

ACA Best Practices for Review of Non-Organic Flavors

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Purpose

This ACA Guidance/Best Practice document describes background, criteria, and procedural steps that certifiers should take to ensure compliance with the §205.605(a) allowance for flavors. The document applies to all certifiers with certified organic processing clients that use non-organic flavors, as allowed at §205.605(a), as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).” We recommend that all certifiers adopt the verification of allowed flavors criteria and the companion Natural Flavors Declaration form to verify compliance of flavors; additional questions may be added to this questionnaire by individual certifiers as deemed necessary.

Background

In 1995, the National Organic Standards Board (NOSB) recommended the use of Natural Flavors in organic foods with the requirement that certified operators demonstrate efforts towards production of organic natural flavors. Flavors have been on the National List at §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)),” since October 2002. As non-agricultural non-synthetic ingredients allowed at §205.605(a), non-organic flavors are permitted to make up less than 5% of a raw or processed agricultural product sold, labeled, or represented as “organic,” according to §205.301(b). The previous annotation for flavors read:

Flavors, nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.

In 2007, the National Organic Program (NOP) published [NOP Guidance for Certifiers on Flavors](#), which clarified confusion around the requirements for certification and/or petitioning of flavors to be added to §205.606 (“Flavors – non-synthetic, natural (non-agricultural), are on the National List and do not need to be petitioned as long as they meet the existing definitions”). The NOP provided additional guidance in 2011 with the publication on [Policy Memo 11-1](#). This memo clarified the current requirements for flavors permitted in organic production and handling and rendered NOP Guidance for Certifiers on Flavors obsolete.

Meanwhile, in 2009, organic certifiers collaborated with members from Flavor Extract Manufacturers Association (FEMA) to develop a [Natural Flavor Product Questionnaire](#), which requests information from flavor manufacturers to confirm the compliance of the flavor with the

annotation for flavors at §205.605(a). This document was shared with NOP and widely adopted and/or modified by certifiers.

On November 6, 2014, the Organic Trade Association submitted a [petition](#) to require the use of organic flavors when they are available in the quality, quantity and form needed. On October 29, 2015, the NOSB unanimously passed [a recommendation](#) to revise the annotation for flavors to require organic when commercially available. On December 27, 2018, the NOP issued a [final rule](#) amending the National List with the implementation date of December 27, 2019:

Flavors—nonsynthetic flavors may be used when organic flavors are not commercially available. All flavors must be derived from organic or nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.

Meanwhile, in 2016, the NOP published Guidance [NOP 5033-1: Decision Tree for Classification of Materials as Synthetic or Nonsynthetic](#) and [Guidance NOP 5033-2: Decision Tree for Classification of Agricultural and Nonagricultural Materials for Organic Livestock Production or Handling](#).

Relevant Regulations

21 CFR 101.22. Foods; labeling of spices, flavorings, colorings and chemical preservatives. (a) (3) the term natural flavor or natural flavoring means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional. Natural flavors include the natural essence or extractives obtained from plants listed in §§ 182.10, 182.20, 182.40, and 182.50 and part 184 of this chapter, and the substances listed in § 172.510 of this chapter.

7 CFR 205.105 Allowed and prohibited substances, methods, and ingredients in organic production and handling.

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

Lack of Consensus

The allowance for flavors as an ingredient or processing aid in or on “organic” or “made with organic...” products at §205.605(a) is at best confusing and at worst contentious. The placement of the annotation and wording, as well as handbook documents published by the National Organic Program, seem to conflict.

The National List of Allowed and Prohibited Substances at §205.605(a) lists non-synthetic, nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).” The original annotation for flavors at this section only required nonsynthetic sources and that they must not be produced using synthetic solvents and carrier systems or any artificial preservatives. The NOP gave guidance via [Policy Memo 11-1](#) that states:

NOP regulations allows the use of natural flavors as long as they meet the FDA definition of a flavor, are from nonsynthetic sources, and are not produced using synthetic solvents and carrier systems or any artificial preservatives.

According to the U.S Food and Drug Administration (FDA) 21 CFR 101.22, the term natural flavor or natural flavoring means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional. Natural flavors include the natural essence or extractives obtained from plants listed in §§ 182.10, 182.20, 182.40, and 182.50 and part 184 of this chapter, and the substances listed in §172.510 of this chapter.

Because, according to the FDA, natural flavors can only be labeled as such if they are derived from the agricultural products listed above, all FDA natural flavors are derived from a non-synthetic source, as required in Policy Memo 11-1.

Based on the guidance in Policy Memo 11-1 and the FDA definition of natural flavor, for many years, certifiers have been allowing flavors under the listing at §205.605(a), provided that manufacturers attest to:

- Confirmation that the flavor meets the FDA definition of a natural flavor.
- Confirmation that flavors are not produced using synthetic solvents and carrier systems or any artificial preservatives.
- Confirmation that the flavor meets the requirements at §205.105(e)-(g):

“To be sold or labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” the product must be produced and handled without the use of: ...

(e) Excluded methods, except for vaccines: Provided, That, the vaccines are approved in accordance with §205.600(a);

(f) Ionizing radiation, as described in Food and Drug Administration regulation, 21 CFR 179.26; and

(g) Sewage sludge.”

Certifiers have historically not asked for complete ingredient information for flavors. Specific verification was and is requested via Natural Flavor Questionnaires (sometimes called Natural

Flavor Verification Forms, Natural Flavor Declarations, or Verification of Natural Flavor Forms), which ask flavor manufacturers to attest to the above requirements.

In 2016, the NOP published Guidance [NOP 5033-1: Decision Tree for Classification of Materials as Synthetic or Nonsynthetic](#) and [Guidance NOP 5033-2: Decision Tree for Classification of Agricultural and Nonagricultural Materials for Organic Livestock Production or Handling](#). The publication of these guidance documents, as well as a final rule updating the annotation for flavors at §205.605(a), have caused confusion among certifiers reviewing and approving flavors. An analysis of the annotation for flavors, Policy Memo 11-1, and NOP 5033-1 indicates that there are inconsistencies between these references. The annotation specifically calls out allowed sources for flavors (organic or nonsynthetic only) and states that they must not be produced using synthetic solvents and carrier systems or any artificial preservative. Policy Memo 11-1 clarifies that flavors declared to meet the FDA definition of natural flavors come from allowed sources, as these flavors are derived from agricultural products. The annotation and policy memo have been the basis of certifier verification of non-synthetic flavors for many years. However, [NOP 5033-1: Decision Tree for Classification of Materials as Synthetic or Nonsynthetic](#) indicates that certifiers should be asking additional questions.

Again, FDA natural flavors do come from a natural source and can be assumed to be extracted, based on the NOP 5033-1 definition of “Extract”, so section 2b from flow chart 5033-1 is the first relevant question in evaluating the classification of a flavor if the recent guidance is applied:

At the end of the extraction process, does the substance meet all of the criteria described at 4.6 of NOP 5033?

Section 4.6 of NOP 5033, then, states:

- At the end of the extraction process, the material has not been transformed into a different substance via chemical change;
- The material has not been altered into a form that does not occur in nature; and
- Any synthetic materials used to separate, isolate, or extract the substance have been removed from the final substance (e.g., via evaporation, distillation, precipitation, or other means) such that they have no technical or functional effect in the final product

If the substance complies with the extraction requirements, 5033-1 next examines whether the substance has undergone a chemical change so that it is chemically or structurally different from how it naturally occurs in the source material. If no, the substance is deemed non-synthetic. If yes, 5033-1 asks if the chemical change is created by a naturally occurring biological process, such as composting, fermentation, or enzymatic digestion; or by heating or burning biological matter. If no, the substance is deemed synthetic; if yes – nonsynthetic.

Since many certifiers have historically relied on Policy Memo 11-1 and the 205.605(a) flavor annotation requiring a non-synthetic source for the natural flavor, the organic industry has permitted the use of many flavors that qualify as natural under the FDA that would be considered synthetic due to a non-permitted chemical change during extraction or subsequent

processing steps if NOP 5033-1 guidance is applied. For example, the esterification of natural ethanol and natural acetic acid, both derived via fermentation, produces ethyl acetate. Ethyl acetate produced in this manner qualifies as a natural flavor under the FDA, but is considered synthetic under the NOP if NOP 5033-1 guidance is applied.

In addition, the publication of [Guidance NOP 5033-2: Decision Tree for Classification of Agricultural and Nonagricultural Materials for Organic Livestock Production or Handling](#) indicates that some flavors that certifiers have approved under the allowance of non-synthetic non-agricultural flavors at §205.605(a) are in fact agricultural. The update of the annotation in 2018 requiring the use of organic flavors when commercially available further complicates this issue, because agricultural flavors are not listed at §205.606. Some certifiers continue to allow agricultural flavors under the listing at §205.605(a), based on previous NOP guidance; therefore, these flavors are only required to be organic if commercially available. However, since §205.605(a) only applies to non-agricultural substances, other certifiers require agricultural flavors to be certified organic regardless of commercial availability, as there is no listing for flavors at §205.606.

Certifiers agree that the review and approval process for flavors under the listing at §205.605(a) is largely inconsistent with the review and approval process for other non-agricultural, non-synthetic substances allowed at this section. The fact that flavors are listed at §205.605(a) as a permitted non-synthetic appears to inherently imply that permitted flavors should be non-synthetic based on NOP 5033-1. This too is murky territory though, confounded by the fact that other materials remain listed at §205.605(a) as allowed non-synthetics that are actually synthetic based on NOP 5033-1, even after NOSB Sunset deliberations conducted post release of 5033-1. Additionally, if it is the intent of the flavor inclusion at §205.605(a) to signal that flavors must be non-synthetic based on 5033-1, it is redundant for the previous and current annotation to specify that they must be from non-synthetic sources. Regardless of these discrepancies, it is true that typically complete ingredient information is required, and based on NOP 5033-1 or 5033-2, additional processing information may be requested to determine the agricultural, non-synthetic, or synthetic status of a substance based on how it is classified on the National List.

Certifiers are not in consensus on whether we should update the review process for flavors to request complete ingredient information and verify non-agricultural, non-synthetic status according to 5033-1 and 5033-2. Some certifiers advocate for the continued verification of the specifics listed in the annotation: non-synthetic source and not produced using synthetic solvents and carrier systems or any artificial preservative. Other certifiers advocate for the collection of complete ingredient information from natural flavor manufacturers. A distrust in the flavor manufacturing industry has arisen, and some certifiers are hesitant to accept the traditional natural flavor questionnaires without additional confirmation and verification of complete ingredient information. The National Organic Program has not archived PM 11-1, indicating that it is still current and correct, and recent communication with the NOP during their review of the ACA Organic Flavor Commercial Availability Best Practices indicates that they do not support the request for complete ingredient information for natural flavors. It is extremely difficult to estimate how many flavors are currently in use by certified operators that were

approved by certifiers under current review criteria. With or without NOP instruction or backing, a change in review criteria for flavors will result in the severe disruption of organic certification for many processors.

Finally, there is a lack of consistency in labeling products containing non-organic flavors. §205.300, Use of the term, “organic,” states:

(a) The term, “organic,” may only be used on labels and in labeling of raw or processed agricultural products, including ingredients, that have been produced and handled in accordance with the regulations in this part. The term, “organic,” may not be used in a product name to modify a nonorganic ingredient in the product.

The Preamble to the National Organic Program Regulations Final Rule further clarifies:

“The NOSB, State organic program (SOP) managers, certifying agents, and a large number of individual commenters strongly recommended that USDA prohibit use of the term, “organic,” to modify an ingredient in a product name if the ingredient, itself, is not produced organically. The examples offered were “organic chocolate ice cream” and “organic cherry sweets” in which the ice cream and candy are at least 95 percent organic but the chocolate and cherry flavoring is not organically produced. We agree with commenters that such product names can be misleading and would be a violation of section 205.300(a). In the examples, the word, “organic,” precedes the words, “chocolate” and “cherry,” and clearly implies that those ingredients are organically produced. The chocolate and cherry flavorings must be organically produced to be used in this way. If the product is at least 95 percent organically produced but the flavoring is nonorganic, the word sequence must be reversed or the word, “flavored,” must be added to the name; e.g., “chocolate organic ice cream” or “chocolate flavored organic ice cream.” A sentence has been added to section 205.300(a) to specify that the term, “organic,” may not be used in a product name to identify an ingredient that is not organically produced.”

However, some organic products may be labeled as “Organic Lemon Tea,” but the certified organic lemon flavor may contain a lemon flavoring component that is not organic; rather, the carrier makes up 95% of the product and is the certified organic ingredient. Can the term “organic” be used to modify the term “lemon” if the lemon flavoring component itself is not an organic component of the certified organic flavor? If an operation is using a flavor that is listed on their supplier's certificate as “organic strawberry type flavor” can they use it in a product that contains no strawberries and call it Organic Strawberry Oatmeal? Similarly, can an organic strawberry type flavor be listed on a finished product ingredient declaration as “organic strawberry flavor”? Must the certifier obtain documentation confirming the presence of organic strawberry in the flavor in order to do so?

The ACA has developed Criteria for Verification of Allowed Flavors. We have also updated the Natural Flavors Declaration commonly used by certifiers to verify flavor compliance. We have not included additional questions asking for complete ingredient information, requiring

agricultural or non-agricultural status (according to 5033-1), or requiring synthetic or non-synthetic status (according to 5033-2), based on the lack of consensus as described above. Certifiers may choose to include these additional questions on their own verification documents. We have not reached consensus on labeling of products containing non-organic flavors.

Criteria for Verification of Allowed Flavors

Non-organic flavors, in accordance with 7 CFR 205.605(a), must:

- Be derived from organic or nonsynthetic sources only
- Be produced without synthetic solvents and carrier systems or any artificial preservative
- Be in compliance with §205.105 Allowed and prohibited substances, methods, and ingredients in organic production and handling, including being produced and handled without genetic modification.
- Function as a flavor within the product labeled as “organic” or “made with organic (specified ingredients or food group(s))”
- Only be used if organic versions are not commercially available - see separate [ACA best practices document on assessing commercial availability of flavors](#)

Additional verification steps may include:

- Verification that all other ingredients (ingredients besides flavors, solvents, carrier systems, and preservatives) are allowed
- Verification that all flavor component ingredients are allowed
- Verification that the flavor is non-agricultural
- Verification that the flavor is non-synthetic according to NOP 5033-1

Natural Flavors Declaration

The [ACA Natural Flavors Declaration](#) (hereafter “Declaration”), updated by this working group, serves to verify the requirements for non-organic flavors as listed above. Additional verification steps are not included in this form, but may be added by individual certifiers as deemed appropriate.

The declaration was purposefully designed to have an initial explanation page, two pages of questions with a section for signature, and a final page with additional relevant definitions. Some flavor manufacturers may need to print this document, so containing the questions and signatures to two pages (pages 2-3) allows for fewer pages to be printed.

The Declaration begins with an explanation of the requirements for non-organic flavors allowed at §205.605(a). We wanted to include this information to educate manufacturers on the requirements, but we did not include it directly in the applicable questions to prevent deliberate inaccuracies from manufacturers. Relevant regulations definitions are included in the Declaration throughout at relevant points and on the final page.

Best practice is to require that the Declaration be completed by the manufacturer of the product, not suppliers, as they might not have complete information on the product. However, signers are legally attesting to providing accurate and truthful information about the flavor, so some certifiers may accept attestations from suppliers. Manufacturer name and flavor name and product code are included to clearly identify the product.

Flavors are required to be “derived from organic or nonsynthetic sources only,” according to §205.605(a). Flavors that meet the FDA definition of natural flavors are derived from non-synthetic sources, so this question is included to verify the non-synthetic source of the flavor without requesting proprietary ingredient information (Question 1). Additionally, we ask the manufacturer to list the specific sources of the flavor (Question 2). This serves as a second checkpoint to verify that the source is, in fact, non-synthetic. Some manufacturers may have difficulty answering this question if, for example, the product is a compound flavor with multiple flavoring components. Regardless, a general answer, such as “plant,” “tree,” “animal,” etc, may be acceptable, provided that source is non-synthetic.

The specific function of the product is requested because it must function as a flavor in the “organic” or “made with organic...” product to be allowed under the listing for flavors at §205.605 (Question 3). If the product does not function as a flavor, the product is prohibited for this use. Some ingredients, commonly referred to as “flavors with modifying properties,” (FMPs) may be represented as flavors by manufacturers, but they only function as flavors if used below certain rates. When used above certain rates, they often serve sweetening and similar non-flavoring roles. This only applies when the product is the only flavoring agent in the overall flavor product. Manufacturers must state whether or not these types of ingredients are used and, if so, what rates they are used at (Question 4). Rates of FMPs used as flavors in “organic” or “made with organic...” products must be below maximum usage rate for the overall flavor material to qualify as a natural flavor (Question 4(a)). Manufacturers of non-organic flavors may need to correspond with operators, as maximum usage rates may depend on the category of food that the flavor is going into. FEMA GRAS categories, as defined at 21 CFR Section 170.3(n), and their associated GRAS publications can be referenced by certifiers to confirm acceptable levels for each flavoring agent.

To further confirm that the product under review is actually functioning as a flavor, the questionnaire asks the manufacturer to confirm that the material can legally be labeled as a “natural flavor” on the finished product label (Question 5). The manufacturer is also asked to declare the common or usual name of the natural flavor if it must be declared on the label by this name (Question 5(a)). This will help reviewers as they evaluate labels of products containing flavors for compliance.

Because flavors are required to be organic when commercially available, the manufacturer must attest to whether or not they sell an organic version of the flavor. If they do, the certifier will need to request documentation from the operator demonstrating why the organic version of this flavor is not an appropriate form, quality, or quantity. Additional commercial availability documentation is regardless of the answer to this question. Please see the [ACA Best Practices for Commercial Availability of Natural Flavors](#) for further information.

All non-flavor constituents, or ingredients included in a flavor product but not acting as a flavor, must be declared by the manufacturer (Question 7). Solvents, carrier systems, and preservatives must be verified for compliance with the annotation for flavors at §205.605(a). Synthetic solvents and carrier systems and artificial preservatives are prohibited. Permitted ingredients may include, but are not limited to: natural ethanol, supercritical carbon dioxide, authentic essential oil, and natural vegetable oils, non-synthetic citric acid, non-synthetic maltodextrin, and organic or non-synthetic glycerin. Relevant documentation, such as a specification sheet or certificate of analysis, is requested to be provided for any non-flavor ingredients. Safety Data Sheets (SDS) are generally not considered useful or relevant documents, as they are not required to list complete ingredient information. Instructions note that additional information may be requested to verify the compliance of these non-flavor ingredients. For example, documentation may be required to assess the non-synthetic versus synthetic status of any solvents, carriers, and preservatives. In addition, if the manufacturer indicates that the product contains an ingredient that does not function as a flavor, solvent carrier system, or preservative, additional documentation may be required to verify the function of this ingredient.

Alcohol or ethanol must be produced via fermentation (Question 8); maltodextrin must be produced via enzyme hydrolysis using non-GMO enzymes (Question 9); glycerin must be organic or non-synthetic (Question 10); and citric acid must be produced via microbial fermentation of a carbohydrate substrate (Question 11). Best practice is to require documentation confirming these requirements from the manufacturer of the ingredients, but some ingredients, such as ethanol, maltodextrin, or citric acid, may be deemed low risk and documentation from the manufacturer of the flavor, not the ingredient itself, may be accepted. Other allowed ingredients must be either:

- confirmed to be non-synthetic, including but not limited to those listed as allowed at §205.605 and §205.606 of the National List of Allowed and Prohibited Substances (National List). When non-synthetic National List ingredients are used as non-flavor constituent ingredients, non-synthetic verification may be needed, but verification with any National List annotation for that particular ingredient is not needed; rather, it must comply with the annotation for flavors at §205.605(a).
or
- A synthetic allowed at §205.605(b), provided that the use of the ingredient complies with any annotation

No hydrocarbon, chlorinated, or halogenated solvents may be used. Propane, hexane, triglycerides, and freon are examples of solvents that are prohibited.

Allowed flavors must be verified to be produced and handled without excluded and prohibited methods. It is not necessary to verify that flavors are produced without sewage sludge. Certifiers verify the non-use of sewage sludge as part of the crop production for the nonorganic agricultural materials on §205.606. The use of sewage sludge does not apply to §205.605 materials. Flavors must be verified to be produced and handled without excluded methods (Question 12(a)). The definition of excluded methods is included, as well as clarification based

on NOSB recommendations. Flavors must also be verified to be produced and handled without ionizing radiation (Question 13(a)). In addition, it is best practice to verify that ingredients are not produced or processed using nanotechnology or technologies intentionally manipulating matter at atomic, molecular, or macromolecular dimensions, as clarified in NOP Policy Memo 15-2 (Question 14(a)).

Finally, a manufacturer signature section is included, followed by additional relevant definitions. The signature section includes explicit instructions that state: *“To be signed by a qualified, technical representative of the manufacturer. Any operation that makes a false statement under The Organic Foods Production Act of 1990 to an accredited certifying agent shall be subject to the provisions of section 1001 of title 18, United States Code (205.100(c)(2)).”* The manufacturer's signature attests that *“Pursuant to applicable regulations, I, on behalf of the manufacturer, hereby attest that the information provided in this form is accurate and truthful to the best of my knowledge.”* This clarifies that this is a legally binding document, and that it is the responsibility of the signer to make sure that the information supplied is correct.

The signature section includes a signature and name, as well as date, to verify that the Declaration is current, and contact information, so that certifiers can follow up with manufacturers if additional information is needed.

Conclusion

The ACA supports the adoption of this policy and companion Natural Flavors Declaration form to verify compliance of flavors; additional questions may be added to this questionnaire by individual certifiers as deemed necessary.

References

[Preamble to the NOP Regulations Final Rule](#)

[NOSB Recommendations 1995. Final Recommendation Addendum Number 14, The Use of Natural Flavors in Organic Food](#) (begins on page 14)

[Overview of Flavor Additives, 2005. Prepared for the USDA NOP and the NOSB, Oct. 14, 2005](#)

[“NOP Guidance for Certifiers on Flavors” February 16, 2007](#) - Obsolete

[2009 Natural Flavor Product Questionnaire](#)

[2014 OTA Petition to amend the annotation to Flavors on the National List as a non-agricultural \(non-organic\) substance allowed in or on processed products labeled as “organic or “made with organic \(specified ingredient\),” at §205.605\(a\)](#)

[2015 NOSB Petition to revise the annotation for Flavors listed at §205.605\(a\)](#)

[2018 Proposed Rule: National Organic Program; Amendments to the National List of Allowed and Prohibited Substances \(Crops, Livestock and Handling\)](#)

[2018 Final Rule: National Organic Program; Amendments to the National List of Allowed and Prohibited Substances \(Crops, Livestock and Handling\)](#)

[ACA Best Practices for Commercial Availability of Natural Flavors](#)

[NOP Policy Memo 11-1](#)

[NOP Policy Memo 15-2](#)

[NOP 5033-1: Decision Tree for Classification of Materials as Synthetic or Nonsynthetic](#)

[NOP 5033-2: Decision Tree for Classification of Agricultural and Nonagricultural Materials for Organic Livestock Production or Handling.](#)

[ACA Natural Flavors Declaration 05.2021](#)