PUBLICLY AVAILABLE SPECIFICATION

PAS 85:2000

# A quality management system to ensure the integrity and traceability of primary products in the agri-food chain

This publication is not a British Standard

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# Contents

# Foreword

This Publicly Available Specification (PAS) has been prepared by BSI in collaboration with Campden & Chorleywood Food Research Association and BSI Inspectorate.

This PAS is not to be regarded as a British Standard. It will be withdrawn upon publication of its contents in, or as, a British Standard.

This PAS shares common management system principles with the ISO 9000 and ISO 14000 series of quality system standards. Organizations may elect to use an existing management system consistent with the ISO 9000 series as a basis for its primary product integrity system. It should be recognised, however, that the application of the various elements of such a management system may be different in a product integrity system due to the different objectives or purposes of the systems and the requirements to which the organization subscribes. While a management system deals with the management system attributes, a primary product integrity system deals with a broad range of primary production activities and addresses the needs of different sectors of the agri-food chain and the evolving needs of the food industry and society in respect of the safety, legality and quality of food products.

This PAS also shares common technical requirements with the British Retail Consortium's Technical Standard for Companies Supplying Retailer Branded Food Products, October 1998 (BRC Standard) [1]. The BRC Standard covers the technical performance at food production sites, such as produce marketing and food and drink manufacturing operations. The BRC Standard requires the adoption of a Hazard Analysis and Critical Control Point (HACCP) Plan, a documented quality system and the control of factory environment standards, product, process and personnel. This PAS covers agri-food sector activities, including farms and grower's holdings, and addresses the technical performance of suppliers of primary agricultural products to food production organizations.

Acknowledgement is given to the members of the Campden & Chorleywood Food Research Association Agri-Food and Quality Management Panels, the British Retail Consortium and the BSI Technical Committee AW/90, Quality systems in the food industry, who were consulted in the development of this specification.



This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

**Compliance with a Publicly Available Specification does not of itself confer immunity from legal obligations.**

**Summary of pages**

This document comprises a front cover, an inside front cover, pages i and ii, pages 1 to 12, an inside back cover and a back cover.

# 0 Introduction

**0.1** Food businesses, and ultimately consumers, are seeking reassurance on traceability and production techniques in the supply of primary agricultural products. Quality management standards and assurance schemes can help promote confidence in the integrity of these products and, for example, in the standards of crop and animal husbandry, handling and storage. They are of increasing importance at all stages of the agri-food chain in providing assurance of the integrity of the chain up to that point.

**0.2** This PAS is a quality management standard which can be used to provide assurance of the provenance of primary products in the agri-food chain in respect of the food safety or production goals specified. The standard sets down a number of requirements that can be interpreted according to the assurance specified, to provide a coherent system that covers a product throughout the agri-food sector. This PAS is designed to enable existing assurance schemes, which focus on particular aspects of production or sectors of the agri-food chain, to be integrated into a unified quality management system. It is designed to be compatible with other quality management standards and link directly with food business assurance schemes including standards for companies supplying food products.

**0.3** This PAS requires:

- a review of operations;
- a documented quality management system;
- control of operations and products.

The review is intended to provide a process for an organization to identify significant product integrity aspects that should be addressed as a priority by the organization's quality management system. Information already developed for regulatory or other purposes may be used in this process. A suitable approach to the review is the application of the HACCP technique [2]. The internationally recognized principles of HACCP are defined by the Codex Alimentarius Commission [3].

HACCP is a science based analytical tool that enables management to establish and maintain an ongoing food safety and quality programme. HACCP involves the systematic assessment of all steps involved in a primary production operation and the identification of those steps that are critical to the correct production of product. Other approaches to a review may include check-lists, interviews, direct inspection and measurement and results of audits or other inspections depending on the nature of the activities.

HACCP is a system of food safety assurance based on the prevention of problems and is accepted by food businesses and national and international authorities as the most cost-effective means of controlling food-borne hazards. HACCP is also flexible in its application and can be applied to quality hazards and primary production activities [4]. HACCP is, therefore, a powerful system that can be applied to a wide range of simple and complex operations.

The application of the HACCP technique within a primary product quality system can result in a food safety and quality system that is more effective than the application of a quality management system alone. For example, the application of the HACCP technique to identify and evaluate hazards that are significant to the intended use of the product will determine those hazards that should be addressed as a priority by the quality management system. Such application of the HACCP technique is related to quality planning. Once the critical points have been identified, the quality system procedures can be used for control, monitoring, corrective action and verification. In addition, procedures for conducting a HACCP study can easily be documented within the quality system.

**0.4** This PAS has been written to be applicable to all types and sizes of organization in diverse geographical and cultural conditions and to accommodate a broad range of activities within the agri-food chain, including base inputs such as seed and animal supplies, crop and animal husbandry, product storage and transport. The success of the system depends on commitment from all levels and functions, especially from top management. A system of this kind enables an organization to establish and maintain a primary product integrity system, to achieve conformance with it, and to demonstrate such conformance to others. The overall aim of this PAS is to provide assurance on the integrity and traceability of primary products and inputs used in their production.

**0.5** It is envisaged that additional guidance on the application of this PAS to specific aspects of production or sectors of the agri-food chain will be developed.

## 1 Scope

This PAS specifies requirements for a quality management system to enable an organization to ensure the integrity and traceability of primary products in the agri-food chain in order to assure food organizations of the provenance of food raw materials used in their operations. It applies to those food safety and quality issues or production aspects over which the organization wishes to demonstrate effective control. It does not itself state specific production performance criteria or product attributes.

This PAS is applicable to any organization that wishes to:

- implement and maintain a product integrity management system;
- assure itself of its conformance with its stated policy;
- demonstrate such conformance to others.

This PAS is applicable to any aspect of the production or condition of primary products over which the organization wishes to demonstrate effective control, including for example one or more of the following items: food safety issues, food quality attributes, contaminants, genetically modified organisms, organic or other production practices, ethical and/or religious issues, animal welfare and geographical origin.

This PAS covers all agri-food sector activities, including base input suppliers (for example, seeds or animals and crop nutrients or animal feedstuffs) primary production (for example, crop and animal husbandry on farms and grower's holdings) storage sites and other primary product handling, treatment or preparation facilities.

NOTE 1 All the requirements of this PAS are intended to be incorporated into any product integrity management system. The extent of the application will depend on factors such as the nature of the production activities and the nature and size of the organization.

NOTE 2 The extent of the application of this PAS needs to be clearly defined by careful identification of the issue(s) over which the organization wishes to demonstrate effective control, including for example the codes of practice and industry guidelines to which the organization subscribes.

## 2 Definitions

For the purpose of this PAS the following definitions apply.

**2.1**
**agri-food chain**

part of the food supply chain that involves the production and supply of primary agricultural products

NOTE For the purposes of this PAS, the definition includes the supply of base inputs used in the production process, crop and animal husbandry, harvesting, the subsequent treatment and storage of the harvested product, product preparation operations and transport to the customer (usually a food preparation, packing or manufacturing operation).

**2.2**
**hazard**

factor, agent or condition of food with the potential for customer risk in the area of the issue(s) under consideration

**2.3**
**integrity**

state of the primary product in respect of its origin and condition that demonstrates that it is of the nature and substance that is expected by the customer

**2.4**
**primary products**
products arising from the primary production process

NOTE Product includes harvested crop products, prepared crop products, animal products and animals reared for meat. Production process includes crop and animal production and other agri-food chain activities.

**2.5**
**traceability**
ability to trace the history of the product through the supply chain to or from the place and time of production, including the identification of the inputs used and production operations undertaken

# 3 Planning

## 3.1 Quality policy

**3.1.1** The organization shall have a clearly defined quality policy. Top management shall ensure that it:

- is appropriate to the nature of the organization's activities and that the area of application is clearly identifiable;
- includes a commitment to comply with the relevant requirements to which the organization subscribes (see **3.3**);
- is documented, implemented and maintained and communicated to all employees.

**3.1.2** The policy shall be sufficiently clear to be capable of being understood by internal and external interested parties. The area of application of this PAS shall be clearly identifiable by indicating compliance to the adopted industry or other standards to which the organization subscribes.

## 3.2 Review of operations

**3.2.1** The organization shall establish and maintain procedures to review their production operation to identify, evaluate and control potential hazards that are significant to the intended use of the product, in order to determine those which should be addressed as a priority by the organization's quality management system.

**3.2.2** The review shall be based on an assessment of risk, and shall identify which hazards are of such a nature that their elimination or reduction to an acceptable level is essential to the maintenance of product integrity.

**3.2.3** The extent of the review shall be consistent with the area of application of this PAS, including the commitment to produce products that meet the requirements to which the organization subscribes.

**3.2.4** The review shall be systematic, comprehensive and thorough and, where appropriate, should be based on the application of the HACCP technique.

NOTE 1. The following are the recognized principles of HACCP, as identified by the Codex Alimentarius Commission.

a) Conduct a hazard analysis.
b) Determine the critical control points (CCP).
c) Establish critical limits.
d) Establish a system to monitor control of the CCP.
e) Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.
f) Establish procedures for verification to confirm that HACCP is working effectively.
g) Establish documentation concerning all procedures and records appropriate to these principles and their application.

NOTE 2. When applying the principles of HACCP due consideration should also be given to the following aspects:

- the terms of reference of the HACCP study, that is, the extent of application;
- the HACCP team members and their training and experience;
- the essential characteristics of the product, that is, description of the product and its intended use;
- the steps in the production operation;
- keeping the HACCP up to date.

In formulating the review, reference shall be made to relevant national legislation, codes of practice, guidelines or other requirements to which the organization subscribes.

The review shall be undertaken by a multidisciplinary team and shall be implemented through the organization's quality management system.

Through the application of the review and/or the HACCP technique, the organization shall be able to demonstrate effective control of all operations undertaken.

NOTE 3. The use of the HACCP technique in quality planning is recommended because it enables the organization to establish and maintain an ongoing food safety and quality programme in a format that is internationally recognized and widely used in the food industry. However, depending on the nature and size of the organization, the use of the HACCP technique may not be appropriate in all situations. Other approaches to a review may include check-lists, interviews, direct inspection and measurement and results of audits or other inspections depending on the activities.

### 3.3 Legal and other requirements

The organization shall be able to demonstrate that it has an adequate level of technical support in respect of product integrity, so that it is kept informed of relevant legal developments and of technical developments and other requirements to which the organization subscribes.

NOTE Examples of other requirements to which the organization can subscribe are:

- industry codes of practice, production standards and assurance schemes;
- non-regulatory guidelines;
- agreements with interested parties, such as customers or public authorities.

## 4 Implementation and operation

### 4.1 Organizational structure and responsibility

**4.1.1** The organization shall have a structure that clearly ensures that the job function, responsibility and reporting relationships of staff whose activities affect the integrity of the product are clearly defined and documented.

**4.1.2** Management shall be responsible for the organization's policy and objectives, and shall provide adequate resources to ensure product integrity. Resources include human resources and specialized skills, technology and financial resources.

**4.1.3** Management shall ensure that levels of responsibility and accountability are clearly defined for key staff involved with product integrity and that employees are aware of their responsibilities.

### 4.2 Quality management system documentation

The organization shall have information, in paper or electronic form, to:

- describe the core elements of the management system;
- provide direction to related documentation.

There is no prescribed format for a quality system. This PAS requires the preparation of a quality manual that should clearly describe the overall structure of the quality system, that states the organization's objectives in relation to product integrity and covers the requirements of this PAS.

### 4.3 Quality system procedures

**4.3.1** The organization shall have, and shall operate in accordance with, written detailed procedures, instructions and reference documents to cover all processes critical to the maintenance of product integrity. Adopted codes, guidelines, production standards or other requirements to which the organization subscribes shall be clearly identified and referenced.

**4.3.2** The organization shall ensure that, where appropriate, relevant specifications exist for raw materials (including packaging materials), finished products and intermediate products (where appropriate). Specifications shall be adequate and accurate and shall ensure compliance with the relevant industry standards to which the organization subscribes and shall allow for the maintenance of product integrity.

**4.3.3** The documents shall be clearly legible, unambiguous and sufficiently detailed to enable their correct application by appropriate personnel, and shall be readily accessible at all times.

**4.3.4** Detailed procedures or work instructions shall be prepared when the absence of them would adversely affect the maintenance of product integrity.

NOTE Procedures may be in a diagrammatic or flow-chart form if this is more suitable for the organization.

### 4.4 Document control

**4.4.1** The organization shall ensure that all documents and records critical to the management of product integrity are in place and effectively controlled.

**4.4.2** All documents in use shall be properly authorised and shall be the correct version. Documentation shall be dated and readily identifiable, including revision date, and shall be maintained in an orderly manner.

**4.4.3** A procedure shall be in place to ensure obsolete documents are promptly removed from all points of issue and use, and where appropriate replaced with a revised version.

### 4.5 Record keeping

The organization shall maintain records to demonstrate effective control of product integrity. The records shall be legible and genuine.

Records shall be collated and maintained in such a way that they are readily retrievable and stored in good condition for an appropriate defined time period.

Records shall be kept in a manner that is appropriate to the nature and size of the organization.

### 4.6 Training

**4.6.1** The organization shall ensure that all employees are adequately trained, instructed and supervised commensurate with their activity.

All personnel performing tasks that can cause significant impacts on product integrity shall be competent on the basis of appropriate education, training and/or experience.

**4.6.2** The organization shall establish and maintain training procedures and full training records.

NOTE The training needs of personnel should be identified in relation to their existing and future needs.

## 4.7 Process control

**4.7.1** The organization shall be able to demonstrate effective control of all operations undertaken during production, handling, storage, preservation and transport. Where specific controls are applied they shall be adequately monitored and recorded.

**4.7.2** Where materials require specific handling procedures, including segregation, these shall be in place to ensure product integrity.

**4.7.3** The organization shall plan production and identify all process criteria that have a bearing on the maintenance of product integrity. The use of flow diagrams, charts or drawings should be considered in describing such procedures.

**4.7.4** Process control should cover, where appropriate, the following items.

### 4.7.4.1 *Production processes*

Precautions shall be in place to ensure the maintenance of product integrity during all stages in production and in the subsequent handling of the primary product.

NOTE The following operations should be included, where appropriate:

- base input supply, for example, crop variety, animal breeding, seed supply, synthetic fertilisers, sewage sludge and animal manures, pesticides, irrigation water;
- choice of site, for example location and position to avoid cross contamination, previous cropping history;
- husbandry practices, for example, cultivations, crop establishment, pest and disease control, animal rearing;
- harvesting of crops;
- post-harvest practices, for example, product cleaning operations, preservation treatments, including drying and fumigation, and packing;
- storage practices, for example, on farm or dedicated storage facilities, segregation of materials;
- product transformations, for example, preparation and processing operations;
- transportation, for example, on farm, between organizations or sites, to customer.

### 4.7.4.2 *Premises, plant, equipment and transport vehicles*

**4.7.4.2.1** Premises, plant, equipment and all vehicles used for transportation shall be suitable for the intended purpose, maintained in good repair and shall be used so as to maintain product integrity.

**4.7.4.2.2** The process flow shall be arranged in such a manner as to maintain product integrity and to ensure that product and materials are segregated to prevent contamination.

**4.7.4.2.3** Appropriate standards of hygiene and housekeeping shall be maintained. Cleaning schedules which describe the cleaning of equipment and facilities shall be established and implemented. The effectiveness of cleaning shall be verified.

### 4.7.4.3 *Personnel*

Personnel hygiene standards and health considerations shall be formulated with due regard to the risk to the product, for example where handling product, such as during or after crop harvest, or working with animals susceptible to disease. Medical screening procedures shall be in place where product safety may be compromised.

NOTE 1. Organizations may subcontract some aspects of the production process, for example subcontracting transport to the customer or to a third party haulier. Such subcontracting does not remove the organization's duty to ensure suitable transport or other service.

NOTE 2. In manufacturing, conformity to a specification of in-process or finished product can usually be immediately measured in a test. However, in agriculture and the agri-food supply chain, the effectiveness of a process commonly cannot be tested and is maintained only by careful control of parameters – for example, time, application rate, staff competence, choice of input. Appropriate measures specified in legislation, codes of practice provided by authoritative bodies or instructions supplied from other sources (such as machinery manuals or agrochemical instructions) should be used whenever applicable.

### 4.8 Purchasing

**4.8.1** The organization shall operate procedures for the approval and monitoring of those suppliers of goods and services that can affect the correct production of product.

**4.8.2** These procedures shall include clear criteria for initial and on-going assessment and standards of performance required. Assessments should take the form of one or more of the following criteria:

- inspections by the organization;
- self-assessment questionnaires;
- historical evidence of consistent and reliable performance of supply;
- approval by customers;
- authoritative recommendation;
- third-party registration or other accepted qualification by a recognized competent body.

This list is not exhaustive.

NOTE The methods and frequency of assessments should be based on history and risk.

**4.8.3** The procedures shall define how exceptions are handled.

NOTE For example, selection of raw materials and other inputs can be temporarily limited or governed by market availability or other factors. Mechanisms should be established, at least to identify the relative reliability of the alternate suppliers and sources, so that additional testing or controls can be implemented.

**4.8.4** A list of approved suppliers shall be held and it shall include details of the means of their approval.

### 4.9 Product identification and traceability

**4.9.1** The organization shall adequately identify all relevant inputs and be able to trace product from or to the point of production in the field or farm or other actual site and during post-harvest operations, storage, transport and, where appropriate, distribution to the customer.

**4.9.2** Identification shall ensure that grades, varieties or batches are not incorrectly mixed or used for the wrong purpose. Where appropriate, batches of product shall be uniquely identified at all times.

**4.9.3** A system of traceability appropriate to the product type and primary production process shall be in operation to enable the history of the product to be traced from or to the time and place of production (for example, the field, farm or other site of production) and where appropriate, the base inputs used and production practices followed.

The system of traceability shall be the most appropriate to the specific circumstance, and be sufficient to enable finished product to be identified to allow a defined assured supply chain to be identified.

NOTE Requirements for traceability will vary and depend on the nature of the product, on farm practices or other agri-food chain operations, customer specifications and legal or codes of practice requirements.

**4.9.4** The effectiveness of the traceability and identification systems shall be tested periodically by carrying out a traceability exercise on a particular product or batch, and by seeing how far along the process the supply chain can be traced and at what level of identification, for example to the field, farm or other production site.

# 5 Monitoring and corrective action

## 5.1 Product monitoring

**5.1.1** The organization shall have in place procedures for a planned sequence of observations or measurements of product at any stage to ensure the continued conformance with requirements.

NOTE Typically this should include the application of inspections, tests or other evaluations to determine compliance with expectations, specifications or contract. The procedures should evaluate product and, where appropriate, incoming raw materials at the receiving stage.

**5.1.2** The organization shall undertake or subcontract analyses critical to product integrity, using appropriate procedures and facilities.

NOTE 1. Test methods should be validated and test facilities should be independently accredited by a competent body (e.g. UKAS[1)] accreditation in the UK, or equivalent outside the UK).

Where the organization has in-house testing facilities, procedures shall be in place to ensure reliability of test results.

NOTE 2. The in-house analytical laboratory service should be accredited for the methods employed and, where appropriate, the organization should take part in independent proficiency test schemes, such as FAPAS[2)] in the UK, or equivalent outside the UK.

Personnel undertaking analyses shall be suitably qualified and/or trained to carry out the analyses required.

## 5.2 Equipment validation

**5.2.1** The organization shall operate procedures that verify that the processes and equipment employed, including production and testing equipment, are capable of producing consistently product of the desired characteristics.

**5.2.2** Measuring equipment used to monitor product characteristics shall be calibrated and where possible traceable to a recognized national standard.

NOTE The accuracy required for each piece of equipment should be appropriate to its function.

The organization shall identify critical equipment that affects product characteristics and is used to check conformity with specifications. Instruments such as thermometers, product weight scales and other meters, and dosing and spraying application equipment shall be maintained and calibrated for accuracy.

1) United Kingdom Accreditation Service, 21-47 High Street, Feltham, Middlesex, TW13 4UN, UK.

Tel. +44 (0)20 8917 8556, email rdj@ukas.com ; web site http://www.ukas.com/

2) Food Analysis Performance Assessment Scheme, Central Science Laboratory, Sand Hutton, York, YO41 1LZ, UK. Tel. +44 (0)01904 462 100, email fapas@csl.gov.uk

**5.2.3** Calibration procedures shall include a calibration schedule (decided after consideration of the importance and past reliability of the equipment), check method, acceptance criteria and, in the case of equipment failure, the action to be taken to review the validity of previous test results and to establish the status of any product that might have been out of specification since the last accurate calibration.

**5.2.4** Records of calibration including certificates shall be maintained in accordance with the organization's procedures.

### 5.3 Internal audits

**5.3.1** The organization shall audit those systems and procedures that are critical to product integrity to ensure that they are in place, appropriate and complied with.

**5.3.2** The audits shall be scheduled, and their extent and frequency shall be established, on the basis of the risks associated with the activity and the results of previous audits.

**5.3.3** Corrective actions, time-scales and responsibilities for their implementation shall be agreed. Corrective action shall be verified to ensure satisfactory completion.

**5.3.4** Internal audits shall be carried out by competent auditors.

NOTE The auditors should be independent of the area of operation being assessed.

**5.3.5** Records of audits and associated corrective actions taken shall be maintained. A summary of audit findings should be presented at management review meetings.

### 5.4 Control of nonconforming/surplus product

**5.4.1** The organization shall ensure that all out of specification product is clearly identified or segregated.

**5.4.2** The organization shall establish and implement procedures for the control of non-conforming material, including rejection, acceptance by concession or regrading for an alternative use.

NOTE 1. All nonconforming product should be handled or disposed of in a manner appropriate to the nature of the problem and/or the specific requirements of the customer.

NOTE 2. Corrective actions should be implemented to avoid the recurrence of non-conformance and adequate documentation should be kept of the action taken (see **5.5**).

### 5.5 Corrective actions

**5.5.1** The organization shall ensure that procedures exist to investigate non-conformances that are critical to product integrity. Action shall be taken to prevent the occurrence of non-conformances.

**5.5.2** Corrective actions shall be accurately documented, assigning responsibility and time-scale for their implementation. The corrective action plan shall be verified to ensure it has been completed satisfactorily.

NOTE 1. Corrective actions should involve the consideration of the following items:

- what went wrong;
- what is going to be done to correct the immediate situation;
- how it can be stopped from happening again in the future;
- who has responsibility for the actions taken and what is the time-scale for implementation.

NOTE 2. A summary of corrective actions should be submitted for management review.

**5.5.3** The action taken shall be logical and rational and shall involve a thorough review.

NOTE The corrective action can be accomplished rapidly and with a minimum of formal planning or it can be a more complex long-term activity. Such actions can include changes to the quality system. The magnitude of the problem, or the degree of risk that ensues from the non-conformance, should be used to judge the speed and nature of the corrective action.

**5.5.4** The organization shall establish and implement a product recall procedure for all products covered by the application of this PAS.

NOTE The procedure should be appropriate to the nature of the operation, formalised and reviewed to ensure its continued adequacy.

## 6 Management review

**6.1** The organization's management shall regularly review its quality and production system to ensure continued effectiveness.

Formal reviews shall be undertaken at appropriate defined intervals, and the review and actions shall be documented.

**6.2** In addition, there shall be an automatic assessment to determine if a review is required when a change occurs outside the normal review period.

NOTE The following are examples of changes that can trigger an automatic review:

- change in plant and equipment;
- change in base inputs;
- change in staff levels and/or responsibilities;
- anticipated change in customer use or requirements;
- change in legislation, codes of practice or other requirements to which the organization subscribes in the country of production or, where appropriate, the country of marketing.

**6.3** The review shall be systematic, comprehensive and thorough.

NOTE 1. Not all elements of the management system need to be reviewed at once and the review process may take place over a period of time.

NOTE 2. Reviews should include the following items:

- results of audits;
- the extent to which objectives and targets have been met;
- the continuing suitability of the management system in relation to changing conditions and information;
- concerns amongst relevant interested parties including customers and regulatory authorities.

**6.4** The review of the quality policy and procedures shall be carried out by the level of management that defined them.

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