SAPT Outages

As noted, certain operators are required to use a preflight availability prediction tool prior to a planned flight. Some operators will use the FAA SAPT for this purpose. The FAA intends that SAPT will be continuously available to operators. However, because unexpected circumstances could lead to a SAPT outage, the inability to access the tool could have an adverse impact on operators with SA-On receivers. As previously noted in Advisory Circular (AC) 90–114, *ADS–B Operations,* ATC will issue a NOTAM announcing when the SAPT is not available.

The FAA understands that a SAPT outage prevents those operators who hold relief under Exemption No. 12555 from confirming the availability of back-up surveillance as required under the exemption's conditions and limitations.[9] It also reduces the ability of non-exemption holders without their own preflight availability prediction tool to determine that a particular operation will meet the performance requirements prior to conducting an operation. The unavailability of the SAPT for brief periods would result in operators having to choose between conducting flights that might result in non-compliance or not conducting an operation that might have complied with ADS–B Out rule performance. The FAA does not intend to inhibit operators from conducting otherwise permissible operations when the SAPT is unavailable. As such, when there is a SAPT outage, the policy described above will apply to operators who rely on the SAPT if their operation falls below the performance requirements.

III. Summary

Unless otherwise authorized by ATC, all aircraft operating in the airspace identified in § 91.225 must comply with the ADS–B Out performance requirements in § 91.227. Under the FAA's revised policy, aircraft equipped with SA-Aware GPS receivers described in this document are not required to perform a preflight service availability prediction, including those aircraft not covered by Exemption 12555. Aircraft equipped with SA-On receivers should continue performing preflight availability predictions and can use the guidance contained in AC 90–114, *ADS–B Operations,* when conducting preflight actions for operations planned within airspace described in § 91.225. Holders of Exemption 12555 must continue to meet the conditions and limitations associated with the exemption. Holders of Exemption 12555 should revise applicable equipage plans to reflect any changes affected by policy contained in this document and submit revised plans to the FAA per conditions specified by the exemption.

As described in this document, there are circumstances outside of an operator's control that may result in a temporary degradation of GPS performance and an apparent violation of § 91.227. An operator may exercise due diligence in performing a preflight availability prediction for its intended route of flight but experience rerouting by ATC after obtaining an initial ATC route clearance, which may cause an unanticipated degradation of performance. Additionally, an operator may encounter actual GPS interference on its intended path of flight, which would affect the ability of an aircraft to meet the performance requirements of § 91.227. Lastly, an operator may not be able to complete a preflight availability prediction for its intended route of flight due to the FAA's SAPT being out of service. As previously explained, the FAA recognizes that these situations are outside of the operator's control. Therefore, the FAA will not take legal enforcement action for apparent noncompliance with § 91.227 due to the circumstances discussed in this document to the extent such an application would impose a standard of conduct wholly outside the operator's control.

IV. Effective Date

Policy in this document is effective immediately and supersedes policy contained in FRN Docket No. FAA–2019–0539. Additional information on the policy described in this document will be contained in the next revision of AC 90–114, *ADS–B Operations.*

Issued in Washington, DC, on May 4, 2022.

Gregory E. Schwab,

Acting Chief of Staff, Air Traffic Organization.

[FR Doc. 2022–09936 Filed 5–9–22; 8:45 am]

BILLING CODE 4910–13–P

[9] The FAA anticipates that any outage would be of short duration and any potential risk would be minimal because, concurrent with the outage, GPS performance would have to fall below rule values on the route of flight and radar coverage would have to be unavailable at the same time and location.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA–2018–C–1007]

Listing of Color Additives Exempt From Certification; Antarctic Krill Meal

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the color additive regulations to provide for the safe use of Antarctic krill meal, composed of the ground and dried tissue of *Euphausia superba,* with or without the lipid fraction, for use in the feed of salmonid fish, to enhance the color of their flesh. We are taking this action in response to a color additive petition (CAP) submitted by Aker BioMarine Antarctic AS (Aker BioMarine or petitioner).

DATES: This rule is effective June 10, 2022. Submit either electronic or written objections and requests for a hearing on the final rule by June 9, 2022. See section XI for further information on the filing of objections.

ADDRESSES: You may submit objections and requests for a hearing as follows. Please note that late, untimely filed objections will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 9, 2022. Objections received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic objections in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Objections submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your objection will be made public, you are solely responsible for ensuring that your objection does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact

information, or other information that identifies you in the body of your objection, that information will be posted on *https://www.regulations.gov.*

• If you want to submit an objection with confidential information that you do not wish to be made available to the public, submit the objection as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper objections submitted to the Dockets Management Staff, FDA will post your objection, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–C–1007 for ''Listing of Color Additives Exempt From Certification; Antarctic Krill Meal.'' Received objections, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit an objection with confidential information that you do not wish to be made publicly available, submit your objections only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Stephen DiFranco, Office of Food Additive Safety (HFS–255), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740–3835, 240–402–2710; or Alexandra Jurewitz, Office of Regulations and Policy (HFS–024), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notification published in the **Federal Register** of April 9, 2018 (83 FR 15089), we announced that we filed a color additive petition (CAP 5C0303) submitted by Aker BioMarine Antarctic AS (Aker BioMarine), c/o Intertek Scientific & Regulatory Consultancy, Rm. 1036, Bldg. A8 Cody Technology Park, Ively Rd., Farnborough, Hampshire, GU14 0LX, United Kingdom. The petition proposed to amend the color additive regulations in part 73 (21 CFR part 73), *Listing of Color Additives Exempt from Certification,* to provide for the safe use of Antarctic krill meal, composed of the ground and dried tissue of *Euphausia superba,* with or without removal of the lipid fraction, for use in the feed of salmonid fish, to enhance the color of their flesh. Aker BioMarine proposed use levels not to exceed 4 percent (weight/weight or w/w) in feed for freshwater salmonids and 12 percent (w/w) in feed for marine salmonids. Antarctic krill meal is primarily intended for use as a nutrient source, partially replacing other meals (especially fish meal) used in the diet of salmonids. Antarctic krill meal is a natural source of astaxanthin, and it has been established that astaxanthin can impart color to the edible tissues of the salmonids.

Antarctic krill meal is not intended to be the sole source of pigmentation in salmonid feed, and other permitted color additives—including other permitted sources of astaxanthin—may be added to achieve the desired level of coloration in the fish flesh. In the **Federal Register** of April 13, 1995 (60 FR 18736), we published a final rule that listed astaxanthin in § 73.35 (21 CFR 73.35) for use in the feed of salmonid fish. In that final rule, we concluded that 80 milligrams (mg) of astaxanthin per kilogram (kg) of finished feed may be safely used to enhance pigmentation of the flesh of salmonid fish, and we limited the astaxanthin content of the finished feed to not more than 80 mg/kg in § 73.35(c)(2). In the **Federal Register** of July 6, 2000 (65 FR 41581 and 65 FR 41584), we published final rules that listed haematococcus algae meal in 21 CFR 73.185 and phaffia yeast in 21 CFR 73.355 as additional sources of astaxanthin permitted for use in the feed of salmonid fish, provided that the quantity of astaxanthin in finished feed from either color additive—when used alone or in combination with other astaxanthin color additive sources listed in part 73—results in no more than 80 mg/kg of astaxanthin in the finished feed. In the **Federal Register** of November 5, 2009 (74 FR 57248), and November 16, 2009 (74 FR 58845), we published final rules that listed astaxanthin dimethyldisuccinate (21 CFR 73.37) and paracoccus pigment (21 CFR 73.352), respectively, as color additive astaxanthin sources permitted in salmonid fish feed with the limitation that they impart no more than 80 mg/kg of astaxanthin when used alone or in combination with other astaxanthin sources listed in part 73 as a condition of use.

Consistent with these regulations, the petitioner proposed that the quantity of astaxanthin in the finished feed contributed by Antarctic krill meal when used under the intended conditions of use, alone or in combination with other permitted sources of astaxanthin, should not exceed 80 mg/kg astaxanthin in the finished feed.

This final rule covers only the intended use of Antarctic krill meal as a color additive in the feed of salmonid fish, as the target animal. Under 21 CFR 70.42, we apply a ''safe-for-use'' principle when evaluating a color additive petition. This approach ensures that each listed color additive will be safe for its intended use or uses in or on food, drugs, or cosmetics. In reviewing this color additive petition for the proposed intended use of Antarctic krill

meal in the feed of salmonid fish, we evaluated the safety of the petitioned use of the additive in the diet of both the target animal and humans. A discussion of this evaluation can be found in sections III and IV of this document. Approvals for other potential uses, such as in non-target animal food, were not the subject of this petition and therefore are not discussed below. However, such approvals may be subject to the provisions of section 409(b) or 721(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 348(b) or 21 U.S.C. 379e(b)) and 21 CFR 570.30 or 71.1.

II. Background

Antarctic krill meal is a brownish-orange powder composed of the cooked, dried, and ground tissue of *Euphausia superba.* To obtain the color additive, Antarctic krill are harvested from Antarctic waters and processed by cooking, drying, and milling to yield whole Antarctic krill meal. The manufacture of defatted Antarctic krill meal includes an additional step of lipid extraction with ethanol. Residual ethanol in the krill biomass is removed by evaporation, yielding defatted Antarctic krill meal. The petition requests approval of the whole Antarctic krill meal and the defatted form of Antarctic krill meal for use as a color additive in salmonid feed.

The primary coloring component in Antarctic krill meal is astaxanthin. Astaxanthin is an oxygenated carotenoid (xanthophyll) with the chemical name 3,3′-dihydroxy-β, β-carotene-4,4′-dione and may consist of cis, trans, and optical isomers. Astaxanthin is found as the mono- and di-astaxanthin esters and as free astaxanthin. Astaxanthin is present at levels of 80 to 170 mg/kg in the whole Antarctic krill meal and 10 to 90 mg/kg in the defatted Antarctic krill meal, calculated as free astaxanthin (Ref. 1).

Ethoxyquin, an additive approved for use in animal feed, may be added as a stabilizer to whole Antarctic krill meal. Under § 573.380 (21 CFR 573.380), ethoxyquin may be safely used in fish feeds as a chemical preservative to retard the oxidation of xanthophylls at a level not to exceed 150 parts per million (150 ppm) in the treated article. The petition proposes the optional addition of ethoxyquin into whole Antarctic krill meal at levels up to 250 mg/kg (250 ppm). When the whole krill meal is formulated with other fish feed ingredients up to a maximum level of 12 percent by weight in feed for marine salmonids and 4 percent by weight in feed for freshwater salmonids to produce a finished feed, the concentration of ethoxyquin from the whole krill meal in the finished feed would be no more than 30 ppm and 10 ppm, respectively.

III. Safety Evaluation

Under section 721(b)(4) of the FD&C Act, a color additive may not be listed for a proposed use unless the data and information available to FDA establish that the color additive is safe for that use. Our color additive regulations at 21 CFR 70.3(i) define ''safe'' to mean that there is convincing evidence establishing with reasonable certainty that no harm will result from the intended use of the color additive. As part of our safety evaluation to establish with reasonable certainty that a color additive is not harmful under its intended conditions of use, we consider the additive's manufacturing and stability; the projected human dietary exposure to the additive and any impurities resulting from the petitioned use of the additive; the additive's toxicological data; and other relevant information (such as published literature) available to us.

Because consumers are not directly exposed to Antarctic krill meal, FDA focused its review on the safety of the substances present in Antarctic krill meal that are deposited in the consumable portions of the fish. We considered the safety of astaxanthin, which is already approved for use in the feed of salmonid fish, as well as the safety of other components found in Antarctic krill meal at levels higher than that in other fish meals, for which Antarctic krill meal is intended to serve as a replacement in salmonid feed. Target animal safety was also evaluated for the salmonids consuming the Antarctic krill meal. Our review was based on the petitioned use in salmonid feed and on human consumption of the consumable portions of these salmonids.

IV. Safety of Petitioned Use of the Color Additive

A. Exposure Estimate

Astaxanthin is found in wild salmonids and is the principal pigment that imparts the pink or red coloring characteristic of the flesh of these fish. As referenced above, astaxanthin is currently approved for use as a color additive in the feed of salmonid fish at levels not to exceed 80 mg/kg of the finished feed. Antarctic krill meal is not intended to be the sole source of pigmentation in salmonid feed, and other permitted sources of astaxanthin may be added in order to achieve the desired level of coloration in the fish flesh. The quantity of astaxanthin in the finished feed contributed by Antarctic krill meal when used under the intended conditions of use, alone or in combination with other permitted sources of astaxanthin, is not to exceed 80 mg/kg astaxanthin. Therefore, the exposure to astaxanthin from the petitioned use of Antarctic krill meal is substitutional for the currently approved uses of astaxanthin, and there would be no increase in human exposure to astaxanthin from this use (Ref. 2).

Additionally, we considered the exposure to astaxanthin from the consumption of wild salmon and the exposure to astaxanthin from the consumption of farm-raised salmonid fish that have been fed approved color additive sources of these carotenoids to be comparable. We conclude that the petitioned use of Antarctic krill meal will not increase the exposure to astaxanthin (Ref. 3).

The petition notes that Antarctic krill meal contains higher levels of fluoride than are present in the fish meal it is intended to partially replace. The petitioner indicated that salmonids that consume a relatively high dietary concentration of fluoride from the petitioned use of Antarctic krill meal may exhibit elevated levels of fluoride in the kidney and bones, but no significant accumulation in the edible tissues (muscle meat and skin) is anticipated. The petitioner indicated that canned salmon may contain bones from the fish that could be consumed by humans. Therefore, we considered fluoride exposure to humans from the consumption of canned salmon (Ref. 2).

B. Toxicological Considerations

To support the safety of the petitioned use of the subject color additive, including astaxanthin, the petitioner noted that synthetically produced and naturally derived astaxanthin has been previously approved for safe use as a color additive in salmonid feed. The petitioner noted that the astaxanthin in Antarctic krill meal occurs in the same optical isomer distribution as is found in wild salmon and in the naturally occurring astaxanthin coloring additives currently permitted for use in salmonid feed. In previous safety evaluations of other sources of astaxanthin, FDA concluded that the esterified forms of astaxanthin that are present in Antarctic krill meal present no additional safety concerns as compared to free astaxanthin because they are converted to the free form during digestion in the fish (Refs. 4 and 5).

The petitioner noted that Antarctic krill meal contains a higher level of

fluoride than is typically present in the fish meal it is intended to partially replace. The petitioner indicated that salmonids that consume an increased dietary concentration of fluoride from the petitioned use of Antarctic krill meal may exhibit elevated levels of fluoride in the kidney and bones. However, no significant accumulation of fluoride in the edible tissues (muscle meat and skin) is anticipated. FDA considered a possible increase in human fluoride exposure due to the consumption of fish fed a diet containing Antarctic krill meal. We concluded that we have no safety concerns regarding the level of fluoride when humans are consuming the flesh of salmonids fed feed containing Antarctic krill meal or when humans are consuming canned salmon made from these fish (Ref. 4).

Regarding the target animal safety of the Antarctic krill meal, the petitioner included data and literature references addressing nutrition, astaxanthin content, and fluoride content of Antarctic krill meal when fed to salmonids. These studies did not reveal any toxicity to the target fish species (Ref. 3).

Based on the substitutional exposure to astaxanthin, the safety of astaxanthin to humans and the target fish species, and our consideration of the fluoride content of the additive, we conclude there is a reasonable certainty of no harm to humans or to the target fish species from the proposed use of Antarctic krill meal.

V. Labeling Requirements

In accordance with § 70.25 (21 CFR 70.25), all color additives must be labeled with sufficient information to assure their safe use and to allow a determination of compliance with any limitations imposed by FDA in other applicable regulations. Therefore, the labeling of the color additive, Antarctic krill meal, and any mixture prepared therefrom, is subject to the requirements of § 70.25.

Under § 70.25(a)(4), an expiration date for a color additive must be stated on its label if stability data require it. The petitioner determined the stability of astaxanthin as a color additive in the product to be approximately 12 months. Although the effect of imparting color may be attenuated after 12 months, the degradation of the astaxanthin-based coloring components does not form any new substances of toxicological concern. FDA finds that because of the potential impact on the stability of astaxanthin in Antarctic krill meal after 12 months, an expiration date must be stated on the label of sealed and open containers, in accordance with § 70.25(a)(4).

In addition to the requirements for labeling the color additive or color additive mixture, the ingredient list on fish feed, to which Antarctic krill meal is added, must identify the presence of the color additive under § 501.4 (21 CFR 501.4). The new regulation, § 73.32(d)(2) (21 CFR 73.32(d)(2)), references § 501.4 to ensure that the presence of Antarctic krill meal as a color additive in the fish feed will be declared on the ingredient label.

The presence of the color additive must be declared on the label of any food. This is to include a declaration on the label of salmonid fish fed feed containing added Antarctic krill meal and on the label of food containing such salmonid fish as an ingredient. Our regulations, at § 101.22(b) (21 CFR 101.22(b)), require a food that bears or contains artificial coloring, such as salmon artificially colored with Antarctic krill meal, to bear labeling even though such food is not in package form. Section 101.22(c) requires that label statements of artificial coloring be likely to be read by the ordinary person under customary conditions of purchase and use of such food. Furthermore, § 101.22(k)(2) requires, in the statement of ingredients for a food to which any coloring has been added, and for which the coloring is not subject to certification, a declaration that makes it clear that a color additive has been used in the food. In addition, the presence of a color additive in a food received in a bulk container that is held at a retail establishment must be declared on the labeling of the bulk container or on a counter card or other similar device under § 101.100(a)(2) (21 CFR 101.100(a)(2)). The ingredient label would alert the consumer that the fish is artificially colored. Without such ingredient labeling, food comprising salmonid fish fed feed with added Antarctic krill meal would be deemed to be misbranded under section 403(k) of the FD&C Act (21 U.S.C. 343(k)), which states that a food shall be deemed to be misbranded if it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact.

Therefore, in accordance with §§ 101.22(b), (c), and (k)(2) and 101.100(a)(2), labeling on any salmonid fish fed feed with added Antarctic krill meal is required to declare the presence of the color additive or color additive mixture. The new regulation, at § 73.32(d)(3), references §§ 101.22(b), (c), and (k)(2) and 101.100(a)(2) to ensure that, at the retail level, the presence of Antarctic krill meal as a color additive in the fish will be declared, and that the labeling of the bulk fish container, including a list of ingredients, will be displayed on the container or on a counter card with similar information.

VI. Conclusion

Based on the data and information in the petition and other available relevant information, we conclude that the petitioned use of Antarctic krill meal, for use as a color additive is safe to the target fish species and to humans who consume this fish, at levels not to exceed 4 percent (w/w) in feed for freshwater salmonids and 12 percent (w/w) in feed for marine salmonids. We further conclude that this color additive will achieve its intended technical effect and is suitable for the petitioned use. Therefore, we are amending the color additive regulations in part 73 to provide for the safe use of this color additive as set forth in this document. In addition, based on the factors in 21 CFR 71.20(b), we conclude that batch certification of Antarctic krill meal is not necessary to protect the public health.

VII. Public Disclosure

In accordance with § 71.15 (21 CFR 71.15), the petition and the documents that we considered and relied upon in reaching our decision to approve the petition will be made available for public disclosure (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 71.15, we will delete from the documents any materials that are not available for public disclosure.

VIII. Analysis of Environmental Impact

We have carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required (Ref. 6). FDA's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

IX. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

X. Section 301(ll) of the FD&C Act

Our review of this petition was limited to section 721 of the FD&C Act. This final rule is not a statement

regarding compliance with other sections of the FD&C Act. For example, section 301(ll) of the FD&C Act (21 U.S.C. 331(ll)) prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act (21 U.S.C. 355), a biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), or a drug or biological product for which substantial clinical investigations have been instituted and their existence has been made public, unless one of the exemptions in section 301(ll)(1) to (4) of the FD&C Act applies. In our review of this petition, we did not consider whether section 301(ll) of the FD&C Act or any of its exemptions apply to food containing this color additive. Accordingly, this final rule should not be construed to be a statement that a food containing this color additive, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll) of the FD&C Act. Furthermore, this language is included in all color additive final rules that pertain to food and therefore should not be construed to be a statement of the likelihood that section 301(ll) of the FD&C Act applies.

XI. Objections

This rule is effective as shown in the **DATES** section, except as to any provisions that may be stayed by the filing of proper objections. If you will be adversely affected by one or more provisions of this regulation, you may file with the Dockets Management Staff (see **ADDRESSES**) either electronic or written objections. You must separately number each objection, and within each numbered objection you must specify with particularity the provision(s) to which you object, and the grounds for your objection. Within each numbered objection, you must specifically state whether you are requesting a hearing on the particular provision that you specify in that numbered objection. If you do not request a hearing for any particular objection, you waive the right to a hearing on that objection. If you request a hearing, your objection must include a detailed description and analysis of the specific factual information you intend to present in support of the objection in the event that a hearing is held. If you do not include such a description and analysis for any particular objection, you waive the right to a hearing on the objection.

Any objections received in response to the regulation may be seen in the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *https://www.regulations.gov.* We will publish notice of the objections that we have received or lack thereof in the **Federal Register**.

XII. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.*

1. Memorandum from E. Miranda-Bermudez, Color Technology Branch, Division of Color Certification and Technology (DCCT), Office of Cosmetics and Colors (OCAC), Center for Food Safety and Applied Nutrition (CFSAN), FDA to S. DiFranco, Division of Food Ingredients (DFI), Office of Food Additive Safety (OFAS), CFSAN, FDA, March 14, 2020.

2. Memorandum from D. Doell, Chemistry Review Team, DFI, OFAS, CFSAN, FDA to S. DiFranco, DFI, OFAS, CFSAN, FDA, March 11, 2020.

3. Memorandum from L. Post, Target Animal Review, Division of Animal Feeds, Office of Surveillance and Compliance, Center for Veterinary Medicine, FDA to S. DiFranco, DFI, OFAS, CFSAN, FDA, July 30, 2019.

4. Memorandum from T. Thurmond, Toxicology Review Team, DFI, OFAS, CFSAN, FDA to S. DiFranco, DFI, OFAS, CFSAN, FDA, March 14, 2020.

5. Memorandum from T. Thurmond, Toxicology Review Team, Division of Petition Review (DPR), OFAS, CFSAN, FDA to F. Ellison, DPR, OFAS, CFSAN, FDA, February 3, 2009.

6. Memorandum from M. Pfeil, Environmental Review Team, Division of Science and Technology, OFAS, CFSAN, FDA to S. DiFranco, DFI, OFAS, CFSAN, FDA, March 23, 2020.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Foods, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of the Food and Drugs, 21 CFR part 73 is amended as follows:

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

■ 2. Add § 73.32 to read as follows:

§ 73.32 Antarctic krill meal.

(a) *Identity.* (1) The color additive Antarctic krill meal consists of the cooked, dried, and ground biomass of whole *Euphausia superba* (Antarctic krill), with or without removal of the lipid fraction. The lipid fraction may be fully or partially extracted with ethanol, followed by removal of residual ethanol, to produce defatted Antarctic krill meal. Whole Antarctic krill meal, produced when the lipid fraction is not removed, may contain ethoxyquin as a preservative.

(2) Color additive mixtures for fish feed use made with Antarctic krill meal may contain only those diluents that are suitable and are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* Antarctic krill meal must conform to the following specifications and must be free from impurities, other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

(1) Physical state, solid.

(2) Ethoxyquin, not more than 250 milligrams per kilogram (mg/kg) (250 parts per million (ppm)) in whole Antarctic krill meal.

(3) Lead, not more than 2 mg/kg (2 ppm).

(4) Arsenic, not more than 5 mg/kg (5 ppm).

(5) Mercury, not more than 1 mg/kg (1 ppm).

(6) Cadmium, not more than 2 mg/kg (2 ppm).

(7) Fluoride, not more than 2,500 mg/kg (2,500 ppm).

(8) Astaxanthin, not more than 170 mg/kg (170 ppm) in whole Antarctic krill meal; not more than 90 mg/kg (90 ppm) in defatted Antarctic krill meal.

(c) *Uses and restrictions.* Antarctic krill meal may be safely used in salmonid feed in accordance with the following prescribed conditions:

(1) The color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish;

(2) The color additive may be used at levels not to exceed 4 percent by weight in freshwater salmonid feed and 12 percent by weight in marine salmonid feed;

(3) The quantity of the color additive incorporated in the feed is such that the finished feed meets the tolerance limitation for ethoxyquin in animal feed prescribed in § 573.380 of this chapter; and

(4) The quantity of astaxanthin in the finished feed, from Antarctic krill meal when used alone or in combination with other astaxanthin color additive sources listed in this part, must not exceed 80 mg/kg astaxanthin (72 grams per ton) in the finished feed.

(d) *Labeling requirements.* (1) The labeling of the color additive and any

premixes prepared therefrom must bear expiration dates for the sealed and open container (established through generally accepted stability testing methods), other information required by § 70.25 of this chapter, a statement of the concentration of ethoxyquin contained therein (whole Antarctic krill meal only), and adequate directions to prepare a final product complying with the limitations prescribed in paragraph (c) of this section.

(2) The presence of the color additive in finished fish feed prepared according to paragraph (c) of this section must be declared in accordance with § 501.4 of this chapter.

(3) The presence of the color additive in salmonid fish that have been fed feeds containing Antarctic krill meal must be declared in accordance with §§ 101.22(b), (c), and (k)(2) and 101.100(a)(2) of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the Federal Food, Drug, and Cosmetic Act.

Dated: May 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–10025 Filed 5–9–22; 8:45 am]

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DEPARTMENT OF JUSTICE

Office of the Attorney General

28 CFR Part 50

[Docket No. OAG 177; AG Order No. 5384–2022]

RIN 1105–AB62

Guidelines and Limitations for Settlement Agreements Involving Payments to Non-Governmental Third Parties

AGENCY: Department of Justice.

ACTION: Interim final rule; request for comments.

SUMMARY: This interim final rule (''rule'') revokes regulations of the Department of Justice (''Department'') that codified a prohibition, subject to limited exceptions, on the inclusion of provisions in settlement agreements directing or providing for a payment or loan, in cash or in kind, to any non-governmental person or entity that is not a party to the dispute. For further information on how the Department intends to approach such settlements going forward, interested parties should consult an Attorney General Memorandum that the Department is issuing on its website in conjunction with this rule. Comments are requested both as to this rule and as to that Memorandum.

DATES:

Effective date: This rule is effective May 10, 2022.

Applicability date: May 5, 2022.

Comments: Comments are due on or before July 11, 2022.

ADDRESSES: To ensure proper handling of comments, please reference Docket No. OAG 177 on all electronic and written correspondence. The Department encourages the electronic submission of all comments through *https://www.regulations.gov* using the electronic comment form provided on that site. For ease of reference, an electronic copy of this document is also available at that website. It is not necessary to submit paper comments that duplicate the electronic submission, as comments submitted to *https://www.regulations.gov* will be posted for public review and are part of the official docket record. However, should you wish to submit written comments through regular or express mail, they should be sent to Robert Hinchman, Senior Counsel, Office of Legal Policy, U.S. Department of Justice, Room 4252 RFK Building, 950 Pennsylvania Avenue NW, Washington, DC 20530. Comments received by mail will be considered timely if they are postmarked on or before July 11, 2022. The electronic Federal eRulemaking portal will accept comments until Midnight Eastern Time at the end of that day.

FOR FURTHER INFORMATION CONTACT: Robert Hinchman, Senior Counsel, Office of Legal Policy, U.S. Department of Justice, telephone (202) 514–8059 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Posting of Public Comments

Please note that all comments received are considered part of the public record and made available for public inspection online at *https://www.regulations.gov.* Information made available for public inspection includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

You are not required to submit personal identifying information in order to comment on this rule. Nevertheless, if you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also locate all the personal identifying information that you do not want posted online in the first paragraph of your comment and identify what information you want the agency to redact. Personal identifying information identified and located as set forth above will be placed in the agency's public docket file, but not posted online.

If you want to submit confidential business information as part of your comment but do not want it to be posted online, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify the confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, the agency may choose not to post that comment (or to post that comment only partially) on *https://www.regulations.gov.* Confidential business information identified and located as set forth above will not be placed in the public docket file, nor will it be posted online.

If you want to inspect the agency's public docket file in person by appointment, please see the **FOR FURTHER INFORMATION CONTACT** section.

II. Discussion

A. Overview

This rule revokes the Department's regulations at 28 CFR 50.28. Going forward, the Department's approach to settlement agreements that direct or provide for a payment or a loan, in cash or in kind, to a non-governmental person or entity that is not a party to the dispute will be governed by a new Attorney General Memorandum being issued on the Department's website concurrently with this rule.

B. Background

For decades prior to 2017, Department components had entered into settlement agreements that involved payments to certain third parties as a means of addressing harms arising from violations of Federal law, particularly in the environmental context but in other contexts as well. In 2017, the Attorney General issued a memorandum prohibiting Department attorneys from ''enter[ing] into any agreement on behalf of the United States in settlement of federal claims or charges, including agreements settling civil litigation, accepting plea agreements, or deferring or declining prosecution in a criminal