

# Differentiating and Communicating Biofortified Products in the Current Regulatory Landscape

**NUTRITION INFORMATION**  
Servings per package: 13  
Serving size: 250mL  
Prepared as directed

Energy	502 kJ
Total Fat	1g
Saturated Fat	0g
Trans Fat	0g
Cholesterol	23g
Sodium	15g
Total Carbohydrate	45g

**NUTRITION FACTS**  
Serving size: approximately 170mL  
Average Quantity Per Serving

Energy	146 kJ
Protein	1.9g
Fat, total	0.6g
Fat, saturated	0.1g
Carbohydrate	5.5g
Sugar	4.0g
Sodium	620 mg

**Nutrition Facts**  
Serving Size 1 Rounded Scoop (32g)  
Servings Per Container 73

Amount Per Serving		Calories from Fat 1g
		% Daily Value*
Total Fat	1g	2%
Saturated Fat	0.5g	3%
Trans Fat	0g	
Cholesterol	30mg	10%
Sodium	10mg	
Total Carbohydrate	5g	
Fiber	3g	
Protein	0.4g	
Vitamin A	0%	
Calcium	10%	

**Pharmacy Aisle:** A person is seen from behind, standing in a pharmacy aisle with shelves of products.

**Field:** A person is working in a field, possibly tending to crops.

## Integrating biofortification in the food industry

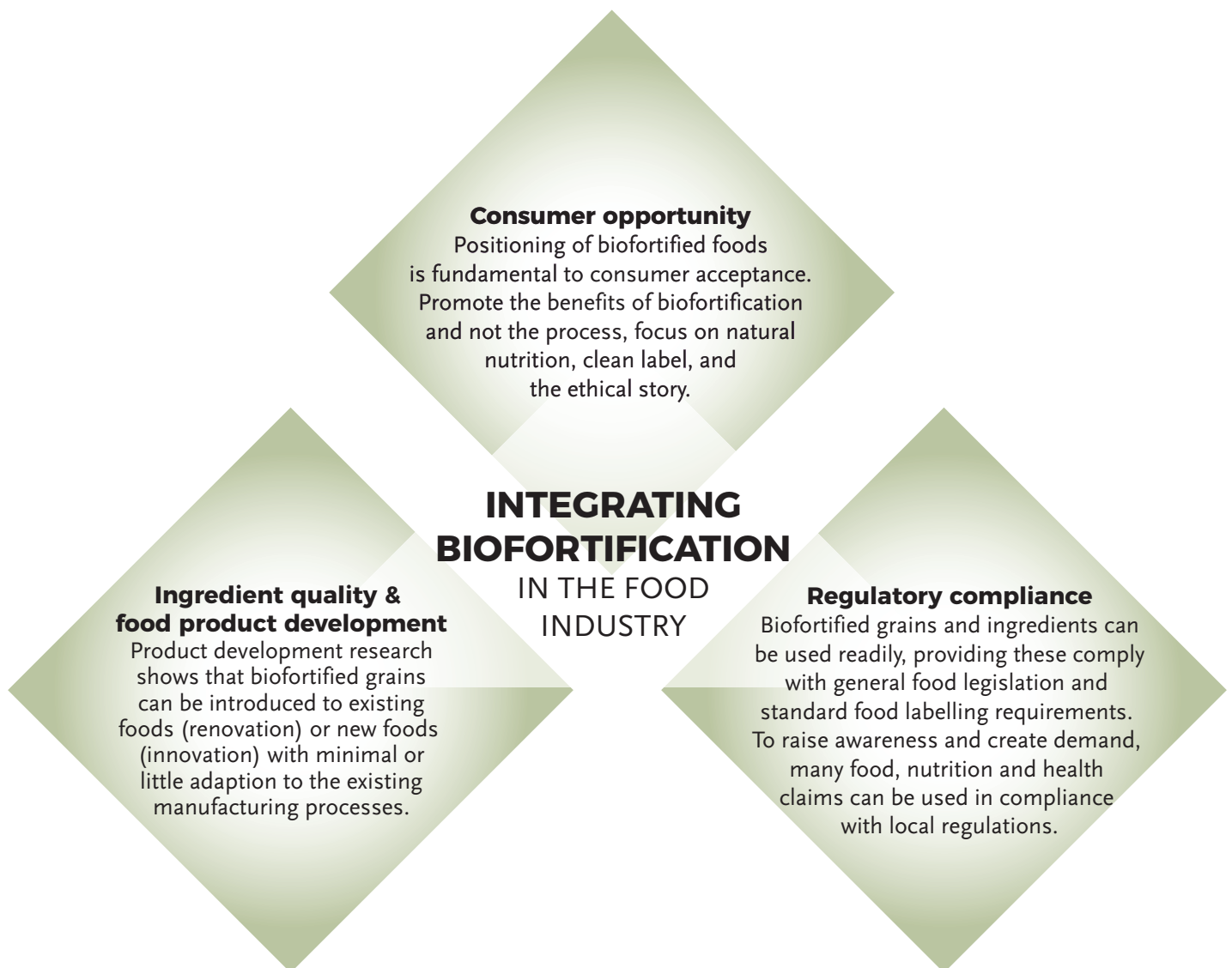
Enhancing the natural nutrient content of foods through biofortification is poised to be an impactful and profitable opportunity for the global food and beverage industry. High-iron pearl millet could be another quinoa phenomenon, and experts predict that by 2025, biofortification as a method to improve nutrition will be widespread.

Biofortification is a unique business opportunity for the global food industry. While biofortified crops and foods have most often been targeted at population segments that are at greatest risk of malnutrition, it is also relevant to the growing segment of health-conscious consumers who seek natural sources of nutrition through their regular diet.

HarvestPlus is an expert in biofortification and can assist food manufacturers of all sizes and types to integrate biofortified ingredients in their supply chains. We have produced a white paper series to support discussion of effective and efficient approaches to achieving this integration.

### The three papers cover:

1. Consumer attitudes and perceptions of biofortification and biofortified foods;
2. Enhancement of manufactured foods with biofortification;
3. Differentiating and communicating biofortified products in the current regulatory landscape.



# Differentiating and Communicating Biofortified Products in the Current Regulatory Landscape

*Prepared in association with Leatherhead Food Research.*

HarvestPlus improves nutrition and public health by developing and promoting biofortified foods that are rich in vitamins and minerals, and providing global leadership on biofortification evidence and technology. Biofortified crops, which are conventionally bred to have higher amounts of micronutrients, can help provide essential vitamins and minerals to the diet. They are effective in reducing hidden hunger and are an integral component of food-based approaches to improve nutrition and food security, including dietary diversification, supplementation, and commercial fortification, among others.

For the purpose of this document, the term biofortification refers to the HarvestPlus and World Health Organization (WHO) definition: “Biofortification is the process by which the nutritional quality of food crops is improved through agronomic practices, conventional plant breeding, or modern biotechnology. Biofortification differs from conventional fortification in that biofortification aims to increase nutrient levels in crops during plant growth rather than through manual means during processing of the crops. Biofortification may therefore present a way to reach populations where supplementation and conventional fortification activities may be difficult to implement and/or limited.”

In this respect, foods made from conventionally-bred biofortified crops/grains are no different to standard crops other than an increased amount of specific micronutrients, notably iron, zinc or vitamin A.

This document covers the use of biofortified grains from conventionally bred crops. It does not cover the use of genetic modification (modern biotechnology), which are subject to different and very specific regulations.

## Document purpose

Knowing how to label and market biofortified foods is essential to for food manufacturers to communicate their benefits to consumers. This document is a guide for food businesses and other interested parties on how to label and market biofortified foods. It is recommended that all food businesses also consult with their internal regulatory experts and consult local regulatory specialists before marketing biofortified foods.

The Codex Alimentarius exists as a global food code; however, food labelling and marketing codes, regulations, and standards vary in each country. When considering the labelling and marketing of a product, it is critical to establish the countries in which the product will be sold.

This document focuses on the regulatory systems in the U.S. and Europe. The development of food labelling regulations in Africa and Asia often follows EU regulations, while countries in Latin America and the Caribbean tend to follow U.S. regulations.

Using the European Union (EU) and the United States (U.S.) as examples, the following factors should be considered before making claims or statements that a product contains an ingredient that is biofortified.

# Biofortification Definitions

There are no legal or regulatory definitions of biofortification in the EU and U.S. markets, and at the time of writing this document, no other country-level legal definition was found. Biofortified crops/grains from conventional breeding techniques can be used freely provided, they comply with general food legislation.

The United States Department of Agriculture has a definition for biofortification in the Agricultural Thesaurus and Glossary released by the National Agricultural Library. This is a technical definition used by the Agricultural Research Service and it is unlikely the EU or the US will introduce a definition within the next 5 to 10 years. It should be noted that discussions at Codex are under way regarding a global definition of the term, but this will not impact the current sale or promotion of biofortified foods from conventionally bred crops.

*An increase in the nutritional value of plant foods obtained through conventional crop breeding methods or through crop genetic engineering techniques.*

*This contrasts with postharvest fortification in which nutrients are added during processing-*

—The United States Department of Agriculture definition of biofortification

## Use of biofortified foods

In the absence of specific regulations, the use and acceptability of biofortified grains, roots, and tubers in foods will be subject to the food safety requirements of the countries in which they are sold. All countries require food to be safe and suitable for their intended use.

## Labelling

Foods that are biofortified or contain biofortified ingredients may potentially distinguish themselves from their conventional counterparts in a number of different ways.

It is possible to do so by directly indicating that they or their ingredients are biofortified, or include a nutrition or health claim based on the increased levels of nutrients contained.

## Direct Representation

As indicated earlier, neither the EU or the U.S. specifically include provisions related to biofortification. In the absence of specific requirements, the messages relating to biofortification would be subject to the general provisions in the country of sale. In both the EU and the U.S., food placed on market must be truthful and not misleading, as required by the following legislation, respectively:

- Food Information to Consumers Regulations, Regulation (EU) No 1169/2011
- Federal Food Drug and Cosmetic Act, United States Code, Title 21

It is important to note that the UK itself has legislation (UK Food Safety Act Section 15) that is slightly stricter than the EU regulations, stating that an offence will be committed if the information is judged likely to mislead.

Since the term “biofortification” does not appear in common use in either markets, it remains to be seen how the term will be interpreted by consumers. In order to ensure the use of the term is truthful and not misleading, it would be prudent to ensure the biofortified ingredient is a significant component of the product and the labelling:

1. In the absence of consumer understanding, use of the term biofortified is suitably qualified; and
2. The difference between the biofortified crop and the standard crop is indicated.

HarvestPlus does not recommend the use of the term “biofortified” on food product packaging or promotional materials because consumers are not familiar with the term and it may confuse or mislead them. It is recommended that the net benefit of biofortification (nutrient content) be communicated through nutrition and health claims when the nutrients are in enough quantities as laid out in the examples on the next page.

# Nutrition and Health Claims

Nutrition and health claims are directly regulated by most countries to ensure a level playing field for industry and that consumers are not misled about the health benefits of consuming a food.

## Nutrition Claims or Nutrient Content Claims

Nutrition claims are claims that expressly or implicitly characterize the level of a nutrient in a food. An expressed claim would be any direct statement about the level (or range) of a nutrient in the food, whereas implied claim would be any claim that suggests a nutrient is absent or present in a certain amount (e.g. high in oat bran) or suggests a food, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an explicit claim or statement about a nutrient.

In relation to biofortified foods, the claims relating to stating a product “contains” or is “high in” a nutrient will be relevant. In both the EU and the U.S., these claims are permitted as long as they meet the established criteria as discussed below.

## EU

Regulation 1924/2006 establishes provisions for the use of the following claims in relation to vitamins and minerals:

- “Source” which relates to 15 percent of the reference intake per 100g;
- “High in” which relates to 30 percent of the Reference Intake per 100g; and
- Comparative claims for vitamins and minerals are excluded by the regulations.

Hence, evaluating the acceptability of a nutrition claim in the EU is straightforward: How much does my product contain per 100g and does it meet the minimum percentages of the reference intake?

## U.S.

In the U.S. the requirements are slightly more complicated. Provisions for the use of such claims are established in Title 21 of the Code of Federal Regulations (21 CFR) part 101. Claims are based on a percent of a reference intake in a similar manner to the UK; however they are not same. The percent requirements differ as well as the terminology, and there is a third category which allows for a comparative claim such as “extra.”

**Table I: US Nutrition Claims**

Claims	Conditions
“good source,” “contains,” or “provides”	The food contains 10 to 19 percent of the Reference Daily Intake (RDI) for vitamins and minerals or the Daily Reference Value (DRV) per reference amount customarily consumed.
“high,” “rich in,” or “excellent source”	The food contains 20 percent or more of the RDI or the DRV per reference amount customarily consumed.
“more,” “fortified,” “enriched,” “added,” “extra,” or “plus”	<ul style="list-style-type: none"> <li>• The food contains at least 10 percent more of the RDI for vitamins or minerals or of the DRV for protein, dietary fiber, or potassium (expressed as a percent of the Daily Value) per 100 g of food than an appropriate reference food.</li> <li>• As a relative claim, the identity of the reference food and percentage (or fraction) that the nutrient was increased relative to the RDI or DRV are declared in immediate proximity to such claim.</li> <li>• Quantitative information comparing the level of the nutrient in the product per specified weight with that of the reference food that it replaces declared adjacent to the claim or to the nutrition panel.</li> </ul>

\* RDI = Recommended Daily Intake; DRV = Daily Reference Value



The claims are based on the reference amount customarily consumed (RACC), not per 100g, which differs between products and are established by regulation. However, the levels of vitamins and minerals are consistent across different products.

**Table II: Example RACC**

Product category	Reference amount
Breakfast cereals (hot cereal type), hominy grits	1 cup prepared; 40 g plain dry cereal; 55 g flavored, sweetened cereal
Beans, plain or in sauce	130 g for beans in sauce or canned in liquid and refried beans prepared; 90 g for others prepared; 35 g dry

It is critical to note that the reference amounts for vitamins and minerals in the U.S. may differ from that used by the EU. National authorities establish reference values specific to their populations, creating differences at an international level. For example, the reference amounts for iron differ in the EU and U.S., respectively:

- 14 mg as established in the Food Information to Consumer Regulations EU 1169/2011.
- 18 mg as established in the 21 CFR 101.9

## Claims used in conjunction with nutrition claims

Claims such as “natural source of” are different from claims around natural foods. Such claims signpost to consumers that the nutrients are naturally occurring and have not been added using fortification.

To date, HarvestPlus has established that the use of “natural source of” or similar claims are permitted in the UK, the EU, Bangladesh, Democratic Republic of the Congo, India, Kenya, Nigeria, Pakistan, Rwanda, Tanzania, Uganda, Zambia, and Zimbabwe.

Some regulations establish different requirements for nutrient content claims, depending on whether the nutrients are naturally present or added.

In the UK, EU legislation explicitly permits the modification of nutrient content claims where the food naturally meets the conditions for the nutrient content claim.

In the U.S., the regulations do not specifically define the term “natural” for food generally and the term may be used generally, provided it is truthful and not misleading. This will apply when using the term to qualify a U.S. nutrient content claim such as “good source of”.

The U.S. Department of Agriculture, responsible for the regulation and labelling of meat products, has defined the term such that when it is used on a meat product, “natural” must be used in accordance with these provisions.



## Health Claims or Nutrient Function Claims

Health claims are generally restricted by regulatory authorities to ensure that consumers do not use food as a medicine. Both the EU and the U.S. permit the use of health claims; however the mechanisms and format used differ between markets.

**Using iron as an example of a nutrient about which a claim may be made:**

### EU

The EU permits health claims through the EFSA Health Claim Register.

“Health claim” means any claim that states, suggests or implies that a relationship exists between a food category, a food, or one of its constituents and health;

Only claims listed and approved in the register may be used on foods or foods used as an ingredient.

The EU health claims register includes provisions for a variety of claims relating to iron such as:

- Iron contributes to normal cognitive function;
- Iron contributes to normal energy-yielding metabolism; and
- Iron contributes to normal formation of red blood cells and haemoglobin.

These claims may be used for food which is at least a source of iron, as defined above. It should be noted that the claims address normal function and any implication that the subject of the claim “makes things better” or “rights something that is wrong” would lead them to be considered medicinal claims (hence prohibited).

### U.S.

By comparison, the U.S. uses three different mechanisms for the authorisation of health claims. A health claim is a claim that relates a substance to reduced risk of a disease or health-related condition.

**NLEA Authorized Health Claims.** These are claims reviewed by the Food and Drug Administration (FDA) against the FDA’s Significant Scientific Agreements (SSA) standard following a petition, and authorized claims are published in the legislation in 21 CFR 101 Subpart E.

**Health Claims based on authoritative statements.** These claims are based on authoritative statements by certain scientific bodies of the U.S. Government or the National Academy of Sciences, which may be used following a notification. (Successful notifications are published on the FDA website)

**Qualified Health Claims.** These are claims that do not meet the FDA’s SSA standard but may be used following a petition for a Letter of Enforcement Discretion. Such claims are qualified to indicate they do not meet the SSA standard. (Letters of Enforcement Discretion are published on the FDA’s website.)

Compared to the EU, the FDA does not permit any health claims for iron under these categories.

However, additional U.S. legislation includes provision for structure function claims, which are distinct from the U.S. definition of a health claim.

These are claims that describe the role of a nutrient or dietary ingredient intended to affect the normal structure or function of the human body (e.g. “calcium builds strong bones”), in a similar manner to the wording used for the iron claims in the EU.

Therefore, some claims authorized in the EU, such as those for iron, would not be considered health claims in the U.S. They would be considered structure-function

## Practical requirements

In order to make a claim that differentiates a product on the basis that it contains a biofortified ingredient as opposed to a standard ingredient, companies would need to be able to guarantee that their products contain the added-value ingredient.

In both the EU and the U.S., there are provisions related to food security and safety that requires companies to identify the immediate source of ingredients and the destination of products. These requirements are established under the following respective regulations:

- Regulation 178/2002 (EU)
- 21 CFR 1 Subpart J – Establishment, Maintenance and Availability of Records (U.S.)

These traceability systems would be insufficient to guarantee that products contain an ingredient for which claims are made; therefore, companies wishing to differentiate their products on this basis would be expected to have an identity preserved system in place that tracks the crop from farm to fork.

claims which may be made without premarket approval, provided of course that that food contains a suitable amount of iron to justify such a claim.

While the EU and the U.S. both use the term “health claim,” the meanings are different and it is important to understand these subtleties to know what claims can be made and identify the requirements to make them.

A number of auditing companies have established their own identity preservation system by which they will audit and certify compliance.

Identity preservation systems are used as an auditing system to ensure against cross contamination of a product. These are mainly used to ensure a GMO-free status, however the practice behind such audits would apply equally to preserving the identity of biofortified crops.

The Agricultural Marketing Service, an agency within the USDA, offers an Identity Preservation Program—a voluntary service to provide independent, third-party verification of the identification, segregation, and traceability of their product’s unique, value-added characteristic.



# Other ways to talk to consumers about biofortification

## Corporate communications

When the finished food does not have sufficient amounts of a nutrient to make a claim, it is possible to advertise the use of biofortified ingredients in other ways.

For example:

- Access to Nutrition Index. Food businesses, as part of the Access to Nutrition Index, have reported their involvement with biofortification in the 2018 index. [www.accesstonutrition.org/resources/2018-atni-report](http://www.accesstonutrition.org/resources/2018-atni-report)
- Corporate social responsibility reporting. Food businesses can communicate their involvement and support for biofortification on business reporting and corporate social responsibility.

## Supporting smallholder farmers and social responsibility claims

It is possible to inform consumers about support of the HarvestPlus Program. There are several other examples of success such as the Fair Trade scheme or the Unilever smallholder farmers interventions exist on the market. Euromonitor Passport recently published a report on the “World Market for Ethical Labels” which highlights consumer interest and opportunities in this area.

## Using the HarvestPlus Logo

The HarvestPlus logo can be licensed for use in the marketing and promotion of food products and businesses. The HarvestPlus logo does not constitute a health or nutrition claim.



### HarvestPlus™

Please contact Jenny Walton at HarvestPlus for more information, [j.walton@cgiar](mailto:j.walton@cgiar)

## Taste claims

An example of a taste claim is the following: *Eight out of 10 people prefer the taste of orange maize to their usual product.*

Such claims can be made if they can be confirmed with relevant test results.

# Conclusion

Provided they are safe for their intended use, biofortified crops and grains and derivatives thereof can be used as foods themselves and/or as food ingredients.

The key to the adoption of biofortified foods is the ability to effectively communicate the difference between biofortified products and conventional products, and the relative benefit of the former. Since biofortified foods are not required to be specifically regulated, this must be achieved through the existing food labelling framework of the countries of where the products are sold.

Both the EU and U.S. markets provide opportunities for biofortified foods, such as those containing a higher level of iron. Such opportunities include:

- factual statements about biofortification that are truthful and not misleading, either on their own or as part of a product name or logo;
- nutrition claims;
- health claims or structure function claims

However, the mechanisms differ between countries, and although similar messaging may be permitted, the regulatory mechanisms can be quite different. Therefore:

1. requirements may differ; and
2. messaging may be market dependent.

Tracing the biofortified ingredient from field to final product will be essential to establish integrity and justify any claims that distinguish the product from the conventional product.

The FDA's Statement of Policy – Foods Derived from New Plant Varieties (1992) relates to both conventionally bred and genetically engineered crops. While legislation does not mandate a consultation with the FDA, the FDA encourages producers of new food ingredients to consult with the Agency if there is a question about an ingredient's regulatory status.

This contrasts with the EU, where genetically modified food is specifically regulated under Regulation (EC) No. 1829/2003. Crops must be reviewed and approved prior to their use in food.

For further information please contact Jenny Walton at HarvestPlus [j.walton@cgiar.org](mailto:j.walton@cgiar.org)

## Disclaimers

**At the time of writing, the UK was part of the EU and pending a possible Brexit.**

We recommend that all food businesses consult with their internal regulatory experts and consult local regulatory specialists or authorities. HarvestPlus or associated organisations and partners are not responsible for food product labelling.

**This document in no shape or form acts as legal or regulatory advice from HarvestPlus or any of its associated organizations. HarvestPlus and associated organizations hold no responsibility for communications around the promotion of foods made using biofortified crops, grains or foods. Any business or organization is fully responsible for their own communication.**



## Acknowledgments

This project was funded by UK Aid from the UK Government.

Biofortification is a groundbreaking technology that was developed to reach the world's most vulnerable and malnourished. In order to reach these population groups quickly and efficiently, strategies are required to integrate biofortified foods in both local and global food systems. By creating a global market for biofortification, the resulting growth in demand will stimulate investment in the science and commercialization of this technology. Smallholder farmers have always been and will remain the target beneficiary of the HarvestPlus program.

*The research was conducted by Leatherhead Food Research on behalf of HarvestPlus, [harvestplus.org](http://harvestplus.org)*