

Issued in Washington, DC, on October 10, 2014.

**John Barbagallo,**

*Deputy Director, FAA Flight Standards Service.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 73

[Docket No. FDA-2014-C-1552]

#### Colorcon, Inc.; Filing of Color Additive Petition

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of petition.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by Colorcon, Inc., proposing that the color additive regulations be amended to provide for the safe use of spirulina extract as a color additive in coating formulations applied to dietary supplement and drug tablets and capsules.

**DATES:** The color additive petition was filed on September 22, 2014.

**FOR FURTHER INFORMATION CONTACT:** Molly A. Harry, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 240-402-1075.

**SUPPLEMENTARY INFORMATION:** Under section 721(d)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379e(d)(1)), we are giving notice that we have filed a color additive petition (CAP 4C0300), submitted by Colorcon, Inc., 275 Ruth Rd., Harleysville, PA 19438. The petition proposes to amend the color additive regulations in 21 CFR part 73 *Listing of Color Additives Exempt From Certification* to provide for the safe use of spirulina extract as a color additive in coating formulations applied to dietary supplement and drug tablets and capsules.

We have determined under 21 CFR 25.32(r) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: October 16, 2014.

**Dennis M. Keefe,**

*Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.*

[FR Doc. 2014-25089 Filed 10-21-14; 8:45 am]

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## DEPARTMENT OF EDUCATION

### 34 CFR Parts 75 and 77

RIN 1855-AA10

[Docket ID ED-2014-OII-0116]

#### Direct Grant Programs and Definitions That Apply to Department Regulations

**AGENCY:** Office of Innovation and Improvement, Department of Education.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** On August 13, 2013, the Department of Education (the Department) published a notice of final regulations in the **Federal Register** to amend our Education Department General Administrative Regulations (EDGAR).

In this document, the Department proposes to further amend EDGAR to add a definition of “What Works Clearinghouse Evidence Standards” (WWC Evidence Standards) in our regulations to standardize references to this term. In addition, the Department proposes to amend the definition of “large sample” in our regulation. We also propose technical edits to our regulations to improve the consistency and clarity of the regulations. Finally, we propose to redesignate our regulations and to include in that redesignated section an additional provision that would allow the Secretary to give special consideration to projects supported by evidence of promise.

**DATES:** We must receive your comments on or before December 8, 2014.

**ADDRESSES:** Submit your comments through the Federal eRulemaking Portal or via postal mail, commercial delivery, or hand delivery. We will not accept comments submitted by fax or by email or those submitted after the comment period. To ensure that we do not receive duplicate copies, please submit your comments only once. In addition, please include the Docket ID at the top of your comments.

• *Federal eRulemaking Portal:* Go to [www.regulations.gov](http://www.regulations.gov) to submit your comments electronically. Information on using [Regulations.gov](http://Regulations.gov), including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under “Are you new to the site?”

• *Postal Mail, Commercial Delivery, or Hand Delivery:* If you mail or deliver your comments about these proposed regulations, address them to Alli Moss, U.S. Department of Education, 400 Maryland Avenue SW., Room 4W319, Washington, DC 20202.

*Privacy Note:* The Department’s policy is to make all comments received from members of the public available for public viewing in their entirety on the Federal eRulemaking Portal at [www.regulations.gov](http://www.regulations.gov). Therefore, commenters should be careful to include in their comments only information that they wish to make publicly available.

**FOR FURTHER INFORMATION CONTACT:**

Allison Moss, U.S. Department of Education, 400 Maryland Avenue SW., Room 4W319, Washington, DC 20202. Telephone: (202) 205-7726 or by email: [allison.moss@ed.gov](mailto:allison.moss@ed.gov).

If you use a telecommunications device for the deaf (TDD) or text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1-800-877-8339.

**SUPPLEMENTARY INFORMATION:** The Department published a notice of final regulations in the **Federal Register** (78 FR 49338) on August 13, 2013 to amend EDGAR. In this document, we propose further amendments to EDGAR to standardize a term and make other amendments to improve the consistency and clarity of these regulations.

*Invitation to Comment:* We invite you to submit comments regarding these proposed regulations. To ensure that your comments have maximum effect in developing the final regulations, we urge you to identify clearly the specific section or sections of the proposed regulations that each of your comments addresses and to arrange your comments in the same order as the proposed regulations.

We invite you to assist us in complying with the specific requirements of Executive Orders 12866 and 13563 and their overall requirement of reducing regulatory burden that might result from these proposed regulations. Please let us know of any further ways we could reduce potential costs or increase potential benefits while preserving the effective and efficient administration of the Department’s programs and activities.

During and after the comment period, you may inspect all public comments about these proposed regulations by accessing [Regulations.gov](http://Regulations.gov). You may also inspect the comments in person in Room 4W335, 400 Maryland Avenue SW., Washington, DC, between 8:30 a.m. and 4:00 p.m., Washington, DC

time, Monday through Friday of each week except Federal holidays. Please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

*Assistance to Individuals with Disabilities in Reviewing the Rulemaking Record:* On request we will provide an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for these proposed regulations. If you want to schedule an appointment for this type of accommodation or auxiliary aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

## Background

### *References to the WWC Handbook*

The Department proposes to add a definition of “What Works Clearinghouse Evidence Standards” to 34 CFR part 77. This definition would incorporate the most recent version of the What Works Clearinghouse (WWC) Procedures and Standards Handbook (WWC Handbook), Version 3.0, which was made public in March 2014. Instead of continuing to separately cite the WWC Handbook in various provisions of parts 75 and 77, we propose to add, to part 77, a single definition of the WWC Evidence Standards that incorporates the current version of the WWC Handbook, and then to use that defined term, as applicable, throughout parts 75 and 77.

The WWC Handbook, first published in 2008, documents the systematic review process and the standards by which the WWC reviews studies. Version 3.0 of the WWC Handbook significantly expands the examples used to illustrate how the WWC Evidence Standards are applied in various contexts. Although previous versions of the WWC Handbook focused on only one WWC product—the intervention report—Version 3.0 includes information on several additional WWC products, including practice guides, single-study reviews, and quick reviews.

By adding a definition of “WWC Evidence Standards” and updating the applicable references throughout 34 CFR parts 75 and 77 to incorporate the most recent version of the WWC Handbook, the Department will provide more effective guidance to applicants and grantees as they design and implement rigorous evaluations of their projects. Because Version 3.0 of the WWC Handbook provides further clarification, and does not introduce new requirements, on evaluation- and evidence-related concepts, updating the

citations does not substantively change the regulations in 34 CFR parts 75 or 77.

## Special Consideration for Discretionary Grant Applications Demonstrating “Evidence of Promise”

Section 75.266 currently provides that the Secretary may give special consideration, through establishing a separate competition or awarding competitive preference, to discretionary grant applications supported by strong evidence of effectiveness or moderate evidence of effectiveness. In our experience using evidence in discretionary grant competitions, we think it may be beneficial to also include in 34 CFR 75.266 (which we propose to redesignate as 34 CFR 75.226) a provision for giving special consideration to applications supported by evidence of promise, which is a less rigorous standard, because evidence of effectiveness in the education field continues to develop. By including evidence of promise in newly redesignated 34 CFR 75.226, we would allow more flexibility to discretionary grant programs oriented towards supporting evidence-based projects.

### Definition of “Large Sample”

The Department proposes to modify the definition of “large sample” in 34 CFR part 77.1 to remove the requirement that analysis units be randomly assigned to treatment or control groups. In implementing our discretionary grant programs, we discovered a discrepancy between the existing definition, specifically its references to random assignment of students, teachers, classrooms, schools, or other single analysis units to treatment or control groups, and the definition of “moderate evidence of effectiveness” in 34 CFR 77.1. Under the definition of “moderate evidence of effectiveness,” a quasi-experimental design study (as defined in 34 CFR 77.1) that includes a large sample could meet the standard, but many such studies do not randomly assign units of analysis to treatment or control groups. We propose to revise the definition of “large sample” to eliminate the random assignment of analysis units into treatment or control groups as a mandatory element. Therefore, for instance, a quasi-experimental design study with a sample of 350 or more students (or other single analysis units), or 50 or more groups (such as classrooms or schools) that contains 10 or more students, could meet the definition of “moderate evidence of effectiveness” in 34 CFR 77.1.

## Significant Proposed Regulations

We group major issues according to subject, with appropriate sections of the proposed regulations referenced in parentheses. We discuss other substantive issues under the sections of the proposed regulations to which they pertain.

Generally, we do not address proposed regulatory changes that are technical or otherwise minor in effect.

### I. WWC Evidence Standards (34 CFR Parts 75 and 77)

*Current Regulations:* The current regulations include multiple references to the WWC Evidence Standards, in each case accompanied by a footnote citing the WWC Handbook, throughout 34 CFR parts 75 and 77, as follows:

1. Factors (viii) and (ix) of the selection criterion “Quality of the project evaluation” in 34 CFR 75.210(h); and
2. Definitions in 34 CFR 77.1(c) of “evidence of promise,” “moderate evidence of effectiveness,” “quasi-experimental design study,” “randomized controlled trial,” and “strong evidence of effectiveness.”

*Proposed Regulations:* In each provision of 34 CFR parts 75 and 77 that references the WWC Evidence Standards, we propose to update the reference to use a common term, and to define that term in part 77 with reference to Version 3.0 of the WWC Handbook.

*Reasons:* By updating all references to WWC Evidence Standards in 34 CFR parts 75 and 77, and adding a common definition that references Version 3.0 of the WWC Handbook, we would: (1) Help ensure that applicants and grantees are aware of the most accurate and appropriate resources that are available relating to the WWC Evidence Standards; (2) no longer need the multiple footnotes that reference the current version of the WWC Handbook; and (3) streamline the process for updating our regulations to reflect future versions of the WWC Handbook.

### II. Special Consideration of Applications Supported by “Evidence of Promise” and Clarification of That Definition (34 CFR 77.1(c))

*Current Regulations:* Under 34 CFR 75.266, the Secretary may give special consideration to applications supported by strong or moderate evidence of effectiveness, by establishing a separate competition or awarding competitive preference. In 34 CFR 77.1(c), the definition of “evidence of promise” references “quasi-experimental study” instead of “quasi-experimental design

study,” a term defined later in the section.

*Proposed Regulations:* We propose to amend 34 CFR 75.266 to provide that the Secretary may give special consideration to applications supported by evidence of promise, and to redesignate that section as 34 CFR 75.226. We also propose to amend the definition of “evidence of promise” to replace the reference to “quasi-experimental study” with “quasi-experimental design study,” to clarify that the term used in the definition of “evidence of promise” is “quasi-experimental design study,” which is defined in 34 CFR 77.1(c). We also propose to change the paragraph designations in this definition for consistency.

*Reasons:* We propose these changes in order to provide greater flexibility to discretionary grant programs that reward evidence-based projects in their competitions, to correct the definition of “evidence of promise,” and to provide applicants and grantees consistent and clear information when referencing that definition. We propose to redesignate 34 CFR 75.266 as 34 CFR 75.226 so that the section will be included under the subheading “Selection Procedures” in subpart D of part 75 instead of under the subheading “Miscellaneous.”

### III. Definition of “Large Sample” (34 CFR 77.1(c))

*Current Regulations:* In 34 CFR 77.1(c), the definition of “large sample” currently refers to students, classrooms, schools, groups, or other single analysis units that “were randomly assigned to a treatment or control group.”

*Proposed Regulations:* We propose to remove the reference to random assignment to treatment or control groups in the definition of “large sample.”

*Reasons:* We propose this change to eliminate inconsistencies between the definition of “large sample” and the definition of “moderate evidence of effectiveness.” We do not believe that random assignment to a treatment or control group is necessary because the concept of random assignment is embedded within the definition of randomized controlled trial (as defined in 34 CFR 77.1(c)). In order for the “large sample” definition to align fully with the “moderate evidence of effectiveness” definition, the “large sample” definition must not require that units of analysis be randomly assigned into treatment or control groups.

### Executive Orders 12866 and 13563

#### Regulatory Impact Analysis

Under Executive Order 12866, the Secretary must determine whether this regulatory action is “significant” and, therefore, subject to the requirements of the Executive order and subject to review by the Office of Management and Budget (OMB). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action likely to result in a rule that may—

(1) Have an annual effect on the economy of \$100 million or more, or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities in a material way (also referred to as an “economically significant” rule);

(2) Create serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles stated in the Executive order.

This proposed regulatory action is not a significant regulatory action subject to review by OMB under section 3(f) of Executive Order 12866.

We have also reviewed these regulations under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only upon a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account—among other things and to the extent practicable—the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives—such as user fees or marketable permits—to encourage the desired behavior, or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency “to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.” The Office of Information and Regulatory Affairs of OMB has emphasized that these techniques may include “identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes.”

We are issuing these proposed regulations only on a reasoned determination that their benefits would justify their costs. In choosing among alternative regulatory approaches, we selected those approaches that would maximize net benefits. Based on the analysis that follows, the Department believes that these proposed regulations are consistent with the principles in Executive Order 13563.

We also have determined that this regulatory action would not unduly interfere with State, local, and tribal governments in the exercise of their governmental functions.

In accordance with both Executive orders, the Department has assessed the potential costs and benefits, both quantitative and qualitative, of this regulatory action. The potential costs associated with this regulatory action are those resulting from statutory requirements and those we have determined to be necessary for administering the Department’s programs and activities.

#### Clarity of the Regulations

Executive Order 12866 and the Presidential memorandum “Plain Language in Government Writing” require each agency to write regulations that are easy to understand.

The Secretary invites comments on how to make these proposed regulations easier to understand, including answers to questions such as the following:

- Are the requirements in the proposed regulations clearly stated?
- Do the proposed regulations contain technical terms or other wording that interferes with their clarity?
- Does the format of the proposed regulations (grouping and order of sections, use of headings, paragraphing, etc.) aid or reduce their clarity?
- Would the proposed regulations be easier to understand if we divided them into more (but shorter) sections? (A

“section” is preceded by the symbol “§” and a numbered heading; for example, § 77.1 Definitions that apply to Department regulations.)

- Could the description of the proposed regulations in the **SUPPLEMENTARY INFORMATION** section of this preamble be more helpful in making the proposed regulations easier to understand? If so, how?

- What else could we do to make the proposed regulations easier to understand?

To send any comments that concern how the Department could make these proposed regulations easier to understand, see the instructions in the **ADDRESSES** section.

#### *Regulatory Flexibility Act Certification*

The Secretary certifies that these proposed regulations would not have a significant economic impact on a substantial number of small entities because the proposed regulations primarily clarify and update regulations previously published in the **Federal Register**.

#### *Paperwork Reduction Act of 1995*

These proposed regulations do not contain any changes to the Department's current information collection requirements.

#### *Intergovernmental Review*

These proposed regulations affect direct grant programs of the Department that are subject to Executive Order 12372 and the regulations in 34 CFR part 79. One of the objectives of the Executive order is to foster an intergovernmental partnership and a strengthened federalism. The Executive order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

This document provides early notification of our specific plans and actions for these programs.

#### *Assessment of Educational Impact*

In accordance with section 411 of the General Education Provisions Act, 20 U.S.C. 1221e-4, the Secretary particularly requests comments on whether these proposed regulations would require transmission of information that any other agency or authority of the United States gathers or makes available.

**Accessible Format:** Individuals with disabilities can obtain this document in an accessible format (e.g., braille, large print, audiotape, or compact disc) on request to the person listed under **FOR FURTHER INFORMATION CONTACT**.

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You may also access documents of the Department published in the **Federal Register** by using the article search feature at: [www.federalregister.gov](http://www.federalregister.gov). Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department. (Catalog of Federal Domestic Assistance Number does not apply.)

#### **List of Subjects**

##### *34 CFR Part 75*

Accounting, Copyright, Education, Grant programs-education, Inventions and patents, Private schools, Reporting and recordkeeping requirements.

##### *34 CFR Part 77*

Education, Grant programs-education.

Dated: October 15, 2014.

**Arne Duncan**,  
Secretary of Education.

For the reasons discussed in the preamble, the Secretary proposes to amend parts 75 and 77 of title 34 of the Code of Federal Regulations as follows:

#### **PART 75—DIRECT GRANT PROGRAMS**

■ 1. The authority citation for part 75 continues to read as follows:

**Authority:** 20 U.S.C. 1221e-3 and 3474, unless otherwise noted.

■ 2. Section 75.210 is amended by revising paragraphs (h)(2)(viii) and (ix) to read as follows.

##### **§ 75.210 General selection criteria.**

\* \* \* \* \*

(h) \* \* \*

(2) \* \* \*

(viii) The extent to which the methods of evaluation will, if well-implemented, produce evidence about the project's effectiveness that would meet the What Works Clearinghouse Evidence Standards without reservations. \* \* \*

(ix) The extent to which the methods of evaluation will, if well-implemented, produce evidence about the project's

effectiveness that would meet the What Works Clearinghouse Evidence Standards with reservations.

\* \* \* \* \*

■ 3. Section 75.266 is redesignated as § 75.226 and the newly redesignated section is revised to read as follows:

#### **§ 75.226 What procedures does the Secretary use if the Secretary decides to give special consideration to applications supported by strong evidence of effectiveness, moderate evidence of effectiveness, or evidence of promise?**

(a) As used in this section, “strong evidence of effectiveness” is defined in 34 CFR 77.1(c);

(b) As used in this section, “moderate evidence of effectiveness” is defined in 34 CFR 77.1(c);

(c) As used in this section, “evidence of promise” is defined in 34 CFR 77.1(c); and

(d) If the Secretary determines that special consideration of applications supported by strong evidence of effectiveness, moderate evidence of effectiveness, or evidence of promise is appropriate, the Secretary may establish a separate competition under the procedures in 34 CFR 75.105(c)(3), or provide competitive preference under the procedures in 34 CFR 75.105(c)(2), for applications supported by:

(1) Evidence of effectiveness that meets the conditions set out in paragraph (a) of the definition of “strong evidence of effectiveness” in 34 CFR 77.1(c);

(2) Evidence of effectiveness that meets the conditions set out in either paragraph (a) or (b) of the definition of “strong evidence of effectiveness” in 34 CFR 77.1(c);

(3) Evidence of effectiveness that meets the conditions set out in the definition of “moderate evidence of effectiveness;” or

(4) Evidence of effectiveness that meets the conditions set out in the definition of “evidence of promise.”

(Authority: 20 U.S.C. 1221e-3 and 3474.)

#### **PART 77—DEFINITIONS THAT APPLY TO DEPARTMENT REGULATIONS**

■ 4. The authority citation for part 77 continues to read as follows:

**Authority:** 20 U.S.C. 1221e-3 and 3474, unless otherwise noted.

■ 5. In § 77.1 paragraph(c) is amended by:

■ A. Revising the definitions of *Evidence of promise*, *Large sample*, *Moderate evidence of effectiveness*, *Quasi-experimental design study*, *Randomized controlled trial*, and *Strong evidence of effectiveness*.

■ B. Adding, in alphabetical order, the definition of *What Works Clearinghouse Evidence Standards*.

The revisions and addition read as follows:

§ 77.1 Definitions that apply to all Department programs.

\* \* \* \* \*
(c) \* \* \*
\* \* \* \* \*

Evidence of promise means there is empirical evidence to support the theoretical linkage(s) between at least one critical component and at least one relevant outcome presented in the logic model for the proposed process, product, strategy, or practice. Specifically, evidence of promise means the conditions in paragraphs (a) and (b) of this section are met:

- (a) There is at least one study that is a—
(1) Correlational study with statistical controls for selection bias;
(2) Quasi-experimental design study that meets the What Works Clearinghouse Evidence Standards with reservations; or
(3) Randomized controlled trial that meets the What Works Clearinghouse Evidence Standards with or without reservations.

(b) The study referenced in paragraph (a) found a statistically significant or substantively important (defined as a difference of 0.25 standard deviations or larger) favorable association between at least one critical component and one relevant outcome presented in the logic model for the proposed process, product, strategy, or practice.

Large sample means an analytic sample of 350 or more students (or other single analysis units), or 50 or more groups (such as classrooms or schools) that contain 10 or more students (or other single analysis units).

Moderate evidence of effectiveness means one of the following conditions is met:

- (a) There is at least one study of the effectiveness of the process, product, strategy, or practice being proposed that meets the What Works Clearinghouse Evidence Standards without reservations, found a statistically significant favorable impact on a relevant outcome (with no statistically significant and overriding unfavorable impacts on that outcome for relevant populations in the study or in other studies of the intervention reviewed by and reported on by the What Works Clearinghouse), and includes a sample that overlaps with the populations or

settings proposed to receive the process, product, strategy, or practice.

- (b) There is at least one study of the effectiveness of the process, product, strategy, or practice being proposed that meets the What Works Clearinghouse Evidence Standards with reservations, found a statistically significant favorable impact on a relevant outcome (with no statistically significant and overriding unfavorable impacts on that outcome for relevant populations in the study or in other studies of the intervention reviewed by and reported on by the What Works Clearinghouse), includes a sample that overlaps with the populations or settings proposed to receive the process, product, strategy, or practice, and includes a large sample and a multi-site sample. (Note: multiple studies can cumulatively meet the large and multi-site sample requirements as long as each study meets the other requirements in this paragraph.)

Quasi-experimental design study means a study using a design that attempts to approximate an experimental design by identifying a comparison group that is similar to the treatment group in important respects. These studies, depending on design and implementation, can meet What Works Clearinghouse Evidence Standards with reservations (but not What Works Clearinghouse Evidence Standards without reservations).

Randomized controlled trial means a study that employs random assignment of, for example, students, teachers, classrooms, schools, or districts to receive the intervention being evaluated (the treatment group) or not to receive the intervention (the control group). The estimated effectiveness of the intervention is the difference between the average outcomes for the treatment group and for the control group. These studies, depending on design and implementation, can meet What Works Clearinghouse Evidence Standards without reservations.

Strong evidence of effectiveness means one of the following conditions is met:

- (a) There is at least one study of the effectiveness of the process, product, strategy, or practice being proposed that meets the What Works Clearinghouse Evidence Standards without reservations, found a statistically significant favorable impact on a relevant outcome (with no statistically significant and overriding unfavorable impacts on that outcome for relevant populations in the study or in other

studies of the intervention reviewed by and reported on by the What Works Clearinghouse), includes a sample that overlaps with the populations and settings proposed to receive the process, product, strategy, or practice, and includes a large sample and a multi-site sample. (Note: multiple studies can cumulatively meet the large and multi-site sample requirements as long as each study meets the other requirements in this paragraph.)

- (b) There are at least two studies of the effectiveness of the process, product, strategy, or practice being proposed, each of which: Meets the What Works Clearinghouse Evidence Standards with reservations, found a statistically significant favorable impact on a relevant outcome (with no statistically significant and overriding unfavorable impacts on that outcome for relevant populations in the studies or in other studies of the intervention reviewed by and reported on by the What Works Clearinghouse), includes a sample that overlaps with the populations and settings proposed to receive the process, product, strategy, or practice, and includes a large sample and a multi-site sample.

What Works Clearinghouse Evidence Standards means the standards set forth in the What Works Clearinghouse Procedures and Standards Handbook (Version 3.0, March 2014), which can be found at the following link: http://ies.ed.gov/ncee/wwc/DocumentSum.aspx?sid=19.

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 222

[Docket No. 140829733-4733-01]

RIN 0648-BE35

2015 Annual Determination To Implement the Sea Turtle Observer Requirement

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

ACTION: Proposed rule.

SUMMARY: The National Marine Fisheries Service (NMFS) publishes a proposed Annual Determination (AD) for 2015, pursuant to its authority under