



Department of Public Health and Human Services

Public Health & Safety Division ♦ Communicable Disease Control & Prevention Bureau
Food & Consumer Safety ♦ PO Box 202951 ♦ 1400 Broadway ♦ Helena, MT 59620-2951
Phone: (406) 444-2837 ♦ Fax: (406) 444-5055

Steve Bullock, Governor

Sheila Hogan, Director

GUIDANCE DOCUMENT Food and Consumer Safety Section

DOCUMENT CODE: WF181001

DATE: January 10, 2018

SUBJECT: Food ingredients

Question

What ingredients are allowed in regular food?

Answer

Ingredients allowed in human food nearly always fall into one of the following categories*

1. Conventional food
2. Approved additives
3. Generally recognized as safe (GRAS).

* Any substance intentionally added to food is subject to prior approval by the federal Food and Drug Administration (FDA) before introduction into commerce, unless it is exempted in an applicable part of the code. Specifically, if the ingredient does not fall into one of the three categories above, Montana and federal law allow for proposed ingredients to undergo petition review for allowance into food, under the GRAS notification program (50-31-108, MCA).

For properly utilizing expertise and ensuring consistency across the state and country, Montana has historically conceded petition review to FDA. The petition process is detailed in the Code of Federal Regulations (CFR), title 21, part 171, section 1 (21 CFR 171.1), which is also in Montana rule (37.110.101(1)(aw), ARM).

A properly completed petition will have reliable and valid scientific facts from qualified experts. If this happens, the frequent result is FDA will have no questions about use of the ingredient, under conditions detailed in the petition. In other words, if there are no questions, the ingredient may be added to food, provided it is used in accordance with circumstances outlined in the petition.

Operators are encouraged to use the FDA petition process when needed. For example, Montana camelina oil advocates were referred by Montana DPHHS to FDA in 2014. Two years later, camelina advocates submitted a petition to FDA. Within a few months, advocates received GRAS Notice 642 that allowed camelina oil to be used in certain foods.

Background

With increasing frequency, food manufacturers have been proposing to add non-traditional ingredients into regular foods. This trend has been especially true for various types of dried teas and specialty beverages.

Some proposed ingredients, such as *Echinacea*, meadowsweet, white willow bark, feverfew, raspberry leaf, stinging nettle root, etc., are not conventional food, generally recognized as safe, or an approved food additive because they have known physical effects on the body beyond ordinary growth and maintenance of healthy bodily functions. For the aforementioned and similar ingredients, their inclusion into regular food would diminish certainty that their use would not be harmful under intended, common or usual conditions. In these situations, the ingredients would be regulated as a stand-alone dietary supplement or possibly a new drug.

The reason for regulating an ingredient or certain ingredients as dietary supplements is to control potency of active substance(s). If regulated as a conventional food, the potency of the active substance(s) would likely vary over a much larger range, which could result in adverse health consequences. In addition, regulating such products as dietary supplements provides consumers more information with which they may make informed decisions about use of the product, since it may have health consequences. If the product was not regulated as a dietary supplement, but just as a conventional food, the consumer would likely be deprived of this more informed decision.

Rule Interpretation

CONVENTIONAL FOOD

There is no legal definition of a “conventional food,” but it is commonly or usually understood by reasonable people among the public to be a food, such as a grape, carrot, potato, etc. A conventional food has a substantial history of being safe for use in ordinary circumstances. Despite this undefined term, several sections of the CFR suggest that a conventional food ingredient is a substance of natural biological origin that was widely consumed for its nutrient properties in the United States prior to January 1, 1958, without known detrimental effects. Specifically, title 21, part 170 of the CFR regarding food additives details this information, which was adopted in rule by the State of Montana (37.110.101(1)(av), ARM).

APPROVED ADDITIVES

Approved food additives are substances included in foods that have a proven safety record. The quantity of the substance added to food must not exceed the amount reasonably required to accomplish its intended physical, nutritive, or other technical effect.

The list in this part of the code that is most often used by sanitarians is for natural flavorings (21 CFR 172.510), which is Montana rule 37.110.101(1)(ax), ARM. The list includes a column for use limitations. This column uses an abbreviation for the term “ditto,” noted as “Do.,” in the list. If you see this abbreviation, refer to the written limitation description that occurs prior to the abbreviation. For example, the plant commonly known as “veronica” is in a row on the list in which the limitations column reads, “Do.” Referring up the list, the term “Do.,” corresponds with the use in “alcoholic beverages only.” This means the food additive veronica is only allowed in beverages that contain at least 0.5 percent ethanol by volume, without undergoing additional safety review.

This same subchapter of the CFR also contains a huge number of allowable preservatives, synthetic flavorings, coatings, flavoring agents, multipurpose additives, and other approved substances.

GENERALLY RECOGNIZED AS SAFE

As one may imagine, listing all substances that could be included in food in one part of the code is impossible, which is why there exists a petition process for safety review. However, substances that have been deemed GRAS for their conditions of use are listed in 21 CFR 182, which is Montana rule 37.110.101(1)(bh), ARM.

Like approved additives, the quantity of the substance added to food must not exceed the amount reasonably required to accomplish its intended physical, nutritive, or other technical effect. Included in this section of the code are several lists. Among the lists are ones for spices, natural seasonings, oils, extracts, distillates, and other substances. GRAS substances listed in 21 CFR 182 may later be reassigned to a different part of the code, after the substance has been reevaluated by FDA. The reevaluated substances could be reassigned into either part 170, 171, 172, 173, 174, 175, 176, 177, 178, 179, 180, 184, 186, or 189, whichever is most appropriate.

Legal references

37.110.101(1)(av through bk), ARM