

PAS 234:2021

Cereals and cereal products – Iron enriched bean and pearl millet grain – Specification



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Foreword

This PAS was sponsored by the Commercialization of Biofortified Crops (CBC) Programme, which is a partnership between the Global Alliance for Improved Nutrition (GAIN) and HarvestPlus, with funding from Netherlands Ministry of Foreign Affairs and German Federal Ministry for Economic Cooperation and Development. Its development was facilitated by BSI Standards Limited and it was published under licence from The British Standards Institution. It came into effect on 30 November 2021.

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Relationship with other publications

PAS 234 is published as one of three related publications:

- PAS 233, Zinc enriched wheat, maize and rice grain – Specification;
- PAS 235, Provitamin A carotenoids (PVAC) enriched maize grain, casava and sweet potato tubers – Specification¹⁾

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¹⁾ In preparation.

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The provisions of this PAS are presented in roman (i.e. upright) type. Its requirements are expressed in sentences in which the principal auxiliary verb is “shall”.

Commentary, explanation and general informative material is presented in smaller italic type, and does not constitute a normative element.

Where words have alternative spellings, the preferred spelling of the Shorter Oxford English Dictionary is used (e.g. “organization” rather than “organisation”).

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0 Introduction

0.1 General

HarvestPlus leads and coordinates a global effort within the Consultative Group on International Agricultural Research (CGIAR) network to improve nutrition by promoting biofortified, nutrient enriched staple crops. This effort focuses on catalyzing the development, production, delivery and consumption of foods that are rich in essential micronutrients, including vitamin A, iron and zinc. In May 2018, HarvestPlus and GAIN launched a landmark partnership to accelerate progress towards improving access to biofortified seed, grain and foods via commercial channels with the Commercialisation of Biofortified Crops (CBC) programme.

The standards outlined in the PAS are meant to enable easier procurement of minimal (postharvest cleaning and removal of agricultural remains) or unprocessed beans and pearl millets at the wholegrain stage in the supply chain. Processing after this point, which may remove part of the grain and reduce micronutrient content, is not covered by this PAS. Further processing and promotion to consumers is not covered.

0.2 Iron

This PAS will focus on crops enriched with iron through biofortification technology. Iron deficiency is one of the most common micronutrient deficiencies in the world and a major contributor to anaemia, especially among young children and women of reproductive age. Nearly 42% of children under 5 years and 40% of pregnant women worldwide are anaemic. [1]. Iron is an essential micronutrient found most abundantly in the blood cells of the body. It is important for several functions in the body, including:

- a) cognitive processing;
- b) immune response competence;
- c) physical work endurance and efficiency; and
- d) red blood cell function in oxygen transport.

When consumed as part of usual daily meals, iron enriched bean and pearl millet could contribute 75 to 90 percent of daily bioavailable iron needs for women and young children.

NOTE 1 See *HarvestPlus publication, Estimated Average Requirements Provided by Biofortification [2]*.

Several factors determine the amount of iron absorbed by the body from iron enriched crops, such as average daily consumption, degree of processing, type of preparation and form of final food product, and the type of iron compound itself. Research has shown that total iron absorption (mg) from iron enriched foods is higher than that from conventional crops. This fact is further corroborated by the consistent findings that regular consumption of iron enriched crops has been shown to improve cognitive function and work performance of adolescents and young women.

NOTE 2 See *Bioavailability of iron, zinc, and provitamin A carotenoids in biofortified staple crops [3] and Food Biofortification — Reaping the Benefits of Science to Overcome Hidden Hunger — A paper in the series on The Need for Agricultural Innovation to Sustainably Feed the World by 2050 [4]*.

0.3 Rationale

Iron enriched grains and beans are visually indistinguishable from standard commercial grains and beans. To facilitate domestic, regional, and international procurement and trade of iron enriched bean and pearl millet, individuals and entities along the value chain need to have specific guidance in order to differentiate the iron content of iron enriched grains and beans. The requirements outlined in this PAS identify global standards for iron enriched crops and aim to aid the widespread adoption and scale-up of these commodities in local and global food systems.

The methods and definitions of the biofortification technology used to create more nutritious crops are set out in several other regulatory and academic publications. Iron enriched bean and pearl millet are the terms used throughout this PAS to define the final bean and grain products. All terms associated with biofortification (i.e. biofortified, biofortify) are not used within this PAS but are accepted terms for identifying nutrient enriched grains and beans. These terms might be used by various entities, including, but not limited to, international nutrition and agriculture agencies, governments, researchers, and private and public enterprises. It is important to note that consumer understanding and acceptance of the term “biofortification” might vary country to country.

PAS 234 is not intended to be a position statement on the different types of breeding technologies available to produce iron enriched bean and pearl millet. This PAS focuses on the iron content in the final grain and bean product and its impact on human nutrition, not on the technology used. The PAS sponsor and steering committee members acknowledge the ongoing international conversation concerning the use and acceptance of conventional and transgenic crops among global stakeholders and consumers. It is the responsibility of the user of this PAS to abide by current regulations within countries and to properly communicate to consumers, as applicable, the source of the grain and bean and the breeding technology used.

At the time of publication, conventional plant breeding was the most widely available and adopted form of iron enriched bean and pearl millet, and there is a robust collection of scientific literature on the subject published in peer-reviewed journals. Other technologies to enhance iron content or bioavailability in crops for human health are currently in development and will be tested and evaluated as these crops become available.

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1 Scope

This PAS specifies requirements for iron enriched bean (*Phaseolus vulgaris L.*) and pearl millet (*Pennisetum glaucum*) intended as food for human consumption. It includes requirements for:

- a) class levels of iron content;
- b) sampling guidance;
- c) packaging; and
- d) labelling.

This PAS is applicable only to iron enriched pearl millet grain and bean produced from seed developed using breeding technologies or agronomic practices such as fertilization.

NOTE 1 *The breeding methods permitted by a country for local production and/or import or export markets are regulated by national and international legislation and are outside the scope of this PAS.*

This PAS is not applicable to pearl millet grain and bean that has undergone post-harvest fortification.

This PAS is intended for all entities, regardless of size, that are producing, procuring, and selling iron enriched bean and pearl millet grain for human consumption.

This PAS is intended to be used by private and public enterprises in sectors of the food supply chain that procure and sell pearl millet grain and bean, governments, and associated quality and compliance agencies.

NOTE 2 *Examples of users of this PAS include, but are not limited to, food aid organizations, aggregators, traders, millers, primary food processors, seed producers, food manufacturers, national agriculture agencies and food standards agencies.*

This PAS does not cover standards for all quality characteristics, contaminants (e.g. heavy metals, pesticide residues, mycotoxins and noxious seeds) or nutrient claims for food labelling.

NOTE 3 *Standards and regulations for these components are described elsewhere in Codex Alimentarius (see <https://www.fao.org/fao-who-codexalimentarius/home/en/>) and by regional or national authorities.*

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies²⁾. For undated references, the latest edition of the referenced document (including any amendments) applies.

BS EN ISO 712 *Cereals and cereal products – Determination of moisture content (Basic reference method)*

BS EN ISO 24333, *Cereals and cereal products – Sampling*

[N1] AOAC INTERNATIONAL. *Lead, Cadmium, Iron, Copper and iron in foods. AOAC 999.10. 2005*

[N2] AFRICAN STANDARD. *CD-ARS-463, Pearl-millet-grains-Specification.*

[N3] CODEX ALIMENTARIUS CODEX *Standard for whole and decorticated pearl millet grains 169*

[N4] EAST AFRICA COMMUNITY. *EAS 284, Pearl millet grains – Specification*

²⁾ Documents that are referred to solely in an informative manner are listed in the Bibliography.

3 Terms and definitions

For the purposes of this PAS, the following terms and definitions apply.

3.1 biofortification

process of increasing the nutrition quality of food crops through conventional plant breeding, improved agronomic practices and/or modern biotechnologies.

3.2 global baseline

average level of iron content found in a specific commercial crop

NOTE For the purposes of this PAS, conservative global baselines of 50 ppm (5.0 mg/100 g) for bean and 47 ppm (4.7 mg/100 g) for pearl millet are used; see Progress Update: Crop Development of Biofortified Staple Food Crops Under HarvestPlus [5].

3.3 nutrient enriched staple food crops

staple food crops containing increased levels of specific micronutrients as a result of plant breeding technologies or agronomic practices

3.4 iron enriched

increased levels of iron above a specified baseline by class (I, II and III) as a result of plant breeding technologies or agronomic practices

4 Bean

COMMENTARY ON CLAUSE 4

This PAS refers to whole bean grain.

4.1 Quality requirements

4.1.1 Iron enriched bean shall be safe and suitable for human consumption.

4.1.2 Iron enriched bean shall be free from abnormal flavours, foreign odours, mould and living insects.

4.1.3 Iron enriched bean shall be dried and stored at a moisture content not exceeding 14%.

NOTE Different moisture content might be required depending on climate and storage conditions.

4.2 Iron content requirements

4.2.1 Classification of iron enriched bean shall be based on iron content limits in accordance with Table 1.

NOTE Class I provides the highest nutrition impact when consumed as a whole bean minimally processed food. Iron enriched bean should be produced under optimal agricultural conditions and agronomic practices to achieve the highest iron content.

Table 1 – Levels of iron content in iron enriched bean grain

Class	Iron content mg/kg	Standard method of analysis (or equivalent)
Class I	≥94	AOAC 999.10 [N1]
Class II	83 – <94	
Class III	72 – <83	

4.2.2 Iron enriched bean shall be safely handled and properly cleaned to prevent mineral contamination (from soil and equipment) during analysis.

NOTE Contamination might cause an elevated reading of iron during analysis and result in an inaccurate assessment of the iron content of iron enriched bean.

4.2.3 Iron enriched bean shall be analyzed using precision analytical methods [e.g. inductively coupled plasma atomic emission spectroscopy (ICP-OES), X-ray fluorescence (XRF)] in a certified laboratory with established quality control measures able to quantify its level of error to obtain accurate and reliable information of the iron content of the crop and indicators of contamination (i.e. measurement of other select minerals, such as aluminium or chromium). XRF is the standard high-throughput method for screening in plant breeding, but to test for index elements for contamination, precision methods such as ICP-OES shall be used. XRF can be used in the future once sensitivity of the methodology increases.

NOTE *Laboratories providing or intending to provide iron content test should demonstrate levels of competence, such as partaking in a proficiency testing programme and quality assurance (e.g. BS EN ISO/IEC 17025 accreditation) for iron enriched bean and/or pearl millet.*

4.2.4 The incremental iron increase shall be calculated against the global baseline iron value of 50 mg/kg (5.0 mg/100 g) for commercial bean varieties.

NOTE 1 *See Annex A for more information on baselines and establishing target levels of iron content.*

NOTE 2 *Levels of Iron content are established based on food consumption for target populations (children 4–6 years old and non-pregnant, non-lactating women of reproductive age), estimated nutrient losses during processing and nutrient bioavailability [6].*

NOTE 3 *Values will be expressed in ppm, mg/kg and mg/100 g where appropriate, throughout the document.*

4.3 Sampling

Representative sampling shall be carried out in accordance with the methods specified in BS EN ISO 24333.

NOTE *See Annex B for further guidance on appropriate amounts to sample based on lot size.*

4.4 Packaging

4.4.1 Iron enriched bean shall be first cleaned and then stored in clean, clearly labelled and intact sacks. Sacks shall be securely closed and sealed during transport and storage to protect from water, pests and micro-organisms.

4.4.2 Iron enriched bean shall be packed in containers to safeguard the hygienic, nutritional, technical and organoleptic qualities of the product.

4.4.3 Containers shall be made of substances that are safe and suitable for the storage of bean for human consumption.

4.5 Labelling

4.5.1 In addition to the requirements of local food and bean labelling standards, each package shall be legibly labelled with the following information:

- a) product name identified as “iron enriched bean”;
- b) iron class (I, II or III);
- c) country of origin;
- d) batch or lot number;
- e) date of harvest;
- f) net weight (kg); and
- g) name and address of manufacturer or packer.

4.5.2 Information for non-retail containers shall be given either on the container or in accompanying documents, except that the name of the product, lot identification, and the name and address of the manufacturer or packer shall appear on the container.

NOTE *Lot identification and the name and address of the manufacturer or packer may be replaced by an identification mark provided that such a mark is clearly identifiable with the accompanying documents.*

5 Pearl millet

COMMENTARY ON CLAUSE 5

This PAS applies to whole pearl millet (decorticated grain).

5.1 Quality requirements

5.1.1 Iron enriched pearl millet shall be safe and suitable for human consumption.

5.1.2 Iron enriched pearl millet shall be free from abnormal flavours, foreign odours, mould and living insects.

5.1.3 Iron enriched pearl millet shall be dried and stored at a moisture content not exceeding 12%, in accordance with BS EN ISO 712.

NOTE Different moisture content might be required depending on climate and storage conditions.

5.1.4 Other key attributes of iron enriched pearl millet shall meet quality standards included in:

- CD ARS 463 [N2];
- CXS 169 [N3]; and
- EAS 284 [N4].

5.2 Iron content requirements

5.2.1 Iron enriched pearl millet shall be classified based on iron content limits in accordance with Table 1 or Table 2.

Table 2 – Levels of iron content in iron enriched pearl millet

Class	Iron content mg/kg	Standard method of analysis (or equivalent)
Class I	≥77	AOAC 999.10 [N1]
Class II	69 – <77	
Class III	62 – <69	

NOTE Class I provides the highest nutrition impact when consumed as a whole grain minimally processed food. Iron enriched pearl millet should be produced using optimal agricultural conditions and agronomic practices to achieve the highest iron content.

5.2.2 Iron enriched pearl millet shall be safely handled and properly cleaned to prevent mineral contamination (from soil and equipment) during analysis.

NOTE 1 Contamination might cause an elevated reading of iron during analysis and result in an inaccurate assessment of the iron content of iron enriched pearl millet.

NOTE 2 Paddy (rough) pearl millet has a high level of soil contamination and therefore should not be used to determine the iron content of iron enriched pearl millet.

5.2.3 Iron enriched pearl millet shall be analyzed using precision analytical methods [e.g. inductively coupled plasma atomic emission spectroscopy (ICP-OES), X-ray fluorescence (XRF)] in a certified laboratory with established quality control measures able to quantify its level of error to obtain accurate and reliable information on the iron content of the crop and indicators of contamination (i.e. measurement of other select minerals, such as aluminium or chromium). XRF is the standard high-throughput method for screening in plant breeding, but to test for index elements for contamination, precision methods such as ICP-OES shall be used. XRF can be used in the future once sensitivity of the methodology increases.

NOTE Laboratories providing or intending to provide a test of iron content should demonstrate levels of competence such as partaking in a proficiency testing programme and quality assurance (e.g. BS EN ISO/IEC 17025 accreditation) for iron enriched bean and pearl millet.

5.2.4 The incremental iron increase shall be calculated against the global baseline iron value of 47 mg/kg (4.7 mg/100 g) for commercial pearl millet.

NOTE See Annex A for more information on baselines and establishing target iron content levels.

5.2.5 The incremental iron increase shall be calculated against the global baseline iron value of 47 mg/kg (4.7 mg/100 g) for commercial milled pearl millet with degree of milling. It is largely consumed as whole grain.

NOTE Iron content levels are established based on physiological requirements and food consumption for target populations (children 4–6 years old and non-pregnant, non-lactating women of reproductive age), estimated nutrient losses during processing and storage, and nutrient bioavailability [6].

5.3 Sampling

Representative sampling shall be carried out in accordance with the methods specified in BS EN ISO 24333.

NOTE See Annex B for further guidance on appropriate amounts to sample based on lot size.

5.4 Packaging

5.4.1 Iron enriched pearl millet shall be first cleaned and then stored in clean, clearly labelled and intact sacks. Sacks shall be securely closed and sealed during transport and storage to protect from water, pests and micro-organisms.

5.4.2 Iron enriched pearl millet shall be packed in containers to safeguard the hygienic, nutritional, technical and organoleptic qualities of the product.

5.4.3 Containers shall be made of substances that are safe and suitable for the storage of pearl millet for human consumption.

5.5 Labelling

5.5.1 In addition to the requirements of local and international food and grain labelling standards, each package shall be legibly labelled with the following information:

- a) product name identified as "iron enriched pearl millet grain";
- b) iron class (I, II or III);
- c) country of origin;
- d) batch or lot number;
- e) date of harvest;
- f) net weight (kg); and
- g) name and address of manufacturer or packer.

5.5.2 Information for non-retail containers shall be given either on the container or in accompanying documents, except that the name of the product, lot identification, and the name and address of the manufacturer or packer shall appear on the container.

NOTE Lot identification and the name and address of the manufacturer or packer may be replaced by an identification mark provided that such a mark is clearly identifiable with the accompanying documents.

Annex A (informative)

Nutrient enriched crops and establishing target iron content values

During the development phase for biofortification, the nutrition target increment for iron was established at +44 mg/kg (4.4 mg/100 g) and +30 mg/kg (3.0 mg/100 g) above the standard global baseline iron content of existing market varieties for bean and pearl millet, respectively. This target was established based on average consumption, losses during storage and processing, and bioavailable amount of the micronutrient (see Table A.1).

Research on the iron bioavailability, retention, and processing losses of iron enriched bean and pearl millet has been conducted by HarvestPlus and several other partners and is ongoing and publicly available in peer-reviewed academic journals.

The average content of a micronutrient, such as iron and several other trace elements, might vary country to country and even within a large country due to different agroecological zones. These natural variations occur and are based on factors external to the plant, including soil health, plant maturation, climate conditions, water availability, and several other environmental and biological elements. Select germplasms might also have naturally higher levels. Due to these variations, a global baseline value is established to set uniform standards to assist breeding programmes, governments, and industries implement and scale biofortification.

Before an iron enriched crop is released by a government and made available to farmers, the crop undergoes field testing in the local growing conditions to verify that the agronomic traits and final micronutrient content (local nutrient content+target increase) are acceptable. These field trials follow guidelines and protocols that are standard practice among researchers, plant breeders and the national agricultural research system (NARS).

Additional protocols and guidelines for micronutrient analysis of nutrient enriched crops have been published in several academic journals and are publicly available.

NOTE See the *HarvestPlus Biofortified Crops Around the World map [7]* to see where iron enriched crops are currently released or in testing or contact the national agricultural authorities in the country of interest.

As increased iron content becomes mainstreamed into breeding programmes, the baseline value of a crop continues to evolve over time. HarvestPlus and other global leaders in biofortification continue to evaluate and update regional and global baseline data as it becomes available.

Figure A.1 – Establishing target increments

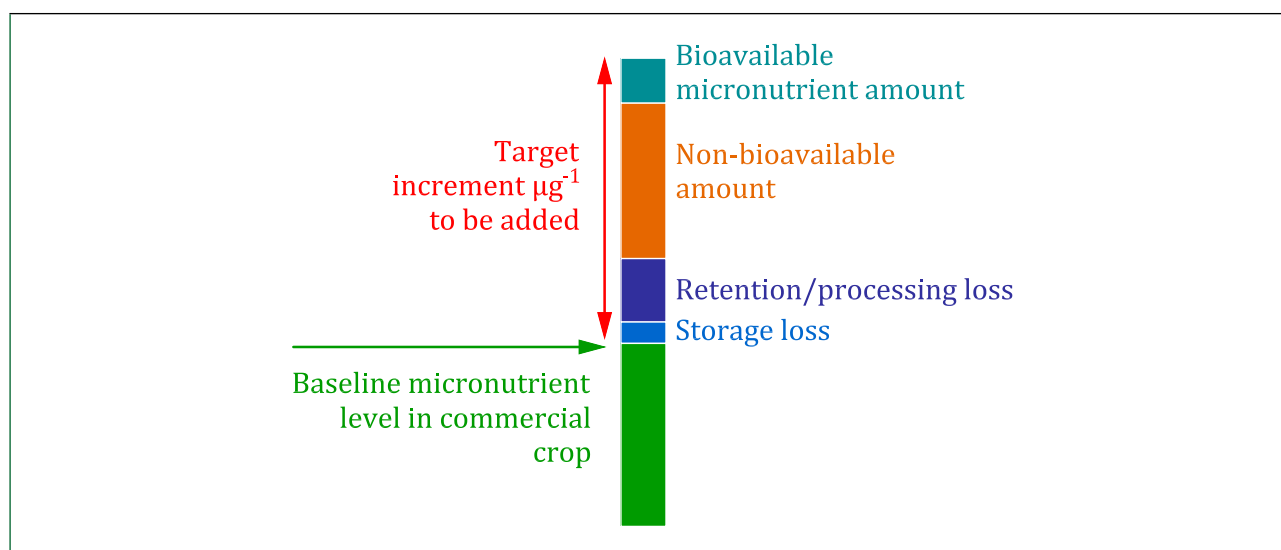


Table A.1 – Global baseline values and target increment for iron enriched crops

Crop	Global baseline	Target increment mg/kg	Class I	Class II	Class III
Iron enriched bean	50 mg/kg	+44 mg/kg	≥44.0 mg/kg above baseline	33.0 – <44.0 mg/kg above baseline	22.0 – <33.0 mg/kg above baseline
Iron enriched pearl millet	47 mg/kg	+30 mg/kg	≥30.0 mg/kg above baseline	22.0 – <30.0 mg/kg above baseline	15.0 – <22.0 mg/kg above baseline

Example

A company in India wants to procure iron enriched pearl millet variety Fe123. A sample of the crop is sent to a certified reference laboratory for analysis and the iron enriched crop has 88 mg/kg iron content. The global baseline value of iron in pearl millet is 47 mg/kg. Variety Fe123 is 41 mg/kg above the baseline and therefore qualifies as a Class I product.

Annex B (informative) Sampling requirements

Obtaining a representative grain and bean sample is essential for accurate analyses. Representative samples can be collected using established standards for international sampling methods (see BS EN ISO 24333). The minimum representative sample size for laboratory analysis of nutrient enriched crops is between 1 kg and 2 kg.

It is recommended that representative sampling be done using a hand probe. The number of probes taken per bag depends on the total number of bags in the lot and the size of the hand probe. If more grain or bean is collected than is required for analysis (e.g. 3 kg), take a subsample to obtain the minimum amount required for laboratory analysis.

- a) For lots or sub-lots <1 metric tonne (MT), randomly collect samples from at least six bags (packed in a 50 kg bag).
- b) For lots or sub-lots 1–3 MT, randomly collect samples from 30% of the bags (packed in a 50 kg bag).
- c) For lots or sub-lots 3–20 MT, randomly collect samples from 10% of the bags (packed in a 50 kg bag).
- d) For lots or sub-lots >20 MT, randomly collect samples from 3% of the bags (packed in a 50 kg bag).

Bibliography

Standards publications

For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

Standards

BS EN ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

Other publications

- [1] WORLD HEALTH ORGANIZATION. <https://www.who.int/data/gho/data/themes/topics/topic-details/GHO/gho-anaemia-in-women-and-children>
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- [5] ANDERSSON, M.S., SALTZMAN, A, VIRK P.S., PFEIFFER, W.H. *Progress Update: Crop Development of Biofortified Staple Food Crops Under HarvestPlus*. *African Journal of Food, Agriculture, Nutrition and Development* Vol. 15, No. 2, April 2017.
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- [7] HARVESTPLUS. *HarvestPlus Biofortified Crops Around the World map*. <https://www.harvestplus.org/content/biofortified-crop-map-what-available-where>

Further reading

CODEX ALIMENTARIUS, *CODEX Standard for whole and decorticated pearl millet grains 169*. <https://www.fao.org/fao-who-codexalimentarius/home/en/>

UNITED STATES DEPARTMENT OF AGRICULTURE. *Standards for Beans*. <https://www.ams.usda.gov/rules-regulations/standards-beans>

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