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## DEPARTMENT OF AGRICULTURE

### Agricultural Marketing Service

#### 7 CFR Part 205

[Document Number AMS–NOP–10–0051; NOP–10–04FR]

RIN 0581–AD04

#### National Organic Program; Amendment to the National List of Allowed and Prohibited Substances (Livestock)

**AGENCY:** Agricultural Marketing Service, USDA.

**ACTION:** Final rule.

**SUMMARY:** The U.S. Department of Agriculture (USDA) is adopting as final, without change, an interim rule published in the **Federal Register** on August 24, 2010 (75 FR 51919). The interim rule amended the National List of Allowed and Prohibited Substances (National List) based upon a recommendation submitted to the Secretary of Agriculture (Secretary) by the National Organic Standards Board (NOSB) on April 29, 2010. Consistent with the recommendation from the NOSB, the interim rule revised the annotation of one substance on the National List, methionine, to extend its use in organic poultry production until October 1, 2012, at the following maximum levels of synthetic methionine per ton of feed: laying chickens—4 pounds; broiler chickens—5 pounds; turkeys and all other poultry—6 pounds.

**DATES:** *Effective Date:* This rule becomes effective March 15, 2011.

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#### SUPPLEMENTARY INFORMATION:

##### I. Background

On December 21, 2000, the Secretary established within the NOP [7 CFR part 205] the National List regulations §§ 205.600 through 205.607. The National List identifies synthetic substances that may be used and the nonsynthetic (natural) substances that may not be used in organic production. The National List also identifies nonagricultural nonsynthetic, nonagricultural synthetic, and nonorganic agricultural substances that may be used in organic handling. The Organic Foods Production Act of 1990 (OFPA), as amended (7 U.S.C. 6501–6522), and NOP regulations, in § 205.105, specifically prohibit the use of any synthetic substance for organic production and handling unless included on the National List. Section 205.105 also requires that any nonorganic agricultural, and any nonsynthetic, nonagricultural substance used in organic handling must also be on the National List.

Under the authority of the OFPA, the National List can be amended by the Secretary based on proposed amendments developed by the NOSB. Since established, the NOP has published fourteen amendments to the National List: October 31, 2003 (68 FR 61987); November 3, 2003 (68 FR 62215); October 21, 2005 (70 FR 61217); June 7, 2006 (71 FR 32803); September 11, 2006 (71 FR 53299); June 27, 2007 (72 FR 35137); October 16, 2007 (72 FR 58469); December 10, 2007 (72 FR 69569); December 12, 2007 (72 FR 70479); September 18, 2008 (73 FR 54057); October 9, 2008 (73 FR 59479); July 6, 2010 (75 FR 38693); August 24, 2010 (75 FR 51919); and December 13, 2010 (75 FR 77521). Additionally, proposed amendments to the National List were published on November 8, 2010 (75 FR 68505).

As a result of a petition requesting to add synthetic methionine to the National List, the NOSB initiated a review of this substance in 1999. Methionine is classified as an essential amino acid because it cannot be biologically produced by poultry and is necessary to maintain viability. The petitioners asserted that methionine was

a necessary dietary supplement for organic poultry and that there was an inadequate supply of allowable organic feeds containing sufficient concentrations of naturally occurring methionine. In 2001, the NOSB evaluated a technical advisory panel analysis of methionine against the criteria provided in the OFPA (7 U.S.C. 6517–6518), and determined that the use of synthetic methionine feed supplementation is compatible with a system of organic poultry production. Consistent with the NOSB's recommendation, the Secretary amended the National List to allow methionine as a synthetic substance for use in organic poultry production at § 205.603 of the NOP regulations beginning on October 31, 2003, with an expiration date of October 21, 2005 (68 FR 61987). Based upon additional NOSB recommendations submitted in March 2005 and May 2008, the Secretary subsequently amended the listing for methionine on the National List by extending its allowance in organic poultry production through October 21, 2008 (70 FR 61217), and again through October 1, 2010 (73 FR 54057).

On July 31, 2009, a coalition of producers identified as the Methionine Task Force (MTF) filed a petition that requested a five-year extension on the allowance for synthetic methionine. The MTF proposed to limit the total amount of synthetic methionine to be fed over the life of the bird calculated as the average pounds of synthetic methionine per ton of feed. The MTF proposed these limits per ton of feed as follows: 4 pounds for laying chickens, 5 pounds for broiler chickens, and 6 pounds for turkeys and all other poultry. Based upon their deliberations and the public comment received, the NOSB concluded that wholly natural sources of methionine are not currently available and that extending the allowance for the synthetic form of methionine was warranted. However, the NOSB did not accept the request to extend its allowance on the National List for five years at the limitations proposed by the petitioners because the NOSB felt that averaging the pounds of synthetic methionine fed over the life of the bird could result in higher levels of the substance being fed during certain growth stages. As a result, the NOSB opted to modify the annotation

proposed by the petitioner by removing the language that would have allowed averaging the maximum level of methionine over the life of the bird and adding different limits on the feed allowance over time. On April 29, 2010, the NOSB issued a recommendation to extend the allowance for synthetic methionine for five years until October 1, 2015, with a step down in the amount allowed after two years. Specifically, the NOSB recommended that the amount of synthetic methionine allowed per ton of feed be limited to 4 pounds for laying chickens, 5 pounds for broiler chickens, and 6 pounds for turkeys and all other poultry until October 1, 2012. The NOSB further recommended that, after October 1, 2012, the allowance be reduced to 2 pounds for laying chickens, 2 pounds for broiler chickens, and 3 pounds for turkeys and all other poultry through October 1, 2015.

On August 24, 2010, the Secretary amended the National List through publication of an interim rule with request for comments in the **Federal Register** to reflect the first part of the NOSB's recommendation (75 FR 51919). This action extended the allowance for synthetic methionine through October 1, 2012, at the levels specified by the NOSB. In the interim rule, the USDA agreed to publish a final rule on the listing of methionine, along with any changes if warranted, by March 2011.

Based upon the NOSB recommendation and comments received, this final rule adopts, without change, the interim rule published on August 24, 2010 (75 FR 51919). Accordingly, this final rule continues the exemption at § 205.603(d)(1) for methionine as follows: DL-Methionine, DL-Methionine-hydroxy analog, and DL-Methionine-hydroxy analog calcium (CAS # 59-51-8; 63-68-3; 348-67-4)—for use only in organic poultry production until October 1, 2012, at the following maximum levels of synthetic methionine per ton of feed: Laying chickens—4 pounds; broiler chickens—5 pounds; turkeys and all other poultry—6 pounds.

## II. Related Documents

Since September 2001, four notices have been published announcing meetings of the NOSB and its planned deliberations on recommendations involving the use of methionine in organic poultry production. The four notices were published in the **Federal Register** as follows: September 21, 2001 (66 FR 48654), February 11, 2005 (70 FR 7224), April 4, 2008 (73 FR 18491), and March 17, 2010 (75 FR 12723).

Methionine was first proposed for addition to the National List in the

**Federal Register** on April 16, 2003 (68 FR 18556). Methionine was added to the National List by final rule in the **Federal Register** on October 31, 2003 (68 FR 61987). A proposal to amend the annotation for methionine was published in the **Federal Register** on July 29, 2005 (70 FR 43786), and the annotation was amended by final rule in the **Federal Register** on October 21, 2005 (70 FR 61217). A proposal to amend the annotation once again was published in the **Federal Register** on July 14, 2008 (73 FR 40197), and the annotation was amended by final rule on September 18, 2008 (73 FR 54057). The annotation for methionine was most recently amended through publication of an interim rule with request for comments in the **Federal Register** on August 24, 2010 (75 FR 51919).

## III. Statutory and Regulatory Authority

The OFPA, as amended (7 U.S.C. 6501–6522), authorizes the Secretary to make amendments to the National List based on proposed amendments developed by the NOSB. Sections 6518(k)(2) and 6518(n) of the OFPA authorize the NOSB to develop proposed amendments to the National List for submission to the Secretary and establish a petition process by which persons may petition the NOSB for the purpose of having substances evaluated for inclusion or deletion from the National List. The National List petition process is implemented under § 205.607 of the NOP regulations. The current petition process (72 FR 2167, January 18, 2007) can be accessed through the NOP Web site at <http://www.ams.usda.gov/nop>.

### A. Executive Order 12866

This action has been determined not significant for purposes of Executive Order 12866, and therefore, has not been reviewed by the Office of Management and Budget.

### 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. The final rule (68 FR 61987), dated October 31, 2003, adding methionine to the National List was reviewed under this Executive Order and no additional information related to Executive Order 12988 has been obtained since then. This final rule is not intended to have a retroactive effect.

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 § 2115(b) of the OFPA (7 U.S.C. 6514(b)). States are also preempted under §§ 2104 through 2108 of the OFPA (7 U.S.C. 6503 through 6507) 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 § 2108(b)(2) of the OFPA (7 U.S.C. 6507(b)(2)), a State organic certification program may contain additional requirements for the production and handling of organically produced agricultural products that are produced in the State and for the certification of organic farm and handling operations located within the State under certain circumstances. 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.

Pursuant to § 2120(f) of the OFPA (7 U.S.C. 6519(f)), this final rule would not alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspections Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*), concerning meat, poultry, and egg products, 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 Environmental Protection Agency under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 *et seq.*).

Section 2121 of the OFPA (7 U.S.C. 6520) provides for the Secretary to establish an expedited administrative appeals procedure under which persons may appeal an action of the Secretary, the applicable governing State official, or a certifying agent under this title that adversely affects such person or is inconsistent with the organic certification program established under this title. The OFPA also provides that the U.S. District Court for the district in which a person is located has jurisdiction to review the Secretary's decision.

### C. Regulatory Flexibility Act

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 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.

Pursuant to the requirements set forth in the RFA, AMS performed an economic impact analysis on small entities in the final rule published in the **Federal Register** on December 21, 2000 (65 FR 80548). AMS has also considered the economic impact of this action on small entities. The impact on entities affected by this final rule would not be significant. The current approval for the use of synthetic methionine in organic poultry production was extended in the interim rule through October 1, 2012, at levels that are consistent with current industry practice. The effect of this final rule is to affirm the continued use of synthetic methionine as amended. AMS concludes that this action would have minimal economic impact on small agricultural service firms. Accordingly, USDA certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Small agricultural service firms, handlers, and accredited certifying agents, have been defined by the Small Business Administration (SBA) (13 CFR 121.201) as those having annual receipts of less than \$7,000,000, and small agricultural producers are defined as those having annual receipts of less than \$750,000.

Based on USDA data from the Economic Research Service (ERS), the U.S. organic sector included nearly 13,000 certified organic crop and livestock operations at the end of 2008. These operations contained more than 4.8 million certified acres consisting of 2,665,382 acres of cropland and 2,160,577 acres of pasture and rangeland. The total acreage under organic management represents a twelve percent increase from 2007. Organic poultry production has steadily contributed to the overall growth in the organic food market. ERS estimated that there were 5,538,011 laying chickens and 9,015,984 broiler chickens raised under organic management in 2008. ERS estimated the number of certified organic turkeys raised in the United

States in 2008 at 398,531.<sup>1</sup> The Nutrition Business Journal calculated the market value for organic laying chickens at \$252,000,000 in 2008.<sup>2</sup> In addition to being sold as whole products, organic eggs and poultry byproducts are used in the production of organic processed products including soups, broths, prepared meals, ice cream and eggnog.

The USDA accredits certifying agents who provide organic certification services to producers and handlers. A complete list of names and addresses of accredited certifying agents may be found on the AMS NOP Web site, at <http://www.ams.usda.gov/nop>. AMS believes that most of these entities would be considered small entities under the criteria established by the SBA.

#### D. Paperwork Reduction Act

No additional collection or recordkeeping requirements are imposed on the public by this final rule. Accordingly, OMB clearance is not required by section 350(h) of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.* or OMB's implementing regulations at 5 CFR part 1320.

The AMS is committed to compliance with the E-Government Act, to promote the use of the Internet and other information technologies increased opportunities for citizen access to Government information and services, and for other purposes.

#### E. Discussion of Comments Received

AMS received 8 comments on the interim rule that extended the use of synthetic methionine in organic poultry production until October 1, 2012, at the following maximum levels of synthetic methionine per ton of feed: laying chickens—4 pounds; broiler chickens—5 pounds; turkeys and all other poultry—6 pounds. Comments were received from two organic livestock producers including one representing multiple individuals, two trade associations, two non-profit advocacy groups and two private individuals.

Some comments endorsed the amendment that extended the allowance for synthetic methionine. These commenters asserted that continuing the allowance was critical to the organic poultry industry, citing methionine as a

nutrient necessary for proper feather development and cell growth. These comments further voiced that, while research continues on meeting the nutritional requirements of poultry through natural sources of methionine, the limited commercial availability of feed containing natural sources of methionine supports the need for continuing the allowance of synthetic forms of the substance on the National List.

One comment strongly advocated for future inclusion of synthetic methionine on the National List for a five-year sunset review cycle after the October 1, 2015, expiration of the current petition-based NOSB recommendation. The interim rule for which we requested comments does not address the listing of methionine beyond its current expiration date of October 1, 2012. We plan to address the allowance for synthetic methionine after this date through a separate rulemaking action.

#### Changes Requested But Not Made

Two comments in favor of extending the use of methionine did not believe the limitations for use in different types of poultry as specified in the interim rule are necessary. One of these comments indicated concern that limiting the use of methionine to certain levels may impact the management practices of poultry producers by reducing the flexibility of producers to balance poultry rations with changing environmental conditions. However, based upon additional statements provided in this comment and testimony provided during NOSB deliberations, we believe that maximum levels in the interim rule are consistent with current industry practice and, therefore, will be feasible for most producers without major changes to their current management approach. The other comment related to limiting the allowable levels of methionine in specific groups of poultry recommended relisting methionine without annotation. The rationale provided by the comment is that the future "step down" proposed by the NOSB has the potential for increased recordkeeping by the producer and the certification agency. Because the action in the interim rule did not address the "step down" portion of the NOSB recommendation, this rationale does not apply to the current amendment and, therefore, we do not believe a change to the annotation as codified in the interim rule is warranted.

A few comments rejected the provisions in the amendment and argued in favor of an immediate prohibition on the use of synthetic

<sup>1</sup> U.S. Department of Agriculture, Economic Research Service, 2009. Data Sets: *U.S. Certified Organic Farmland Acreage, Livestock Numbers and Farm Operations, 1992–2008*. <http://www.ers.usda.gov/Data/Organic/>.

<sup>2</sup> *Nutrition Business Journal*, 2009. *U.S. Organic Food Sales by Product (\$Mil) 1997–2008, 2009(e)–2014(e)*—Chart 22. Penton Media, Inc.

methionine in organic poultry production. One comment did not express an opinion pertinent to the specifics of the amendment. The few comments opposing the extension of the allowance for synthetic methionine stated that use of the substance was incompatible with the regulatory definition of "organic production." Another comment objecting to extending the allowance questioned whether OFPA sanctions the use of a synthetic amino acid. This comment also cited natural alternatives to synthetic methionine and suggested that the continued allowance of synthetic methionine continues to delay the commercial development of alternatives to the synthetic form.

In developing their recommendation on the continued allowance for synthetic methionine on the National List, the NOSB reviewed the substance against the evaluation criteria of 7 U.S.C. 6517 and 6518 of the OFPA. The NOSB recommended that, after October 1, 2012, the annotation for methionine be amended to reduce the maximum amount of the substance allowed and establish October 1, 2015, as the expiration date. The NOSB's intent is that a step down in the levels allowed after October 1, 2012, will stimulate further market development of natural alternatives and drive management changes in the organic poultry industry. We plan to address this step down through a future rulemaking action. We believe that the current amendment should remain as codified in the interim rule. At this time, the record supports the rationale of the NOSB that synthetic methionine remains critical in organic poultry production and that its removal from the National List would have significant adverse impacts on the industry.

Two comments maintained that adequate wholly natural sources of methionine are in fact available and suggested that these alternatives should be sufficient for organic poultry production. The NOSB considered the availability of such alternatives in development of their recommendation and, based upon the public comment received, determined that alternatives are not available in sufficient quantities to meet the needs of the organic poultry industry. We concur with the NOSB's finding and, therefore, disagree with the comments suggesting that there are presently viable alternatives to justify removal of synthetic methionine from the National List.

After full consideration of these comments, we have determined that the record supports retaining the provisions in the interim rule to extend the use of

synthetic methionine in organic poultry production until October 1, 2012, at the following maximum levels of synthetic methionine per ton of feed: laying chickens—4 pounds; broiler chickens—5 pounds; turkeys and all other poultry—6 pounds. This provision remains consistent with the NOSB's April 29, 2010 recommendation.

#### List of Subjects in 7 CFR Part 205

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

#### PART 205—NATIONAL ORGANIC PROGRAM

Accordingly, the interim rule amending 7 CFR part 205, subpart G published at 75 FR 51919 on August 24, 2010, is adopted as a final rule without change.

Dated: March 4, 2011.

**David R. Shipman,**

*Associate Administrator, Agricultural Marketing Service.*

[FR Doc. 2011-5716 Filed 3-11-11; 8:45 am]

**BILLING CODE 3410-02-P**

#### NATIONAL CREDIT UNION ADMINISTRATION

##### 12 CFR Parts 708a and 708b

**RIN 3133-AD84; 3133-AD85**

#### Conversions of Insured Credit Unions

**AGENCY:** National Credit Union Administration (NCUA).

**ACTION:** Final rule.

**SUMMARY:** NCUA is confirming as final a December 23, 2010, interim final rule on the definition of the phrase "Regional Director" in NCUA's rule on credit union to mutual savings bank conversions. For clarification purposes, this rule modifies the aforementioned definition.

**DATES:** This rule is effective March 14, 2011.

#### FOR FURTHER INFORMATION CONTACT:

Jacqueline Lussier, Staff Attorney, Office of General Counsel, National Credit Union Administration, 1775 Duke Street, Alexandria, VA 22314-3428, or telephone (703) 518-6540.

#### SUPPLEMENTARY INFORMATION:

##### Background

In 2009, the NCUA Board created the NCUA Office of Consumer Protection

(OCP) to become operational on January 1, 2010. NCUA is in the process of moving responsibility for the review and approval of certain types of credit union conversions from the Regional Directors to the Director of the OCP, including credit union conversions to mutual savings banks or mutual savings associations (MSBs) in 12 CFR part 708a and the conversion from National Credit Union Share Insurance Fund (NCUSIF) share insurance to nonfederal share insurance in 12 CFR part 708b. To accommodate this reassignment of staff functions, the NCUA Board issued an interim final rule in December 2010, adding the Director of the OCP to the definition of the phrase "Regional Director" in part 708a and adding a new definition of the phrase "Regional Director" to part 708b that mirrors the revised definition in part 708a. 75 FR 80678 (Dec. 23, 2010).

NCUA received one comment letter that supported inclusion of the Director of the OCP in the definition of "Regional Director" in parts 708a and 708b.

#### Final Rule

The interim final rule instructed the Office of Federal Register (OFR) to amend § 708a.1 (now § 708a.101)<sup>1</sup> of part 708a by adding a definition of "Regional Director" to include the Director of the OCP. The interim final rule, however, should have instructed the OFR that § 708a.1 (now § 708a.101) be amended not by adding a new definition but rather by revising the existing definition of "Regional Director." This final rule confirms the December 23, 2010, interim rule as final and instructs the OFR that the existing definition of "Regional Director" in § 708a.101 be revised to include the Director of the OCP.

#### Immediate Effective Date

NCUA is issuing this rulemaking as a final rule effective upon publication in the **Federal Register**. The Administrative Procedure Act (APA), 5 U.S.C. 553, requires that a final rule must have a delayed effective date of 30 days from the date of publication, except for good cause. In this regard, NCUA believes the 30-day delayed effective date is inapplicable because the amendments to parts 708a and 708b are not substantive but merely update the regulation to provide NCUA with

<sup>1</sup> In December 2010, the NCUA Board issued a final rule that, in part, reorganized part 708a into subparts A through C and redesignated the existing section numbers in subpart A as §§ 708a.101 through 708a.113. 75 FR 81378 (Dec. 28, 2010). As reorganized, subpart A applies to conversions of federally-insured credit unions to MSBs and former § 708a.1 is now numbered § 708a.101. That final rule became effective on January 27, 2011.