Document Information

Title: NSF Protocol P463-2019 NSF Raised Without Antibiotics	
Document #: 16616	**Revision:** 06
Status: Release	**Release Date:** 21 Jan 2019

NSF INTERNATIONAL

Protocol P463 – 2019

Raised Without Antibiotics

The Public Health and Safety Company.™

NSF International, an independent, not-for-profit, non-governmental organization, is dedicated to being the leading global provider of public health and safety-based risk management solutions while serving the interests of all stakeholders.

Not for Distribution or Sale

This Protocol is subject to revision.
Contact NSF to confirm this version is current.

Users of this Protocol may request clarifications and interpretations, or propose revisions by contacting:

NSF International
789 Dixboro Road, P.O. Box 130140
Ann Arbor, Michigan 48113-0140
Phone: (734) 769-8010 Telex: 753215 NSF INTL
FAX: (734) 769-0109
E-mail: info@nsf.org
Web: http://www.nsf.org

NSF Protocol P463

NSF Raised Without Antibiotics

Not for Distribution or Sale

Protocol Developer
NSF International
Consumer Values Verified

Not for Distribution or Sale

Publish Date: **November 2, 2018**

Revised Date(s): March 2017
July 2017
January 2019

Published by

NSF International
PO Box 130140, Ann Arbor, Michigan 48113-0140, USA

For ordering copies or for making inquiries with regard to this Protocol, please reference the protocol title.

Copyright © 2019 by NSF International. All rights reserved.

Previous editions © 2017

Without the written permission of NSF, it is strictly prohibited to use this designation in whole or in part, to indicate conformance with this Protocol through the marking of products or packaging, or by any other means.

Printed in the United States of America.

Objectives and Disclaimers

This NSF Protocol provides basic criteria to promote and protect “Raised Without Antibiotics” certification integrity. Provisions for food safety are not included in this protocol as the scope of this protocol is limited to the avoidance of antibiotic usage in the production of livestock. NSF International does not assume, displace, or undertake to discharge any obligations or responsibilities of the manufacturer or any other party, including but not limited to those responsibilities and obligations arising from the other certifications or standards incorporated into this Protocol. Under no circumstances shall NSF International be liable for direct, indirect, incidental, consequential, special, and punitive or any other use of this protocol. This Protocol may be revised from time to time.

Participation in NSF protocol development activities by regulatory agency representatives (federal, local, state) shall not constitute their agency’s endorsement of NSF or any of its Protocol. NSF’s Protocol Development is consensus driven, seeking input from all interested parties. Use of this Protocol is strictly voluntary.

Not for Distribution or Sale

Not for Distribution or Sale

This page is intentionally left blank.

Contents

Not for Distribution or Sale

Not for Distribution or Sale

This page is intentionally left blank.

NSF Protocol P463

NSF Raised Without Antibiotics Certification Program

1 General

1.1 Purpose

This Protocol provides for an independent process based review of farm practices, health management procedures, and audit of the farm to verify compliance and ensure the accurate representation of package goods as certified "Raised Without Antibiotics". Certified organizations are authorized to use the NSF mark and related claims in the marketing and labelling of certified products.

1.2 Scope

For the purpose of NSF Certification as Raised Without Antibiotics, any substance that is considered an antibiotic, as described in the protocol by category, cannot be used in the production of food animals.
To earn the Raised Without Antibiotics certification, a farm, feed mill, abattoir, and food processing facility, must prove it has the necessary practices in place to ensure antibiotics are not used.

This protocol provides a framework of compliance requirements for livestock producers and evaluation activities employed by NSF to confirm implementation and conformance to these requirements. The livestock producer must demonstrate through practices and records that the animals are raised in a manner which avoids the use of antibiotics as described in the protocol by category.

Additionally, the protocol defines the requirements of supply chain traceability to preserve the identity of certified animal products from farm to finished packaged product. Compliance is verified via risk assessment, desk review, and onsite audit of procedures and records.

The Raised Without Antibiotics Protocol has been established to be marketed as a global standard. The protocol includes three categories. Refer to Section 4.

Applicants shall exercise due diligence to ensure compliance with all applicable regulatory requirements. Compliance with this protocol does not imply that all regulatory requirements have been met.

The welfare of the livestock / animals cannot be compromised in an effort to maintain the Raised Without Antibiotics status.

Not for Distribution or Sale

2 Normative references

The following documents contain provisions that, through reference, constitute provisions of this Protocol. At the time this Protocol was written, the editions listed below are current and valid. All documents are subject to revision, and parties are encouraged to investigate the possibility of applying the most recent editions of the documents indicated below. The most recent published edition of the document shall be used.

American Veterinary Medical Association (AVMA): *AVMA Animal Welfare Principles*[1]

[1] American Veterinary Medical Association. 1931 North Meacham Road, Suite 100 Schaumburg, IL 60173-4360 <www.avma.org>.

Canadian Food Inspection Agency (CFIA) Method of Production Claims: *"Raised Without the Use of Antibiotics" Claims*[2]

OIE (World Organization for Animal Health). Chapter 7.1. *Introduction to the recommendations for animal welfare. Terrestrial Animal Health Code 2010*[3]

3 Definitions

3.1 antibiotic: a medicine (such as penicillin or its derivatives) that inhibits the growth of or destroys microorganisms; chemical substances produced by various microorganisms and fungi, having the capacity to inhibit the growth of, or to destroy bacteria and other microorganisms.

3.2 antimicrobial / antibiotic resistance: the ability of microbes to grow in the presence of a chemical (drug) that would normally kill them or limit their growth.

3.3 audit / review: A systemic evaluation to determine if programs and related activities achieve planned expectations including the review or challenging of written programs, documentation of activities, corrective actions, and trends to determine the correlations between documented procedures and activities and actual execution.

Not for Distribution or Sale

3.4 coccidiostats: a chemical agent added to animal feed (as for poultry) that serves to retard the life cycle or reduce the population of pathogenic coccidia to the point that disease is minimized and the host develops immunity.

3.5 ionophores (microbial coccidiostats): any molecule, as of a drug, that increases the permeability of cell membranes to a specific ion.

3.6 licensed veterinarian: a person who is trained to give medical care and treatment to animals; an animal doctor.

3.7 livestock: animals raised in an agricultural setting for use or consumption by humans. This includes animals raised for meat, seafood, eggs and dairy.

3.8 lot number: A distinctive combination of letters, numbers or symbols, or any combination thereof from which the complete history of the production, manufacture, processing, packaging, holding, and distribution of a batch or lot of a finished products can be identified.

3.9 management system: A framework of processes and procedures used to ensure that an organization can fulfill all tasks required to achieve its objectives.

3.10 manufacture or manufacturing: All unit operational processes associated with the production of "Raised Without Antibiotics" ingredients or finished products including packaging, labeling, testing, and quality control of a "Raised Without Antibiotics" ingredient or finished product.

3.11 mid-year audit: an unannounced audit that occurs approximately six months after the initial date of certification or following the annual renewal date

3.12 raised without antibiotics: From birth / hatching and during suckling period, animals and animal products represented as certified shall be raised without the use of antibiotic treatments, as described in the protocol by category. Parent animals involved in suckling or laying are also within scope.

[2] Canadian Food Inspection Agency. 1400 Merivale Road, Tower 1, Room 0-149 Ottawa, ON K1A 0Y9 <www.canada.ca>.

[3] OIE World Organisation for Animal Health. 12, rue de Prony 75017 Paris, France <www.oie.int>.

When medically necessary as determined by a licensed veterinarian, any animals treated with antibiotics, or exposed to antibiotics through maternal exposure via suckling, at any time may no longer be represented as NSF Certified "Raised Without Antibiotics" in any form.

NOTE: Antibiotic accompanying vaccination of eggs for live bird production is prohibited.

4 NSF "Raised Without Antibiotics" Certification Categories and Facility Requirements

Certification Categories:

A. Ionophores allowed. Chemical coccidiostats allowed.

B. Ionophores prohibited. Chemical coccidiostats prohibited.

C. Ionophores prohibited. Chemical coccidiostats allowed.

Refer to Annex A for category marks.

4.1 Documentation and records of compliance

4.1.1 All applicants shall document the following policies and procedures and maintain associated records for a period of two years. Farms, feed manufacturers, abattoirs, and food processing facilities including those responsible for the finished packaged retail product, must be compliant with these requirements.

Not for Distribution or Sale

4.1.2 Procedures and records subject to review by NSF shall include, but are not limited to:

- description of facilities, activities, and animal/product types;
- process flow chart;
- finished product profiles (formula, labels), where applicable to the scope of certification;
- contract service providers;
- names of suppliers of feed and medications/treatments;
- purchase records of feed and medications/treatments,
- veterinary activity records, where applicable;
- feed formulas, where applicable;
- employee training;
- traceability;
  - method for segregation and identification of noncompliant live animals and withholding from program production, where applicable.
  - segregation and labeling of feed storage.
  - evidence of traceability of livestock, feed, and all other supplies for livestock operations from the livestock raising site to the processor.
- commingling prevention;
- cleaning and sanitation procedures;
  - cleaning of farm facilities, water systems, feed mills, abattoir, transportation units.
- control of non-conforming product;
  - records of "product hold" incidents;
  - records of segregation/quarantine;
  - records of disposition of non-conforming inputs, products, animals;
  - records of destruction of non-conforming inputs or products;
- animal wellness practices per Section 4.1.4

4.1.3 At the time of the initial on-site audit, records of the life of the livestock shall be available for review.

NOTE — No livestock slaughtered and processed prior to the initial audit is authorized to be represented as certified once certification is granted.

4.1.4 Animal wellness policies and procedures shall include, but are not limited to:

- housing systems
- space allowances
- gestation stalls where relevant
- farrowing systems where relevant
- flooring
- cleaning and sanitation
- access to food
- access to clean water
- pest management
- litter management

Evidence of compliance with an animal wellness audit by a third party may be used to show compliance with 4.1.4. Acceptable certifications include:

- Certified Humane
- Genesis Gap
- American Humane Certified
- Other programs deemed valid by NSF

Not for Distribution or Sale

4.1.5 Veterinary Health Plan

An internal plan is required to reduce the need for antimicrobial drugs by preventing infectious disease, and when antimicrobial drugs are needed, a commitment that antimicrobial drugs are used appropriately to optimize health and minimize selection for antimicrobial resistance. The welfare of the livestock/animals cannot be compromised in an effort to maintain the Raised Without Antibiotics status.

4.2 Livestock handling and transport

4.2.1 All livestock and products of animal origin collected at the livestock facility shall be transported and handled during transport in a manner which does not compromise the NSF Raised Without Antibiotics compliant status of the livestock.

4.2.2 The certified operation with ownership of the livestock is responsible to provide for necessary conditions and feed materials required for transport of livestock.

4.2.3 Records shall be maintained of livestock transport activities and the feed provided during transport, if applicable.

4.3 Internal quality control and compliance monitoring

4.3.1 Documents / procedures / records detailing the internal quality control and compliance monitoring efforts to ensure compliance shall include, but are not limited to:

- Purchased feed specifications (i.e. feed free of antibiotics).

- Documented procedures carried out consistently by trained personnel.

- Records showing when medical treatment with antibiotics occurred and the effected animals excluded from certified Raised Without Antibiotics sale.

4.4 Unannounced audits

4.4.1 Farms, feed mills and abattoirs are within an applicant's scope and will be subject to an announced audit during the applicant's initial application period. These sites are also subject to unannounced audits after certification per Annex B, Table B.1. Additional unannounced audits may be warranted due to major non-conformances.

Food processing facilities that are not certified to a 3rd party benchmarked GFSI food safety scheme may require an unannounced audit.

Non-Conformities include but are not limited to:

- Lack of traceability within all departments/operations that are within scope of the protocol
- Lack of animal wellness practices being followed/maintained
- Lack of documentation demonstrating compliance in all areas of raising, vaccinating, transportation, and slaughter of livestock

4.4.2 The site(s) will be notified in advance that an unannounced audit shall occur within a defined timeframe to ensure relevant production may be observed. The site(s) will then be notified of the unannounced audit 48 hours in advance. The auditor will have had no livestock contact for a minimum of 72 hours to allow for appropriate biosecurity considerations. The auditor will work within the individual company bio-security regulations.

NOTE: It is the site's responsibility to provide the auditor with bio-security protective clothing (face mask, suit, boots, gloves, etc.) at the time of audit(s).

Not for Distribution or Sale

4.4.3 An applicant's facility has 30 days to respond to all issued non-conformities in order to obtain certification. A certified facility has 30 days to respond to all issued non-conformities in order to maintain certification.

4.5 Training

4.5.1 Documents / procedures / records of proper training on ensuring the NSF Raised Without Antibiotics program integrity shall include but are not limited to:

4.5.1.1 Initial and annual refresher training for employees that includes:

- Purpose and requirements of the program as applicable to job responsibilities;

- Policies and procedures related to compliance with the program requirements as applicable to the job responsibilities; and

- Work instructions related to specific tasks required to maintain compliance.

4.5.2 All employee training records shall be maintained at the applicable facility for a period of two years and available for review during on-site audits.

4.5.3 All training shall be available and communicated in the predominant languages of the workforce.

4.6 Recall Procedures

4.6.1 Organizations shall have means for instituting a product recall for any product that is found to be non-compliant with the program requirements and requires recall from the stream of commerce.

4.6.2 Organizations shall have in place policies and procedures that define the recall of a product(s)

should it become necessary, and these documents shall be included with the facility's policies and procedures.

4.6.3 Certified organizations shall contact NSF program office (see certificate for contact information) in case of a product recall related to program compliance of an NSF Raised Without Antibiotics certified product.

5 Complaint handling – NSF Raised Without Antibiotics certified products

5.1 Organizations shall have in place documented policies and procedures to handle complaints related to NSF Raised Without Antibiotics certified products.

5.1.1 The organization shall maintain records of complaints and actions taken.

5.1.2 Complaints shall be kept on file for a period of two years and available during on-site audit at each production location.

6 Labeling

Not for Distribution or Sale

6.1 Participating NSF certified products, if displaying the Program or NSF mark, shall be labeled in accordance with Annex A NSF Labeling and Marketing Requirements.

6.2 Any product that bears a claim regarding NSF Raised Without Antibiotics certification on its labeling and fails to comply with the program requirements will be deemed to be noncompliant.

6.3 NSF Raised Without Antibiotics certified operations may display other third party logos or claims respecting Raised Without Antibiotics (or equivalent) status as permitted by law, and may include descriptions of their control program provided it does not contradict NSF Raised Without Antibiotics program requirements.

6.4 If a certified Operation wishes to request a variance or deviation to the NSF Labeling and Marketing Requirements, the operation shall submit the deviation or variance request using a form supplied by NSF. NSF will consider requests but is not obligated to grant the deviation or variance, and will not be obligated to return any portion of fees paid if the applicant chooses to discontinue certification as a result of NSF's decision.

6.4.1 NSF shall not be responsible for any costs incurred by applicants related to the printed labels which are the subject of rejected variance requests or other product noncompliance. It is the applicant's responsibility to ensure it has received written confirmation of label compliance by NSF prior to printing participating product labels.

7 Request for Variance

7.1 Any request for a variance to NSF Raised Without Antibiotics Certification Program requirements shall be submitted using a form supplied by NSF.

7.2 NSF shall consider the request but is not obligated to grant the request and will not be obligated to return any portion of fees paid if the applicant chooses to discontinue certification as a result of NSF's decision.

7.3 NSF shall not be responsible for any costs incurred by applicants related to nonconforming product which is the subject of rejected variance request or other product noncompliance.

7.4 To apply for a variance, the client must complete the Request for Variance – NSF Raised Without Antibiotics Certification Program form and submit to NSF. Fees will apply as per the fee schedule for NSF Raised Without Antibiotics certification services.

8 Review of NSF Raised Without Antibiotics Certification Protocol

8.1 Review of NSF Raised Without Antibiotics protocol requirements will take place periodically and any changes in requirements shall be communicated to the organizations within 30 days of finalized changes with an effective date no sooner than 90 days from the notification date.

8.2 Organizations shall be required to demonstrate at the next annual review that changes were implemented within 90 days of receipt of the Notice of Changes, or alternatively, that the organization is in compliance with any extension or variance granted by NSF.

Not for Distribution or Sale

Not for Distribution or Sale

This page is intentionally left blank.

Annex A

NSF Raised Without Antibiotics Labeling and Marketing Requirements

A.1 Marks

Category A

Category B

Category C

Operations producing certified product(s) shall use the certified category mark (or approved alternative) on certified product(s).

Refer to Section 4 for category requirements.

A.1.1 Other color/black and white options in accordance with NSF's Labeling and Marketing requirements are available to the certified entity upon request.

Not for Distribution or Sale

A.2 Labeling Approval

All product packaging labels must be reviewed by NSF prior to representing product as certified. NSF shall review claims, marks and statements for compliance with the use of the NSF Raised Without Antibiotics certification program mark and claim.

NOTE — The Applicants and certified operations are responsible for maintaining compliance with regulatory labeling guidance and rules of any markets where it intends to offer its products for sale and is solely responsible for any expenses or damages it incurs related to labels and label claims in the marketplace.

A.3 Content Claims

A.3.1 Use of the Mark and statement

Products such as pre-packaged meals containing vegetables, sauces, and certified livestock may use the Mark accompanied by a content claim.

The content claim "Made With X Raised Without Antibiotics" where X refers to specific livestock may be permitted when:

— The livestock is currently certified to the RWA protocol.

— All livestock present in the finished product shall be certified.

— Evidence is provided such as proof of purchase and production records showing traceability from purchase of the RWA certified livestock ingredient(s) to the final product.

A.3.2 Procedures and records subject to review by NSF shall include, but are not limited to:

— Product Formulas and labels / packaging

— Facility Risk Assessment

— Traceability

— Commingling prevention

— Cleaning and sanitation procedures

— Process Flow Chart

— Meat service provider contract

— Proof of facility certification or audit to a food safety scheme

Not for Distribution or Sale

Annex B

Audit requirements

Table B.1 Audit frequency and Traceability Requirements

Audit frequency by location	Audit frequency	Certification required	Traceability
Individual farm site	1 Initial Announced Audit 1 Unannounced* Mid-Year Audit	Yes	From Farm to Birthing/Hatch facility
Abattoir	1 Initial Announced Audit 1 Unannounced* Mid-Year Audit	No; only compliance.	From Abattoir to Farm AND from packaging to abattoir
Individual feed mill/ feed processing facility	1 Initial Announced Audit 1 Unannounced* Mid-Year Audit	No; only compliance.	From farm to feed mill

All participating sites will be audited initially.

*Unannounced audits at mid-year and annual renewal cycles will be based on the following; 25% of the total number of sites at mid-year; an additional 25% of the total number of sites at renewal.

Not for Distribution or Sale

***THE HOPE OF MANKIND** rests in the ability of man to define and seek out the environment which will permit him to live with fellow creatures of the earth, in health, in peace, and in mutual respect.*