What you need to know about FOOD ADDITIVES

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SSAFE

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Introduction

Many of the foods we eat, whether prepared at home or manufactured elsewhere, are a combination of two or more ingredients. Even if you are making something as simple as pancakes for breakfast at home, there will be ingredients such as flour and milk, but you may also add baking soda - otherwise known as sodium bicarbonate or E500 - as a chemical leavening agent to give your pancakes a light and fluffy texture.

There are many different types of additives in all kinds of foods. But how much do you know about food additives? Where do they come from? How are they used? Are they regulated? This paper sets out why food additives are used, how their use is regulated and how - through science-based processes - consumers are protected.

Why this paper

It seems that food additives are rarely out of the news these days. There are questions raised over the preponderance of food additives and their possible effects on consumer health, and rightfully so. It is important to ask these questions. And some of this has resulted in the development of consumer preferences for natural food additives rather than synthetic ones and the move towards “clean labels”, where food products have fewer ingredients, in particular fewer synthetic food additives. In both cases, the food industry has been innovative and responsive to these consumer preferences while ensuring the food and beverages consumed by people and pets is safe.

Science is central to the assessment and regulation of these food additives. The current approach to food additives, based on the evaluation and analysis of science by independent experts from around the world through a robust and well-defined process, is the best approach we have to protect consumers while maintaining the supply, shelf life and convenience of the foods we all depend on. And although science is not static and our understanding of food additives and their potential effects in the human body continues to develop, it is important to recognize that food additives go through a rigorous process to make sure they are safe to humans and that the safety of food additives is re-assessed as new scientific evidence emerges. Science does not have all the answers, but nor do the competing narratives in the media and in society at large. This paper sets out this approach in detail, so you can make up your own mind.

Objective & Audience

The goal of this paper is to help the audience understand what food additives are, where they come from and the rigorous science-based approval process they go through at an international level. The target audience for this document is anyone interested in food additives, whether that is governments, regulators, intergovernmental organizations, academia, the media and the general food sector at large.

Food additives | What are they?

Food additives are a class of food ingredients. They are substances intentionally added to food for specific technological reasons, such as to improve shelf life, to enhance color and flavor, or to provide the texture and taste that consumers want. While some are age-old, like salt, sugar and vinegar, numerous other ingredients are classified and regulated as food additives today.

Social and cultural perspectives on food additives differ around the world. For example, monosodium glutamate, better known by its initials MSG, gained notoriety in the West following a letter to the New England Journal of Medicine in 1968. The letter suggested that symptoms such as headache, nausea and numbness that the writer experienced when eating in Asian restaurants were due to the use of monosodium glutamate in those cuisines. On the other hand, in Japan, for instance, additives such as monosodium glutamate that enhance umami (one of the five basic tastes alongside sweet, sour, salt and bitter) have been used for centuries and are seen as a way to bring out the natural flavors of food, rather than as an artificial addition.

Food additives | International standards to guide national regulations

The Codex Alimentarius Commission, or **Codex** for short, is the pre-eminent international body for food safety and quality standards. These include standards for the safe use of additives in food.

Codex standards provide a valuable and trusted resource for its 188 member countries, particularly those who may not have the resources or expertise available to undertake their own safety assessments. In reaching decisions on the adoption of standards for food additives, the Codex Alimentarius Commission considers the recommendations of its Codex Committee on Food Additives (CCFA), which is where technical experts from Codex member countries have discussions, at times extensive, on the safety assessments that are performed and published by the WHO/FAO Joint FAO/WHO Expert Committee on Food Additives (JECFA). The work of JECFA and the importance of science to this cycle of assessment, discussion, standard-setting and review is described in more detail below.

The transparent processes used by Codex facilitate understanding of the standards and also facilitate their use in **domestic rule-making**. Implementation of Codex standards delivers consumer protection, drives harmonization and supports trade in food between countries. The adoption of Codex standards by member countries is voluntary and requires the Codex standards to be incorporated into relevant domestic legislation for them to have effect, and for implementation to include measures to monitor and incentivize compliance. The approaches taken vary between countries (see Box 1).

Where a country adopts Codex standards, it is presumed to meet all relevant World Trade Organization (WTO) obligations. Alternatively, countries may decide to set rules for use of food additives that are stricter than Codex standards, in which case their domestic rules must meet their general WTO obligations, for example that the rules are science-based, non-discriminatory and transparent.

While food additives regulations differ between countries and jurisdictions, they have in common a strong level of oversight, including an evaluation before market approval to ensure that the food containing the additives is safe for the entire population. A positive list of approved food additives is usually publicly available in each jurisdiction.

Box 1

Example of incorporation of Codex standards into national legislation

In Samoa, the Food Act of 2015 directs the Cabinet, before making recommendations to the Head of State regarding food regulations, to take account of "the desirability of maintaining consistency between the regulations and any relevant standards, requirements, or recommended practices that apply or are accepted internationally including standards, guidelines and related texts published by the Codex Alimentarius Commission".

In Bangladesh, the Food Safety Act of 2013 created the Bangladesh Food Safety Authority (BFSA) and tasked it, in the conduct of its functions and duties, "to identify strategies to harmonize safety and quality standards between the international and domestic food articles". Accordingly, BFSA led a program to draft national food standards harmonized with Codex standards and, in 2023, BFSA announced the successful drafting of 11,200 harmonized food standards.

What criteria do food additives need to meet before international standards are set?

The Codex ***General Standard for Food Additives*** sets out four criteria that food additives need to meet before they are approved for use at specifically defined levels: they are **safe**; their use is **justified**; they are used according to **good manufacturing practice**; and they meet agreed **specifications of identity and purity**. These four criteria are explored in turn in the sections below.

The Codex ***General Standard for Food Additives*** describes the criteria in more detail. It states that the use of food additives is justified only when it meets all of the following criteria:

- it does not present an appreciable health risk to consumers;
- it does not mislead the consumer;
- it serves one or more of the recognized technological functions; and
- it provides an advantage over existing technologies and additives - more specifically achieves one of the following objectives where they cannot be achieved by other means that are economically and technologically practicable:
    - to preserve the nutritional quality of the food;
    - to provide necessary ingredients or constituents for foods manufactured for groups of consumers having special dietary needs;
    - to enhance the keeping quality or stability of a food or to improve its organoleptic properties, provided that this does not change the nature, substance or quality of the food so as to deceive the consumer;
    - to provide aids in the manufacture, processing, preparation, treatment, packing, transport or storage of food, provided that the additive is not used to disguise the effects of the use of faulty raw materials or of undesirable or unhygienic practices.

The Codex ***General Standard for Food Additives*** is updated each time the Codex Alimentarius Commission considers and adopts additions and amendments proposed by the Codex Committee on Food Additives (CCFA). The assessment and re-assessment of food additive safety is a continuing and dynamic process, driven by the availability of new data. For example, the 2023 update of the Codex Standard includes:

- three new food additives with their permitted uses and maximum usage levels;
- expansion in the permitted uses of seventeen food additives;
- modifications to the maximum use levels of five food additives; and
- several food additives which are no longer approved for use in some types of food.

Not all additives meet the above criteria when they are assessed or re-assessed. The 2023 update also deleted two food additives which can no longer be used in any foods, due to the lack of data to support evaluation, or lack of current evidence of their use.

Food additives | Are they safe?

Ensuring food safety is critical. The evaluation of food additive safety is typically undertaken by **independent** experts who are convened to inform regulatory decision-making. For Codex, this task is performed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and its advice on the safety of additives is openly published in meeting reports and monographs. JECFA's working procedures are governed by the ***FAO/WHO Framework for the Provision of Scientific Advice on Food Safety and Nutrition*** and the ***WHO Regulations for Expert Advisory Panels and Committees***. These have at their heart core principles including **objectivity, fairness, transparency** and **inclusiveness**. They also contain important safeguards for the **integrity** of the independent expert advisory process, including expert advisors declaring their other interests and administrative action to avoid and manage any conflicts of interest. The approaches taken by JECFA to assess the safety of food additives are set out in detail in ***Environmental Health Criteria 240: Principles and Methods for the Risk Assessment of Chemicals in Food***.

The process of commissioning an expert evaluation of the safety of a food additive by a JECFA meeting follows a longstanding process, which is summarized in Figure 1. Independent experts will consider the **type of evidence** available and its **relevance** to human health. By taking this approach to evaluating the evidence, more informed decisions can be made about the safety of food additives at expected levels of consumption.

Figure 1 – The Lifecycle and Key Elements in Evaluation of a Food Additive

1. **Chemical characterization of the food additive.**
   - Food additive specifications
   - Stability and fate of additive in foods
   - Analytical methods
2. **Hazard identification and characterization from laboratory and human studies**
   - Absorption, distribution, metabolism and excretion
   - General systemic toxicity
   - Acute toxicity
   - Genotoxicity
   - Carcinogenicity
   - Reproductive and development toxicity
   - Neurotoxicity
   - Immunotoxicity
   - Allergy and other hypersensitivities
   - Gastrointestinal tract considerations, including effects on gut flora
3. **Dose-response assessment and establishment of Acceptable Daily Intake**
   - Dose-response modelling
   - Setting an Acceptable Daily Intake
4. **Dietary exposure assessment**
   - Globally representative food consumption data
   - Assessment of range of likely exposures and comparison to toxicological endpoints

Evaluating the safety of food additives requires careful consideration of the available scientific **evidence**. Different testing methods, including cell studies, animal studies, and human studies, each provide valuable insights into the potential health effects of additives. New methodologies are emerging that will reduce dependence on animal studies in the future. For example, recent advances in machine learning and artificial intelligence have led to the development of computer models and software which aim to predict how laboratory animals could react to any given chemical in animal studies.

It is important to recognize and understand the limitations of each testing method.

Cell studies:

These studies are conducted in a laboratory using cells to observe the effects of additives. While they provide valuable preliminary evidence, it's important to remember that the results may not fully represent how a substance affects a living organism.

Animal studies:

Laboratory animal studies provide additional information about the effects of additives. However, it's important to note that animal metabolism may not fully mimic human metabolism. Therefore, observations from animal studies are interpreted cautiously when considering human safety and, typically, conservative safety margins are used when extrapolating from effects in animals to possible effects in humans.

Human studies:

Ethical considerations generally limit the direct testing of food additives on humans. Therefore, human studies are typically observational and gather data from populations over time. These studies can provide valuable insights but should be interpreted in the context of other evidence.

Where there is sufficient evidence for JECFA to complete a favorable evaluation, it will usually set a numerical **Acceptable Daily Intake (ADI)**, expressed in terms of the amount of the food additive that can be consumed relative to the body weight of the individual, daily over a lifetime, without appreciable health risk. Only food additives that have been assigned an ADI, or otherwise determined to be safe by JECFA, will be considered for inclusion in the Codex General Standard for Food Additives.

JECFA may, on occasion, allocate a food additive an ADI "not specified". This means that the additive could in principle be allowed for use in foods with no limitation other than such use being in accordance with Good Manufacturing Practices (GMP). It should, however, be born in mind that ADI not specified does not mean that unlimited intake is acceptable.[1]

The levels of food additives in a food and the amount of that food that is consumed also play a crucial role in determining the safety of food additives. Therefore, assessing likely human exposures to food additives is a key part of the independent expert assessment. Tools are available to support the estimation of probable daily dietary exposure to a food additive from all food sources. Codex has published ***Guidelines for the Development of Maximum Levels for the Use of Food Additives with Numerical Acceptable Daily Intakes*** which provides guidance to screen proposals for use of additives based on consideration of their maximum use level and the physiological upper limit to the amount of food and drink that can be consumed each day.

[1] In some cases, JECFA has been unable to allocate an ADI but nevertheless found a specific use of a substance acceptable. In such cases, the additive in question should only be authorized in accordance with the conditions specified by JECFA.

Codex uses these guidelines to set **maximum use levels for food additives in various food categories** that ensure that the intake of an additive from all its uses does not exceed its ADI.

Where more detailed consideration of likely food additive intakes is required, there are tools to support assessments undertaken on a national or regional basis, such as the FAO/WHO Global Individual Food Consumption Data Tool (FAO/WHO GIFT). This is an open-access online platform, hosted by FAO and supported by WHO, providing access to harmonized individual quantitative food consumption data, especially in low- and middle-income countries. The platform is a growing data repository, which currently holds over 60 datasets from 30 countries.

When the food additive is to be used in foods eaten by special groups of consumers (e.g., diabetics, those on special medical diets, sick individuals on formulated liquid diets), account needs to be taken of the probable daily dietary exposure to the food additive by those consumers. This is particularly true where additives are used in foods consumed by children as, when aged between one and five years, children eat three to four times the amount of food per kg of body weight than the average adult.

Food additives | Justification for use

Many substances that are approved as food additives are also naturally-occurring constituents of common foods. For example, an apple naturally contains riboflavin, anthocyanins, citric acid, glutamic acid, pectin and L-cysteine. However, once these same substances are synthesized or extracted and then intentionally added to foods to achieve specific purposes, such as preserving freshness, enhancing flavor, improving appearance, or modifying texture, these substances become additives, and subject to regulation.

Whether natural or synthetic, food additives are **categorized by their function**. A full list of internationally recognized functional classes of food additives (e.g. color, preservative, sweetener) can be found in the Codex text on ***Class Names and the International Numbering System for Food Additives***.

The allocation of a food additive to one or more functional classes is not just an academic exercise. It supports one of the four criteria that food additives should meet before they are approved for use - which is that their use is **justified**. Justification relates to technological need, but many food additives also have the potential to contribute to broader food system objectives, such as contributing to food security through preventing spoilage and waste.

The allocation of a food additive to a functional class is also then reflected in the **labelling** of the final food. This is an important and valued element of the information available to the consumer at point of purchase. The Codex ***General Standard for the Labelling of Pre-Packaged Food*** requires that a label on pre-packaged food includes, for each food additive it contains, not just the specific name or recognized numerical identifier of the additive, but also the relevant Codex functional class.

The role of Good Manufacturing Practice

Good Manufacturing Practice (GMP) is the collective term for accepted guidelines and regulations for the manufacturing, processing, packaging, and storage of food products. The objective of GMP for any ingredient of a food is to ensure that manufacture results in an ingredient that is safe, is not contaminated or adulterated, is prepared, packed and stored in sanitary conditions, meets desired quality characteristics and is fit for its intended use.

For food additives, GMP goes further. The Codex Standard also requires:

- the **quantity of the additive added to food shall be limited to the lowest possible level necessary** to accomplish its desired effect; and
- the quantity of the additive that becomes a component of food as a result of its use in the manufacturing, processing or packaging of a food and which is not intended to accomplish any physical, or other technical effect in the food itself, is reduced to the extent reasonably possible.

These requirements complement the commercial imperative not to use more of a food additive than is required to fulfil its desired function.

Ensuring the quality of food additives - specifications for identity and purity

As part of its risk assessment of food additives, JECFA will develop specifications for the **identity** and **purity** of those additives. These help to ensure that commercially available food additives:

- are of appropriate quality;
- can be manufactured consistently; and
- are equivalent to the material that was subjected to the toxicological testing.

These are important safeguards that assure the ongoing safety of food additives in use. Safety is assured where food additives conform to Codex specifications and to all the requirements of GMP through their manufacture, processing, packaging, transport, storage and use. Specifications also help guard against fraud in the supply of food additives, particularly those that command a high market price such as vanilla extract.

Codex compiles and maintains a list of specifications, published as the ***List of Codex Specifications for Food Additives***.

Keeping food additive standards up to date

Food additive assessments are based on science. Regular review and re-evaluation of food additives are conducted as new data become available. In the Codex system, CCFA keeps all provisions for food additives under review, and makes recommendations to the Codex Alimentarius Commission to prioritize and schedule existing food additives for re-evaluation. Re-evaluation by JECFA may lead to confirmation of existing provisions, changes to provisions so that consumer exposures remain within acceptable limits, or to provisions being deleted in which case that food additive should no longer be used (see Box 2 and Box 3 for examples).

Box 2

A case study of re–assessment confirming current controls | aspartame

Aspartame is an artificial sweetener which has been widely used in various food and beverage products since the 1980s, including diet drinks, chewing gum, gelatin, ice cream, breakfast cereal and dairy products such as yogurt, as well as in toothpaste and medications such as cough drops and chewable vitamins.

In July 2023, JECFA and the International Agency for Research on Cancer (IARC) together published the outcomes of their independent but complementary reviews of aspartame. This was the first time that IARC had evaluated aspartame and the third time for JECFA.

Citing "limited evidence" for carcinogenicity in humans, IARC classified aspartame as possibly carcinogenic to humans (IARC Group 2B) and JECFA reaffirmed the acceptable daily intake of 40 mg/kg body weight. At first sight, these outcomes might seem contradictory - how can two expert evaluations, each based on scientific data collected from a range of sources, conclude that on the one hand there are acceptable intakes of aspartame while on the other hand classifying aspartame as a possible human carcinogen? The answer to this question demonstrates the multi-stage process of risk assessment undertaken by JECFA.

IARC looked only at the hazardous nature of the substance in isolation. IARC's hazard identifications are the first fundamental step to understand the carcinogenicity of an agent by identifying its specific properties and its potential to cause cancer. Critically, IARC classifications reflect the strength of scientific evidence as to whether an agent can cause cancer in humans, but they do not reflect the risk of actually developing cancer at a given exposure level. Risk assessment is a more extensive process and in addition to hazard identification, it also characterises the hazard, assesses exposure, and characterises the risk at those levels of exposure. JECFA conducted a risk assessment including all these stages.

These lead to an assessment of the probability of a specific type of harm, in this case cancer, to occur under certain conditions and levels of exposure expected from food.

JECFA concluded that the evidence of an association between aspartame consumption and cancer in humans is not convincing. JECFA concluded that the data provided no sufficient reason to change its previously established acceptable daily intake (ADI) of 0–40 mg/kg body weight for aspartame. JECFA therefore reaffirmed that it is safe for a person to consume within this limit per day - for example, for diet soft drinks containing 200 or 300 mg of aspartame in a single can, an adult weighing 70kg would need to consume more than 9–14 cans per day every day over a lifetime to exceed the acceptable daily intake, assuming no other intake from other food sources.

Box 3

A case study of re–assessment leading to tighter controls - erythrosine

Erythrosine is a synthetic due that produces a bright cherry-red color which has been used to enhance the visual appeal of food, drinks, and cosmetics. Codex has assigned it the international number INS 127, although it is also known as E127 in Europe and as Red Dye No. 3 in the USA.

Erythrosine has been evaluated by JECFA on eight occasions, most recently in 2018. Over this period, the JECFA ADI for erythrosine has been reduced several times in the light of new scientific evidence and new analysis. At its eighteenth meeting the Committee allocated an ADI of 0–2.5 milligrams per kilogram of bodyweight (mg/kg bw). This ADI was halved at the twenty-eighth meeting to 0–1.25 mg/kg bw and made temporary following observations that erythrosine produced effects on thyroid function in rats and that male rats receiving very high doses of erythrosine in their diet developed benign thyroid tumours. At the thirtieth meeting the Committee reduced the temporary ADI further to 0–0.6 mg/kg bw, based on new information on the effects of erythrosine on thyroid hormone metabolism and regulation in rats. At the thirty-third meeting the Committee further reduced the temporary ADI to 0–0.05 mg/kg bw, having considered a study showing slightly increased thyroid-stimulating hormone responsiveness in humans ingesting erythrosine at high doses for 14 days, and applying an uncertainty factor of 20. At its thirty-seventh meeting, the Committee re-evaluated previously reviewed studies, and evaluated those studies that had since been published including newer studies on thyroid physiology in rats. The Committee concluded that the thyroid tumours in male rats previously reported in long-term toxicity studies were secondary to thyroid hormone changes and were the result of species-specific sensitivity. In view of the differences in thyroid physiology between humans and rats, the Committee decided to continue to base its evaluation on the human data and applied an uncertainty factor of 10, giving an ADI of 0–0.1 mg/kg bw.

At its 86th meeting in 2018, the Committee again re-evaluated erythrosine at the request of CCFA. A toxicological dossier that included new studies on genotoxicity, reproductive and developmental toxicity, neurological effects and hypersensitivity was submitted. A comprehensive literature search retrieved three additional studies relevant to the evaluation. The Committee also considered studies evaluated at previous meetings. The Committee concluded that the new data that had become available since the previous evaluation do not give reason to revise the ADI and confirmed the previous ADI of 0–0.1 mg/kg bw. Over the period in which JECFA has reduced its ADI for erythrosine, we have seen other changes in the views of consumers and regulators, to which the food industry has responded. Concerns have been raised over the potential link between erythrosine (and similar food colors) and hyperactivity in children, and consumer preferences have shifted from synthetic food colors to natural food colors such as fruit and vegetable extracts.

Although erythrosine remains in the GSFA and is allowed for use in many countries, we have seen some countries introduce rules that restrict or even ban the use of erythrosine in food. For example, since 1994, the use of erythrosine in food in the European Union has been restricted to glace cherries and certain candied fruits. More recently, the US Food and Drug Administration announced in January 2025 that it was revoking its authorization for the use of erythrosine in foods. These regulatory changes have been characterized by some commentators as reflecting a cautious stance that balances safety with consumer preferences.

Key challenges

As was stated in the introduction, while the scientific approach ensures a robust, methodical and fact-based framework for decision making, science does not have all the answers and some key challenges and unresolved questions remain.

The safety of each food additive is generally considered in isolation. Yet a diet which contains a range of manufactured foods is also likely to contain a mixture of different food additives. Where food additives, or other ingredients and chemical components of food, affect the same organ of the body or have a similar mode of action, the approach used for safety evaluation already provides guidance on how exposure to a mixture of chemical components from multiple food products might be assessed. For other mixtures or combinations of food additives and other chemical components of food, the extent of any interactions in their effects in the body is largely unknown, and is the subject of research around the world.

One other particularly active field of study is how certain food additives may affect the communities of bacteria, viruses and fungi that live in a healthy human gut - the microbiome - and how these communities interact with the human host in functions such as digestion and immune response. A recent review undertaken by the Food and Agriculture Organization of the United Nations found that while some of the additives that have been studied had no or limited effects on the gut microbiome, some others led to contradictory results. The review concluded that research approaches needed to improve in several important aspects before they can generate scientific data are robust enough to be suitable for risk assessment.

Summary

Food additives are added to food for specific technological reasons, such as to improve shelf life, to enhance color and flavor, or to provide the texture and taste that consumers want. While food additives regulations differ between countries and jurisdictions, they have in common a strong level of oversight, including an evaluation of risk before market approval to ensure that the food containing the additives is safe for the entire population.

The Codex Alimentarius Commission, as the pre-eminent international body for food safety and quality standards, sets maximum levels for the use of those food additives for which the FAO/WHO Joint Expert Committee on Food Additives has assigned an Acceptable Daily Intake. These maximum use levels ensure that the amount of that additive routinely consumed by adults, children, or specific groups of consumers, from all uses of that additive, does not exceed its Acceptable Daily Intake. Implementation of Codex standards into national legislation delivers consumer protection, drives harmonization and supports trade in food between countries.

In addition to ensuring **safety**, the assessment of a food additive ensures that its use is **justified**, it is used according to **good manufacturing practice**, and it meets agreed **specifications of identity and purity**.

In the words of Professor Samuel Godefroy, President of the International Union of Food Science and Technology: "Additives are not artificial intrusions, but carefully studied and regulated tools that preserve safety, nutrition and quality… They are critical to reducing waste, combating malnutrition and maintaining consumer trust."

Suggested further reading

Codex standards, guidelines and related texts

- Codex Alimentarius Commission ***General Standard for Food Additives*** (CXS 192). Most recently revised 2025.
- Codex Alimentarius Commission ***Guidelines for the Development of Maximum Levels for the Use of Food Additives with Numerical Acceptable Daily Intakes***. Annex A to the above.
- Codex Alimentarius Commission ***Class Names and the International Numbering System for Food Additives*** (CXG 36-1989). Most recently revised 2024.
- Codex Alimentarius Commission ***General Standard for the Labelling of Pre-Packaged Food*** (CXS 1-1985). Most recently revised 2024.
- Codex Alimentarius Commission ***List of Codex Specifications for Food Additive***s (CXA 6-2025). Most recently revised 2025.
- FAO and WHO (2025). ***Risk Analysis Principles Applied by the Codex Committee on Food Additives***. Section 4.3 of the Codex Alimentarius Commission Procedural Manual, 31st edition.

JECFA processes

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Food additives regulatory approaches in selected jurisdictions

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500 Westover Dr #30533
Sanford, NC 27330
USA

info@ssafe-food.org
www.ssafe-food.org