatory definition does not augment or improve the statutory language. EPA's interpretation turns on the purpose of the drying rather than the means or degree of the drying. EPA's interpretation is consistent with EPA's current practice and therefore will not require that any dried commodity be reclassified from its designation as a processed food to a raw agricultural commodity or vice versa.

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SUPPLEMENTARY INFORMATION:

I. Introduction

In *Les v. Reilly*, 968 F.2d 985 (9th Cir. 1992), *cert. denied*, 113 S.Ct. 1361 (1993), the Ninth Circuit U.S. Court of Appeals held that the Delaney anti-cancer clause in the food additives provision of the Federal Food, Drug, and Cosmetic Act (FFDCA) was not subject to an exception for pesticide uses which pose a *de minimis* cancer risk. Because the food additives provision applies to pesticides in processed food but not to pesticides in raw agricultural commodities, in the wake of the *Les* decision, a number of people have requested that EPA reclassify certain foods now treated as processed as raw agricultural commodities. This notice explains EPA's interpretation of the term ''raw agricultural commodity'' (RAC) as it pertains to dried agricultural commodities.

II. Background

A. Statutory Background

The FFDCA, 21 U.S.C. 301 et seq., authorizes the establishment by regulation of maximum permissible levels of pesticides in foods. Such regulations are commonly referred to as ''tolerances.'' Without such a tolerance or an exemption from the requirement of a tolerance, a food containing a pesticide residue is ''adulterated'' under section 402 of the FFDCA and may not be legally moved in interstate commerce. 21 U.S.C. 331, 342. EPA was authorized to establish pesticide tolerances under Reorganization Plan No. 3 of 1970. 5 U.S.C. App. at 1343 (1988). Monitoring and enforcement of pesticide tolerances are carried out by the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture.

The FFDCA has separate provisions for tolerances for pesticide residues on raw agricultural commodities (RACs) and for residues on processed food. For pesticide residues in or on RACs, EPA establishes tolerances, or exemptions from tolerances when appropriate, under section 408 of the act. 21 U.S.C. 346a. EPA regulates pesticide residues in processed foods under section 409 of the act, which pertains to ''food additives.'' 21 U.S.C. 348. Maximum residue regulations established under section 409 are commonly referred to as food additive tolerances or food additive regulations (FARs). Section 409 FARs are needed, however, only for certain pesticide residues in processed food. Under section 402(a)(2) of the FFDCA, a pesticide residue in processed food generally will not render the food adulterated if the residue results from application of the pesticide to a RAC and the residue in the processed food when ''ready to eat'' is below the RAC tolerance set under section 408. This exemption in section 402(a)(2) is commonly referred to as the ''flow-through'' provision because it allows the section 408 raw food tolerance to flow through to the processed food form. Thus, a section 409 FAR is only necessary to prevent foods from being deemed adulterated when the concentration of the pesticide residue in a processed food when ready to eat is greater than the tolerance prescribed for the RAC, or if the processed food itself is treated or comes in contact with a pesticide.

To establish a tolerance regulation under section 408, EPA must find that the regulation would ''protect the public health.'' 21 U.S.C. 346a(b). In reaching this determination, EPA is directed to consider, among other things, the ''necessity for the production of an adequate, wholesome, and economical food supply.'' *Id*. Prior to establishing a food additive tolerance under section 409, EPA must determine that the ''proposed use of the food additive [pesticide], under the conditions of use to be specified in the regulation, will be safe.'' 21 U.S.C. 348(c)(3). Section 409 specifically addresses the safety of carcinogenic substances in the so-called Delaney clause, which provides that ''no additive shall be deemed safe if it has been found to induce cancer when ingested by man or animal or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal * * * .'' *Id*. Although EPA has interpreted the general standard under section 408 to require a balancing of risks and benefits, where a pesticide which is an animal or human cancinogen is involved, the section 409 Delaney clause, in contrast to section 408 and FIFRA, explicitly bars such balancing no matter how infintesimal the potential human cancer risk. *Les v. Reilly*, 968 F.2d at 989.

B. Regulatory Background

The consequences of the RAC/processed food determination can be significant. Pesticide residues in RACs do not require section 409 FARs and thus only pesticide residues in processed food face the possibility that they will be evaluated against the Delaney clause. Moreover, it has been EPA's traditional policy to deny a section 408 tolerance for residues of a pesticide in a particular RAC if a section 409 FAR is needed for residues of that pesticide in the processed form of the RAC but such FAR is barred by the Delaney clause. Elsewhere in this issue of the Federal Register, EPA reiterates that policy in a response to a petition filed by the National Food Processors' Association.

Hops growers pressed EPA for several years to reclassify dried hops from a processed food to a RAC. In 1993, EPA granted the hops growers' request (refer to Unit III below in this document). In the wake of the *Les v. Reilly* decision, reclassification requests have increased dramatically. Some of these requests have come in the form of petitions; others have been in comments responding to a petition filed by the National Food Processors Association (58 FR 7470, Feb. 5, 1993), or specific EPA tolerance actions. All of these requests have concerned dried commodities, such as dried fruits.

III. Proper Classification of Dried Commodities

The dried hops situation as well as the many requests EPA has received for reclassification of other dried commodities as RACs persuaded EPA that the classification of dried

commodities generally needed to be evaluated and the regulated community and public apprised of EPA's approach to this issue. Accordingly, in this document, EPA is setting forth its interpretation of how the statutory term ''raw agricultural commodity'' applies to dried commodities.

A. The Statute and Legislative History

A RAC is defined in FFDCA section 201(r) as ''any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.'' 21 U.S.C. 321(r). This definition is further amplified by the statute, EPA's regulations, and the legislative history of section 408 through language which specifies steps which remove a food from its raw or natural state, namely, ''canning, cooking, freezing, dehydrating, or milling.'' Section 402(a)(2), 21 U.S.C. 342(a)(2); 40 CFR 180.1(e); H. Rep. No. 1385, 83d Cong., 2d Sess. 7 (1954) *reprinted in* XII A Legislative History of the Federal Food, Drug, and Cosmetic Act 839 (hereinafter cited as ''Leg. Hist.'').

The legislative history of section 408 explains that the term RAC is intended to apply to ''food in its raw or natural state as usually purchased by the consumer or food processor.'' H. Rep. No. 1385, 83d Cong., 2d Sess. 6 (1954), XII Leg. Hist. 838. Both House and Senate committee reports list the following examples of foods Congress considered to be RACs: ''fresh fruits and vegetables, grains, nuts, eggs, and milk and similar agricultural produce grown or produced at the farm level.'' *Id.*; S. Rep. 1635, 83d Cong., 2d Sess. 6, XII Leg. Hist. at 1014. On the other hand, both reports mention apple juice and applesauce as examples of processed foods not considered to be RACs. Id. The Senate report alone also notes that ''sun-dried or artificially dehydrated fruits'' should not be considered RACs. S. Rep. 1635, 83d Cong., 2d Sess. 6, XII Leg. Hist. at 1014.

The Senate report reference to dried fruits was added in reaction to the confusion of the dried fruit industry concerning the coverage of the term RAC. At the conclusion of the Senate hearing on the pesticides bill, the following colloquy occurred between committee staff and the Commissioner of the FDA:

MR. SNEED. Dr. Crawford, it has come to the attention of the committee that the dried fruit industry is uncertain as to whether that industry is intended to be included under the provisions in this bill. What is your interpretation of the intent of the bill in that regard?

DR. CRAWFORD. We had regarded the term ''raw agricultural commodities'' as used in this bill and as interpreted when used in other statutes that have been on the books for some time as excluding processed foods, and dry [sic] fruits are processed foods.

MR. SNEED. Do you think it is necessary to amend the bill to clarify that matter?

DR. CRAWFORD. I doubt if it is necessary, particularly if the committee report makes that clear.

Residues of Pesticide Chemicals: Hearing Before the Subcomm. on Health of the Senate Comm. on Labor and Public Welfare, 83d Cong., 2d Sess. 90-91 (1954), XII Leg. Hist. at 975-76. Presumably, in referring to ''other statutes,'' Dr. Crawford was referring to the legislation authorizing USDA to establish identity standards for ''raw and processed'' foods. 7 U.S.C. 414. Under that authority, USDA had set identity standards for dried fruits, including ''processed raisins,'' as processed foods. 7 CFR 52.1841 (1953).

Congress briefly revisited this issue in the 1994 Appropriations Bill by barring EPA from spending any money to treat dried hops as a processed food. Pub. L. No. 103-124, Title III, 107 Stat. 1275, 1295 (1993). The legislative history of this measure suggests that Congress believed that EPA had misclassified dried hops given that EPA had treated many other dried commodities (principally, grains) as RACs. 139 Cong. Rec. S12179, S12204 (1993). As a result of the congressional action, EPA issued guidance stating it would treat dried hops as a RAC. PR Notice 93-12 (December 23, 1993).

B. Possible Interpretations

Application of the term RAC is difficult because of the many variations in drying practices. Some crops are dried while still on the vine; others are harvested but left to dry in the field or elsewhere on the farm. Still other crops are dried off the farm in some other location. Many crops are dried at more than one of the above stages. Crops also receive different degrees of drying: for some crops drying results in minimal moisture reduction and for others the moisture reduction is significant. Further, the drying process can be a natural process, an artificial process designed to emulate natural drying, or a wholly artificial process which achieves greater moisture reduction than natural drying. On many occasions, artificial drying is used to speed the natural drying process. Finally, the purposes of drying can differ. In many instances crops are dried as a routine part of storage and transportation. Other crops, however, are dried for the purpose of creating a separately marketable commodity.

The statute does not clearly address the drying issue. As noted, a RAC is defined as ''any food in its raw *or* natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.'' 21 U.S.C. 321(r) (emphasis added). A dried commodity probably could not considered to be ''raw,'' but could be construed to be ''natural.'' Further, the drying of a commodity may qualify as a form of treatment of a commodity in its ''unpeeled natural form.'' On the other hand, Congress in 1958 included ''dehydration'' in a list in FFDCA sec. 402 of procedures intended to exemplify processing. All drying could be regard as dehydrating, and thus a processing step which converts a RAC to a non-RAC processed food. However, if all drying is regarded as processing this appears to read the term ''natural'' out of the statute because it is difficult to identify foods other than dried commodities which could qualify as non-raw natural foods.

The legislative history further clouds the issue. Congress listed two commodities that are commonly dried to some extent, grains and nuts, as RACs. Drying of these commodities occurs by both natural and artificial means. However, the Senate specified that sun-drying or artificial dehydration of fruits removed dried fruits from the RAC category.

EPA has concluded that the statutory guidance provided on this issue is ambiguous. Congress clearly thought some dried commodities would be RACs and others not, but Congress gave EPA little instruction on how to draw the dividing line. With respect to crops allowed to dry on the plant before cutting or harvesting, EPA believes the only reasonable interpretation of the statute is that such commodities are RACs. With respect to crops dried after harvest, EPA considered four approaches to the classification of commodities dried after harvest, which EPA believes are reasonable constructions of the statute. These interpretations are based on the method of drying, the degree of drying, and the purpose of drying.

The first interpretation draws a distinction between RAC drying and non-RAC dehydration based on whether the drying is done by natural or mechanical or artificial means. This approach is based on the fact that, in the statute, the term dehydration is grouped with a number of processes (canning, cooking, freezing, and milling) which generally involve mechanical or artificial as opposed to natural processes. This interpretation, however appears inconsistent with the legislative

history and general purpose of the legislation. The legislative history indicates that two crops that are commonly dried, grains and nuts, should be treated as RACs. However, because most crops that are dried frequently receive a mix of natural and artificial drying, most dried crops, including grains and nuts, would be excluded from section 408 under this interpretation. Additionally, this interpretation is not only inconsistent with Congress' specific direction regarding grains and nuts but with Congress' understanding of section 408 as a comprehensive provision addressing pesticides. Finally, this interpretation—focusing on whether the drying was accomplished by natural or artificial means—would present difficult implementation and enforcement issues. Where the same crop can be dried either naturally or artificially, different lots of the same commodity could be classified differently. From an enforcement perspective, this approach would be unworkable since it is impossible to determine, for example, whether a particular lot of peanuts was dried naturally or artificially.

The second and third alternative interpretations attempt to draw the dividing line between drying and dehydration based on the degree of drying. The second interpretation would categorize as a RAC food which is dried by natural processes (e.g., sunlight) or by an artificial process that emulates the result achieved by natural drying. Any drying that removed more water from the product than could be achieved naturally would be categorized as the processing step dehydration.

This interpretation would shift dried fruits such as raisins from the category of processed food to RAC. As such, it is inconsistent with the direct statement in the Senate committee report on dried fruits.

The third interpretation divides dried foods into RAC and non-RAC foods based solely on the degree of moisture removal that occurs during drying. EPA's experience is that there are two general groups of commodities that are dried: first, the grains, certain legumes (e.g., dried beans and peas), and nuts which are harvested with a moisture content in the range of roughly 15 to 30 percent and are dried to a range of roughly 10 to 20 percent; and second, crops such as fruits, hops, and hays which have a relatively high moisture content at harvest (usually greater than 60 percent) yet are dried to a similar level as the first group. Under the third interpretation, only the significant drying that occurs with this second group (fruits, hops, and hay) would be considered as converting a RAC to a non-RAC processed food. This interpretation shows fidelity to the Senate committee report language on dried fruit, but would require EPA to reclassify two commodities currently classified as raw. First, dried hops would have to be reclassified as a processed food only shortly after Congress barred EPA from regulating dried hops under such a classification. Second, hay would become a processed food. Although the cultural practices in the drying of hay are very similar to raisins, it would seem to strain the common vernacular to speak of hay as a processed food and not as food in its raw or natural state.

The last interpretation draws a distinction between routine drying for storage and transportation purposes and drying intended to create a new product. Under this approach, grains and nuts, and similar commodities such as legumes, hays, and hops, would be treated as RACs because such commodities are routinely dried for storage or transportation purposes. Dried fruits would not be RACs because the drying of these commodities would be done to create a distinct commodity. This approach treats the Senate report's reference to dried fruit not as an example of a process (drying) that removes a food from the RAC category but as a type of food (newly created food products) that would not be considered RACs. Admittedly, this approach is not explicitly endorsed in the legislative history, but this approach does harmonize the various references to specific commodities in the legislative history.

IV. EPA's Interpretation

EPA intends to follow the fourth interpretation that focuses on whether the drying is routinely intended for storage or transportation purposes or is designed to create a new commodity (e.g., converting fresh grapes into raisins). EPA believes this approach best harmonizes the potential conflict between the terms ''natural'' and ''dehydrating'' in the statute, is fully consistent with the legislative history, and, with only one exception (dried hops), mirrors FDA's and EPA's practice over the last 37 years. EPA would note that, as to the one instance in which this interpretation is inconsistent with FDA's and EPA's historical practice (i.e., dried hops), Congress has quite strongly suggested only recently that EPA's classification of that commodity was incorrect and EPA promptly reclassified the commodity.

V. Impacts of EPA Interpretation

The determination that a food or feed commodity is raw or processed assumes significance and has potential impacts only because of the Delaney clause of section 409 of the FFDCA, which prohibits the establishment of processed food tolerances for a pesticide which induces cancer in man or animals.

This interpretation is unlikely to have human health impacts, because EPA would act under its other statutory authorities to revoke any pesticide tolerance (and remove the use) that it determined posed unreasonable risks.

Each of the interpretations considered by the Agency has potential economic impacts upon some commodities. The interpretation defines the universe of commodities potentially subject to the Delaney clause because they are processed. It is not possible to quantify impacts attributable to the various interpretations, however, because other factors are considered in determining whether the Delaney clause actually applies to a processed food tolerance. EPA has discussed those factors more fully in its policy statement on concentration and the definition of ''ready-to-eat,'' issued on June 14, 1995 (60 FR 31300).

The first interpretation, which delineates commodities by type of drying, would leave significant uncertainty about the status of a commodity, since a single commodity could be both raw and processed. For regulatory and enforcement purposes, EPA and FDA would have to treat commodities such as nuts and grains as processed, which would increase the universe of processed commodities potentially subject to the Delaney clause.

The second interpretation would have the least potential economic impact, since it would treat as processed only those commodities dried beyond natural drying. Under this interpretation, dried fruits would likely be treated as RACs, thereby removing them from any potential Delaney impacts, and no current RACs would become processed commodities.

The third interpretation, focussed on the degree of drying, could have the highest potential economic impact. Commodities currently classified as raw which are significantly dried, such as hops and hay, would become processed commodities, while no commodities currently classified as processed would become RACs.

EPA's interpretation, which is based upon the purpose of drying, and which maintains the current classification of all commodities, has potentially

significant impacts upon dried fruits, which are retained as processed commodities.

Under EPA's interpretation, for example, tolerances for raisins as processed foods are subject to the Delaney clause. Under current Agency policies, 8 pesticides (2 insecticides and 6 fungicides) used on grapes that may be processed into raisins could be subject to revocation. If all 8 tolerances are revoked and the uses canceled, EPA's best estimate of the aggregate first year impact to grape growers who use these pesticides is $110 million ($69 million for insecticides and $41 million for fungicides). This estimated impact is for all types of grapes, including those grown for raisins, and represents about 5% of the total value of U.S. grape production. As noted above, because there are numerous other factors which determine whether the Delaney clause actually applies to a processed food tolerance, these impacts could be significantly less.

VI. Regulatory Assessment Requirements

A. Executive Order 12866

Under Executive Order 12866 (50 FR 51735, October 4, 1993), it has been determined that this interpretive rule is a ''significant regulatory action'' because it may raise novel policy issues arising out of legal mandates. Therefore, this interpretive rule was submitted to the Office of Management and Budget (OMB) for review and any changes made during OMB review have been documented in the public record.

B. Regulatory Flexibility Act

This interpretive rule has no direct impact on any entity, including small entities. As noted above, any adverse impacts arise indirectly and solely because of the application of the Delaney clause. Moreover, this interpretive rule does not change the status of any current commodity. I therefore certify that this interpretive rule does not require a separate Impact Analysis under the Regulatory Flexibility Act.

List of Subjects

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

Dated: January 19, 1996.

Lynn R. Goldman,

Assistant Administrator for Prevention, Pesticides and Toxic Substances.

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