



DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Document Number AMS-NOP-19-0053; NOP-19-02]

RIN 0581-AD92

National Organic Program; Proposed Amendments to the National List of Allowed and Prohibited Substances per April 2019 NOSB Recommendations (Livestock and Handling)

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend the National List of Allowed and Prohibited Substances (National List) section of the United States Department of Agriculture's (USDA's) organic regulations to implement recommendations submitted to the Secretary of Agriculture (Secretary) by the National Organic Standards Board (NOSB). This rule proposes to add the following substances to the National List: oxalic acid dihydrate as a pesticide for organic apiculture; pullulan for use in organic handling in products labeled, "Made with organic (specified ingredients or food group(s))"; and collagen gel casing as a nonorganic agricultural substance for use in organic handling when organic forms of collagen gel casing are not commercially available.

DATES: Comments must be received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Interested persons may comment on the proposed rule using the following procedures:

Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments.

Mail: Robert Pooler, Standards Division, National Organic Program, USDA-AMS-NOP, 1400 Independence Ave., SW, Room 2642-S., Ag Stop 0268, Washington, DC 20250-0268.

Telephone: (202) 720-3252.

Instructions: All submissions received must include the docket number AMS-NOP-19-0053, NOP-19-02, and/or Regulatory Information Number (RIN) 0581-AD83 for this rulemaking.

When submitting a comment, clearly indicate the proposed rule topic and section number to which the comment refers. In addition, comments should clearly indicate whether the commenter supports the action being proposed and, also clearly indicate the reason(s) for the position. Comments can also include information on alternative management practices, where applicable, that support alternatives to the proposed amendments. Comments should also offer any recommended language change(s) that would be appropriate to the position. Please include relevant information and data to support the position such as scientific, environmental, manufacturing, industry, or impact information, or similar sources. Only relevant material supporting the position should be submitted. All comments received will be posted without change to <https://www.regulations.gov>.

Document: To access the document and read background documents or comments received, go to <https://www.regulations.gov>. Comments submitted in response to this proposed rule will also be available for viewing in person at USDA-AMS, National Organic Program, Room 2642-South Building, 1400 Independence Ave., SW., Washington, DC, from 9 a.m. to 12 noon and from 1 p.m. to 4 p.m. Eastern Time, Monday through Friday (except official Federal holidays).

Persons wanting to visit the USDA South Building to view comments received in response to this proposed rule are requested to make an appointment in advance by calling (202) 720-3252.

FOR FURTHER INFORMATION CONTACT: Robert Pooler, Standards Division, National Organic Program. Telephone: (202) 720-3252.

SUPPLEMENTARY INFORMATION:

I. Background

On December 21, 2000, the Secretary established the National List within part 205 of the USDA organic regulations (7 CFR 205.600 through 205.607). The National List identifies the synthetic substance allowances and the nonsynthetic substance prohibitions in organic farming. The National List also identifies synthetic and nonsynthetic nonagricultural substances and nonorganic agricultural substances that may be used in organic handling.

The Organic Foods Production Act of 1990, as amended (7 U.S.C. 6501–6524) (OFPA), and the USDA organic regulations specifically prohibit the use of any synthetic substance in organic production and handling unless the synthetic substance is on the National List. Section 205.105 also requires that any nonorganic agricultural and any nonsynthetic nonagricultural substance used in organic handling be on the National List. Under the authority of OFPA, the National List can be amended by the Secretary based on recommendations presented by the NOSB. Since the final rule establishing the National Organic Program (NOP) became effective on October 21, 2002, USDA’s Agricultural Marketing Service (AMS) has published multiple rules amending the National List.

This proposed rule addresses NOSB recommendations to amend the National List that were submitted to the Secretary on April 26, 2019. Table 1 summarizes the proposed changes to the National List based on these NOSB recommendations.

Table 1. Substances being added to the National List or current listings being amended.

| Substance | National List Section | Proposed rule action |
|-----------------------|-----------------------|----------------------|
| Oxalic acid dihydrate | § 205.603 | Add to National List |
| Pullulan | § 205.605 | Add to National List |
| Collagen gel casing | § 205.606 | Add to National List |

II. Overview of Proposed Amendments

The following provides an overview of the proposed amendments to designated sections of the National List regulations:

§ 205.603 Synthetic substances allowed for use in organic livestock production.

Oxalic acid dihydrate

The proposed rule would amend the National List to add oxalic acid dihydrate to § 205.603 as a synthetic substance allowed for use in livestock production. Table 2 illustrates the proposed listing.

Table 2. Proposed rule action for oxalic acid dihydrate.

| | |
|------------------------------|--|
| Current rule: | N/A |
| Proposed rule action: | Add oxalic acid dihydrate to § 205.603(b). |

On October 3, 2017, AMS received a petition to add oxalic acid dihydrate to the National List as a parasiticide treatment of *Varroa destructor* (“*Varroa*”) mites in beehives.¹ Oxalic acid is a naturally occurring substance and oxalic acid dihydrate is produced through a chemical process. The EPA has approved the use of oxalic acid dihydrate to control *Varroa* mites (EPA Registration no. 91266-1).² Oxalic acid dihydrate may be applied to beehives by solution or vapor treatment and to package bees by solution. According to the petition, the only treatment

¹ Oxalic acid petition: <https://www.ams.usda.gov/sites/default/files/media/OxalicAcidPetition10032017.pdf>.

²U.S. Environmental Protection Agency, Notice of Pesticide Registration, March 10, 2015, https://www3.epa.gov/pesticides/chem_search/ppls/091266-00001-20150310.pdf.

for controlling *Varroa* mite infestation in beehives that is currently available to organic honey producers is formic acid.

In its recommendation to add oxalic acid dihydrate to the National List, the NOSB noted that formic acid hive fumigation may be detrimental to the bee brood. The NOSB determined that oxalic acid dihydrate would provide organic honey producers with a substance that may be an alternative to, or used in rotation with, formic acid to lessen the potential for pesticide resistance.

The NOSB reviewed and considered this petition, a technical report, and public comments on oxalic acid dihydrate at its public meeting on April 26, 2019.^{3,4} At this meeting, the NOSB determined that adding oxalic acid dihydrate to the National List is consistent with the OFPA criteria. In its recommendation to add oxalic acid dihydrate as a pesticide in apiculture, the NOSB noted that there were no environmental concerns with this substance, it would provide additional use benefits over formic acid, and would be supported by beekeepers.⁵

AMS reviewed the petition, technical report, and NOSB's recommendation for oxalic acid dihydrate. AMS concurs with the NOSB's determination that oxalic acid dihydrate, when manufactured as described in the petition, is a synthetic substance.

To address the NOSB's recommendation, AMS is proposing to add oxalic acid dihydrate to the National List as an allowed pesticide only in apiculture. As described in the petition, the only effective *Varroa* mite treatment on the National List that is currently available to organic honey producers is formic acid. Sucrose octanoate esters is also on the National List as a

³ Technical Evaluation Report for oxalic acid dihydrate:

<https://www.ams.usda.gov/sites/default/files/media/OxalicAcidTR.pdf>.

⁴ Access to written and oral public comments submitted for the April 2019 NOSB meeting is available here:

<https://www.ams.usda.gov/event/national-organic-standards-board-nosb-meeting-seattle-wa>

⁵ NOSB recommendation for oxalic acid dihydrate:

<https://www.ams.usda.gov/sites/default/files/media/LSOxalicAcidApril2019FinalRec.pdf>.

treatment for *Varroa* mite infestation. However, there are no current EPA registered products for sucrose octanoate esters, and the NOSB has recommended that sucrose octanoate esters be removed from the National List.⁶ AMS agrees with the NOSB recommendation that it is necessary for organic producers to have another substance, in addition to formic acid, to control *Varroa* mite infestation. Oxalic acid dihydrate may be used in place of formic acid because of lower toxicity to the bee brood or in rotation with formic acid to reduce the potential for pesticide resistance. Consequently, this proposed rule would allow oxalic acid dihydrate as a pesticide in organic apiculture.

§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

Pullulan

The proposed rule would amend the National List to add pullulan to § 205.605(a) as an ingredient allowed in products labeled, “Made with organic (specified ingredients or food group(s)).” Table 3 illustrates the proposed listing.

Table 3. Proposed rule action for pullulan.

| | |
|------------------------------|-------------------------------|
| Current rule: | N/A |
| Proposed rule action: | Add pullulan to § 205.605(a). |

On January 31, 2018, AMS received a petition⁷ to add pullulan as a nonsynthetic substance allowed for use in organic handling as an ingredient in tablets and capsules for dietary supplements labeled “made with organic (specified ingredients or food group(s)).” Pullulan, as described in a technical report solicited by the NOSB, is a natural extracellular polysaccharide

⁶ NOSB recommendation (October 2018) available at: <https://www.ams.usda.gov/sites/default/files/media/LS2020SunsetFinalRecOct2018.pdf>.

⁷ Pullulan petition: <https://www.ams.usda.gov/sites/default/files/media/PullulanPetition18131.pdf>.

excretion resulting from carbohydrate fermentation by the yeast-like fungus *Aureobasidium pullulans* and other non-toxic fungi strains.⁸ The fungus *A. pullulans* is ubiquitous in nature and is most common in temperate zones in locations such as forest soil, freshwater, on plant leaves, and on seeds. The technical report also explains that the U.S. Food and Drug Administration (FDA) allows pullulan for use as a tablet coating, as an excipient, and as an alternative to gelatin in capsule production. Pullulan has been self-affirmed as GRAS (Generally Recognized as Safe) for specified uses in food including as an emulsifier, nutrient supplement, thickener, and texturizer (GRN No. 99).⁹

At its April 26, 2019, public meeting, the NOSB considered the petition, technical report, and public comments, and determined that (1) pullulan is a nonsynthetic substance and (2) the use of pullulan as an ingredient used in tablets and capsules for dietary supplements is consistent with the OFPA evaluation criteria for National List substances. Therefore, the NOSB recommended adding pullulan to § 205.605(a) as a nonsynthetic, nonagricultural substance allowed for use in organic handling.¹⁰

AMS has reviewed the NOSB recommendation on pullulan and agrees that pullulan, as petitioned, is a nonsynthetic, nonagricultural substance that meets the OFPA criteria for listing as a substance allowed for use in organic handling. AMS recognizes that other manufacturing methods may yield pullulan which could be classified as agricultural and certified organic. Consistent with the NOSB recommendation, AMS proposes to amend the National List by adding pullulan for use in tablets and capsules for dietary supplements labeled “Made with

⁸ Pullulan technical report:
<https://www.ams.usda.gov/sites/default/files/media/PullulanTechnicalReportFinal09072018.pdf>.

⁹ GRAS Notice (GRN) No. 99, “Pullulan,” available at:
<https://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices>

¹⁰ NOSB Pullulan recommendation:
<https://www.ams.usda.gov/sites/default/files/media/HSPullulanApr2019FinalRec.pdf>.

organic (specified ingredients and food group(s)).” AMS welcomes additional information on the proposed classification of pullulan as a nonsynthetic, nonagricultural substance and whether it may be certifiable as organic.

§ 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.”

Collagen gel casing

The proposed rule would amend the National List to add collagen gel casing as a nonorganic agricultural substance listed in § 205.606 for use in organic handling.

Table 4. Proposed rule action for collagen gel casing.

| | |
|------------------------------|---------------------------------------|
| Current rule: | N/A |
| Proposed rule action: | Add collagen gel casing to § 205.606. |

On February 23, 2018, AMS received a petition to add collagen gel to the National List for use in organic handling as an ingredient in a co-extrusion organic sausage production system.¹¹ The petition explains that in sausage production collagen gel forms an edible film that binds and forms the meat, acts as a protective barrier, and is an ingredient in the final product. Collagen gel is an alternative to natural (animal byproducts) or manufactured (cellulose) casings traditionally used in sausage production. Collagen gel, as described in the petition, is derived from animal collagen that has been subjected to a limited (partial) protein hydrolysis via acid/base treatment, and a particle size reduction through a physical sieve. Water is then added to the resulting collagen pulp and the mixture is physically agitated to produce a gel. The final step involves lowering the gel pH to a range of 2.4 – 2.8 with an acid treatment.

¹¹ Collagen gel petition: <https://www.ams.usda.gov/sites/default/files/media/CollagenGelPetition.pdf>.

At its April 26, 2019, public meeting, the NOSB considered the petition to add collagen gel to the National List for use in organic handling. As part of its review, the NOSB considered a technical report on collagen gel that described its manufacture, industry uses, chemical properties, and regulation.¹² The USDA Food Safety and Inspection Service regulates collagen gel as an ingredient in meat products (9 CFR 319.104 and 319.140).

After considering the petition, technical report, and public comments on collagen gel, the NOSB determined that the allowance of nonorganic collagen gel for use as an ingredient in organic handling is consistent with the OFPA evaluation criteria for National List substances.¹³ The NOSB handling subcommittee discussed the collagen gel manufacturing process and considered whether this process induces change in the collagen chemical structure which would classify this as a synthetic substance. The NOSB determined that it is an agricultural substance and should be listed in § 205.606 because the collagen protein is denatured, but the structure is not chemically changed. Subsequently, the NOSB recommended adding collagen gel casing to § 205.606 as a nonorganically produced agricultural product allowed as an ingredient in or on processed products labeled as “organic” when organic forms are not commercially available.

AMS has reviewed the NOSB recommendation on collagen gel and agrees that collagen gel meets the OFPA evaluation criteria for an allowed substance on the National List. AMS is proposing to list collagen gel casing as a nonorganic agricultural ingredient allowed when an organic form is not commercially available. This action would require organic handlers to source

¹² Collagen gel technical evaluation report:
<https://www.ams.usda.gov/sites/default/files/media/CollagenGelGelatinCasingsTechnicalReport01282019.pdf>.

¹³ NOSB recommendation, collagen gel:
<https://www.ams.usda.gov/sites/default/files/media/HSCollagenGelApr2019FinalRec.pdf>.

organic forms of collagen gel before using any nonorganic source of this ingredient. If the organic form of the ingredient is not commercially available, the nonorganic form may be used.¹⁴

AMS is seeking comment on whether collagen gel is properly classified as an agricultural substance and could potentially be certified organic. According to the collagen gel petition, the manufacturing process includes a procedure that adjusts the pH of the gel to a target range between 2.4 – 2.8 (strongly acidic) by treating it with three acids: acetic, lactic, and hydrochloric acids. AMS welcomes additional information on whether the use of acid induces chemical change(s) in the collagen gel which should cause the substance to be classified as a nonagricultural, synthetic substance.¹⁵

III. Related Documents

AMS published a notice in the Federal Register (83 FR 60373) on November 26, 2018, announcing the Spring 2019 NOSB meeting. This notice invited public comments on the NOSB recommendations on the substances addressed in this proposed rule.

IV. Statutory and Regulatory Authority

The OFPA authorizes the Secretary to make amendments to the National List based on recommendations developed by the NOSB. Sections 6518(k) and 6518(n) of the OFPA authorize the NOSB to develop recommendations for submission to the Secretary to amend the National List and establish a process by which persons may petition the NOSB for the purpose of having substances evaluated for inclusion on or deletion from the National List. Section 205.607 of the USDA organic regulations permits any person to petition to add or remove a substance from the National List and directs petitioners to obtain the petition procedures from USDA. The

¹⁴ See 7 CFR 205.606 and 7 CFR 205.2 for definition of “Commercially available.”

¹⁵ A change in collagen gel’s chemical structure would potentially categorize it as a synthetic substance, as defined by the OFPA (7 U.S.C. 6502(22)).

current petition procedures published in the Federal Register (81 FR 12680, March 10, 2016) for amending the National List can be accessed through the NOP Program Handbook on the NOP Web site at <https://www.ams.usda.gov/rules-regulations/organic/handbook>.

A. Executive Orders 12866 and 13771, and Regulatory Flexibility Act

This action falls within a category of regulatory actions that the Office of Management and Budget (OMB) has exempted from Executive Order 12866. Additionally, because this proposal does not meet the definition of a significant regulatory action, it does not trigger the requirements contained in Executive Order 13771. *See* OMB's Memorandum titled "Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017 titled 'Reducing Regulation and Controlling Regulatory Costs'" (February 2, 2017).

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) requires agencies to consider the economic impact of each rule on small entities and evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the market. The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to the action. Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

The Small Business Administration (SBA) sets size criteria for each industry described in the North American Industry Classification System (NAICS) to delineate which operations qualify as small businesses. The SBA has classified small agricultural producers that engage in crop and animal production as those with average annual receipts of less than \$1,000,000. Handlers are involved in a broad spectrum of food production activities and fall into various categories in the NAICS Food Manufacturing sector. The small business thresholds for food

manufacturing operations are based on the number of employees and range from 500 to 1,250 employees, depending on the specific type of manufacturing. Certifying agents fall under the NAICS subsector, “All other professional, scientific and technical services.” For this category, the small business threshold is average annual receipts of less than \$16.5 million.

AMS has considered the economic impact of this proposed rulemaking on small agricultural entities. Data collected by the USDA National Agricultural Statistics Service (NASS) and the NOP indicate most of the certified organic production operations in the United States would be considered small entities. According to the 2017 Census of Agriculture, 18,166 organic farms in the United States reported sales of organic products and total farmgate sales in excess of \$7.2 billion.¹⁶ Based on that data, organic sales average \$400,000 per farm. Assuming a normal distribution of producers, we expect that most of these producers would fall under the \$750,000 sales threshold to qualify as a small business.

According to the NOP’s Organic Integrity Database, there are 19,671 organic handlers that are certified under the USDA organic regulations.¹⁷ The Organic Trade Association’s 2018 Organic Industry Survey has information about employment trends among organic manufacturers. The reported data are stratified into three groups by the number of employees per company: less than 5; 5 to 49; and 50 plus. These data are representative of the organic manufacturing sector and the lower bound (50) of the range for the larger manufacturers is significantly smaller than the SBA’s small business thresholds (500 to 1,250). Therefore, AMS expects that most organic handlers would qualify as small businesses.

¹⁶ U.S. Department of Agriculture, National Agricultural Statistics Service. 2017 Census of Agriculture. https://www.nass.usda.gov/Publications/AgCensus/2017/Full_Report/Volume_1,_Chapter_1_US/. The number of organic farms includes both certified and exempt farms.

¹⁷ Organic Integrity Database: <https://organic.ams.usda.gov/Integrity/>. Accessed on April 13, 2020.

The USDA has 78 accredited certifying agents who provide organic certification services to producers and handlers. The certifying agent that reports the most certified operations, nearly 3,500, would need to charge approximately \$4,200 in certification fees in order to exceed the SBA's small business threshold of \$15 million. The costs for certification generally range from \$500 to \$3,500, depending on the complexity of the operation. Therefore, AMS expects that most of the accredited certifying agents would qualify as small entities under the SBA criteria.

The economic impact on entities affected by this rule would not be significant. The effect of this proposed rule would be to allow the use of three additional substances in organic crop production and organic handling. Adding three substances to the National List would increase regulatory flexibility and would give small entities more tools to use in day-to-day operations.

AMS welcomes public comment on our assessment of costs and benefits and whether commenters have any additional information that would help establish that the action has total costs less than zero and therefore qualifies as an EO 13771 deregulatory action. One way to have 'costs less than zero' is to show that the rule allows business activity that is not allowed under the current regulations. Providing the monetary amount of such allowed business activity would be ideal.

B. Executive Order 12988.

Executive Order 12988 instructs each executive agency to adhere to certain requirements in the development of new and revised regulations in order to avoid unduly burdening the court system. This proposed rule is not intended to have a retroactive effect. Accordingly, to prevent duplicative regulation, states and local jurisdictions are preempted under the OFPA from creating programs of accreditation for private persons or state officials who want to become certifying

agents of organic farms or handling operations. A governing state official would have to apply to USDA to be accredited as a certifying agent, as described in section 6514(b) of the OFPA. States are also preempted under sections 6503 through 6507 of the OFPA from creating certification programs to certify organic farms or handling operations unless the state programs have been submitted to, and approved by, the Secretary as meeting the requirements of the OFPA.

Pursuant to section 6507(b)(2) of the OFPA, a state organic certification program that has been approved by the Secretary may, under certain circumstances, contain additional requirements for the production and handling of agricultural products organically produced in the state and for the certification of organic farm and handling operations located within the state. Such additional requirements must (a) further the purposes of the OFPA, (b) not be inconsistent with the OFPA, (c) not be discriminatory toward agricultural commodities organically produced in other States, and (d) not be effective until approved by the Secretary.

In addition, pursuant to section 6519(c)(6) of the OFPA, this proposed rule would not supersede or alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601–624), the Poultry Products Inspection Act (21 U.S.C. 451–471), or the Egg Products Inspection Act (21 U.S.C. 1031–1056), concerning meat, poultry, and egg products, respectively, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 *et seq.*), nor the authority of the Administrator of the EPA under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 *et seq.*).

C. Paperwork Reduction Act.

No additional collection or recordkeeping requirements are imposed on the public by this proposed rule. Accordingly, OMB clearance is not required by the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, Chapter 35.

D. Executive Order 13175

This proposed rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation will not have substantial and direct effects on tribal governments and will not have significant tribal implications.

F. General Notice of Public Rulemaking.

This proposed rule reflects recommendations submitted by the NOSB to the Secretary to add three substances to the National List. A 60-day period for interested persons to comment on this rule is provided.

List of Subjects in 7 CFR Part 205

Administrative practice and procedure, Agricultural commodities, Agriculture, Animals, Archives and records, Fees, Imports, Labeling, Organically produced products, Plants, Reporting and recordkeeping requirements, Seals and insignia, Soil conservation.

For the reasons set forth in the preamble, 7 CFR part 205 is proposed to be amended as follows:

PART 205—NATIONAL ORGANIC PROGRAM

1. The authority citation for 7 CFR part 205 continues to read as follows:

Authority: 7 U.S.C. 6501–6522.

2. Amend § 205.603 by redesignating paragraphs (b)(8) through (11) as paragraphs (b)(9) through (12) and adding new paragraph (b)(8) to read as follows:

§ 205.603 Synthetic substances allowed for use in organic livestock production.

* * * * *

(b) * * *

(8) Oxalic acid dihydrate—for use as a pesticide solely for apiculture.

* * * * *

3. Amend § 205.605 in paragraph (a) by adding, in alphabetical order an entry for “Pullulan” to read as follows:

§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

(a) * * *

Pullulan—for use only in tablets and capsules for dietary supplements labeled “made with organic (specified ingredients or food group(s)).”

* * * * *

4. Amend § 205.606 by redesignating paragraphs (d) through (w) as paragraphs (e) through (x) and adding new paragraph (d) to read as follows:

§ 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.”

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(d) Collagen gel casing.

* * * * *

Bruce Summers,

Administrator,
Agricultural Marketing Service.

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