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# GS1 Global Traceability Compliance Criteria Standard

Describes the assessment criteria for full chain traceability, providing a single process of meeting regulatory & industrial requirements using the GS1 Standards

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## Document Summary

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# 1 Introduction

A traceability gap analysis tool is critical for any Organisation or sector that produces goods or provides services that must meet specific customer, regulatory and operational objectives. An existing traceability system can be tested through a robust tool with guidelines that ensure required data and information is recorded and is reflected along the supply chain, from point of production to customer.

The GS1 Global Traceability Checklist-Control Points and Compliance Criteria is a tool developed for continuous improvement of traceability systems using global standards. This process-based tool helps to build compliance for mandatory traceability requirements within quality management systems and benchmarks them against global standards and other key traceability regulations.

Traceability systems should be supported by best practices, based on evolution of industry's needs, international regulations and global standards. System complexity may vary depending on its placement along the supply chain (i.e. producer, manufacturer, distributor, retail, etc.), the product's characteristics and the required business objectives.

The GS1 Global Traceability Checklist-Control Points and Compliance Criteria Standard is the basis for checking the key traceability components to design a traceability system framework of identifying, capturing and sharing traceability information between trading partners across the extended supply chain.

## 1.1 Scope

This document outlines assessment criteria for Global Traceability Conformance for the wide range of food and non-food consumer goods. It defines essential elements for the development of best-practices for the global production and distribution of trade items by any industry where traceability is needed or required.

The GS1 Global Traceability Checklist-Control Points and Compliance Criteria has been designed with the objective to implement and/or review existing Traceability Systems in manufacturing Organisations, producers/handlers and providers of product supplies and services to the supply chain.

**A producer/manufacturer/handler** is defined as any organisation that produces, synthesises, prepares, treats, modifies, packs or manipulates changes in products including product supplies, packaging material and raw material.

**A provider** is defined as any organisation that supplies any type of material that comes into direct contact with manufactured or processed products.

**A service provider** is defined as any organisation that provides services which come into direct contact with manufactured or processed products.

In accordance with the aforementioned definitions, any of the following organisations qualify for the application of the assessment presented in this document:

- Container and Packaging Manufacturers
- Farmers/Growers
- Importers and Exporters
- Logistic Providers
- Manufacturers/Processors
- Retailers
- Storage and Deposits providers
- Third Party Logistics Providers
- Transporters and carriers
- Distributors/Wholesalers

## 1.2 Structure

The outline of the document is as follows:

- **Introduction:** Introduces the compliance criteria based on the GS1 Global Traceability Standard

(GS1 GTS), the compliance levels and relationship with other traceability standards, regulatory and commercial requirements.

- **Control Points:** Describes the requirements and key considerations the assessed Organisation must fulfil, in order to meet the compliance criteria, the GS1 Global Traceability Checklist.
- **Business Rules and Business Requirements**
- **Terms and Definitions:** Presents the standard vocabulary used throughout this document.
- **Appendix:** Maps the relationship between the Global Traceability Checklist with other standards. This will help organisations benchmark their traceability system against other traceability requirements. In addition, there is a table whereby changes of control points are being mapped from the previous version to the latest one.

### 1.3 Regulations References

In the preparation of this standard, the following international regulations are the basis of key traceability requirements:

- **The EU Regulation (CE) N° 178/2002**, "Laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety" of the European Parliament and of the Council of January 28, 2002.
- **US Public Health Security and Bioterrorism Preparedness and Response Act of 2002**, "To improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies", United States Food and Drug Administration (FDA), June 12, 2002.
- Additionally, this standard adheres to the **EU General Product Safety Directive (2001/95/EC)** which is intended to ensure a high level of product safety throughout the EU for consumer products that are not covered by specific sector legislation (e.g. toys, chemicals, cosmetics, machinery). The Directive also complements the provisions of sector legislation which do not cover certain matters, for instance in relation to producers' obligations and the authorities' powers and tasks.

### 1.4 Standard References

The following referenced traceability and codification standard documents are essential as the basis of this document. For dated references, only the edition cited is applicable. For undated references, the latest edition of the referenced document (including any amendments) is applicable.

- [GS1 Global Traceability Standard](#) - GS1's framework for the design of interoperable traceability systems for supply chains, *Release 2.0*.
- [GS1 General Specifications](#), *Release 20.0*.
- ISO 22005:2007, Traceability in feed and food chain – General principles and basic requirements for system design and implementation.

### 1.5 Compliance Levels

This document contains all the levels of compliance that an organisation must meet to successfully complete a Traceability Assessment. Key control points must be fulfilled to comply with the traceability framework based on the GS1 GTS. The document is divided into 12 sections. It contains a total of **73** Control Points, divided into the following levels:

- **Mandatory Musts:** There are **29** "Mandatory" Control Points in the GS1 Global Traceability Checklist (shaded in red). These Control Points address the most important **Business Requirements, presented in section 3 of this document, and/or ISO 22005**. These control points cannot be indicated as **NOT Applicable (N/A)** by the assessor.
- **Mandatory Conditional Musts:** There are **24** "Mandatory Conditional" Control Points in the GS1 Global Traceability Checklist (shaded in green). These Control Points address the most important **Business Requirements, presented in section 3 of this document, and/or ISO 22005** that could be indicated as **NOT Applicable (N/A)** by the assessor, according to specific realities or situations practiced in every organisation.
- **Optionals:** There are **10** "Optional" Control Points in the GS1 Global Traceability Checklist (shaded in yellow). These Control Points address the **Business Requirements, presented in section 3 of this document**, that are under the responsibility of the trading partner of the trade items received

by the assessed organisation. It is to be noted that these control points are centered on GS1 Standards.

- **Recommendations:** There are **10** “Recommended” Control Points in the GS1 Global Traceability Checklist (unshaded). These Control Points address Traceability Requirements of other Standards, Best Manufacturing Practices or International Traceability Guidelines (see [A. Relationship between the GTC Checklist and other Standards](#)).

Possible responses to each Control Point may include:

Compliance (Yes); Non-Compliance (No) or NOT Applicable (N/A). N/A may not be used as a response to those control activities that state “No N/A” (i.e. “Mandatory Musts”). Only the **assessment team leader is authorised** to decide if a Control Point can be a **NOT Applicable (N/A) or otherwise**.

In order to obtain compliance to the GS1 Global Traceability Standard (GS1 GTS), the applicant is required to successfully complete the assessment and fulfil each of the Control Points as follows:

- **Mandatory Musts:** 100% compliance of all Mandatory Must Control Points is compulsory.
- **Mandatory Conditional Musts:** 100% compliance of all applicable Mandatory Conditional Must Control Points is compulsory.
- **Optionals:** No minimum percentage of compliance is set.
- **Recommendations:** No minimum percentage of compliance is set.

All Control Points in the GS1 Global Traceability Checklist must be assessed.

## 1.6 GS1 Global Traceability Checklist following a set of Business Requirements and Business Rules

The GS1 Global Traceability Checklist is based on a set of Traceability Business Requirements and Business Rules developed by GS1. In the Control Points section, Mandatory Musts, Mandatory Conditional or Optional Control Point are linked to their corresponding Business Requirement (BR) and/or the corresponding Business Rule (BRU) in section 3, where applicable, e.g.,: (BR1).

## 1.7 The GS1 Global Traceability Checklist and its Relationship with other Traceability & Best Manufacture Practices (BMP) Standards

There are several traceability Control Points in the GS1 Global Traceability Checklist that fulfil traceability requirements present in other Traceability Standards or BMP Standards.

If during the assessment, an Organisation would like to benchmark its traceability system against other standards using this GS1 Global Traceability Checklist, please refer to [Relationship between the GTC Checklist and other Standards](#) at the end of this document.

## 1.8 Control Points Usage Guide

The GS1 Global Traceability Checklist contains 73 Control Points. It is divided into 12 sections whereby each section has a different traceability objective. By following every section, this will cover important components of a traceability system. The table explains requirements that is to be assessed in every section.

| Section                   | Control Points | Description   |
|---------------------------|----------------|---|
| 1. Objectives             | 1.1 - 1.4      | Knowledge of local, commercial and international traceability system requirements                   |
| 2. Product Definition     | 2.1 - 2.5      | Trade item assignment in Master Data systems for all trade items received, produced and/ or shipped |
| 3. Supply Chain Placement | 3.1 - 3.3      | Identification of internal and external parties in Master Data systems                              |
|                           | 3.4 - 3.7      | Identification of internal and external locations in Master Data systems                            |

| Section                         | Control Points | Description   |
|---------------------------------|----------------|---|
| 4. Establishment of Procedures  | 4.1 - 4.5      | Defined procedures for all traceable trade items and intermediate items which are received, produced and distributed with definition of batch/lot and/or serial numbers   |
|                                 | 4.6 - 4.7      | Defined procedures of aligning critical master data between trading partners  |
|                                 | 4.8 - 4.11     | Defined procedures or tools to enable collection, recording, sharing and communication of traceability information internally and between key stakeholders  |
| 5. Flow of Materials            | 5.1 - 5.10     | Physical identification and symbology on all hierarchy levels of traceable items which are received, produced and/or shipped:<br>Unique global trade item number (e.g., GTIN/ UPC)<br>Production batch/lot code (consumer, case, pallet)<br>Unique serial number (Logistics-pallet level only)<br>Unique shipment identification number (shipment only)   |
|                                 | 5.11 - 5.12    | Process flow for transformation/manufacturing processes (from raw materials/ packaging to finished goods) and trace request response between trading partners   |
| 6. Information Requirements     | 6.1 - 6.8      | Minimum traceability related information for all hierarchy levels of traceable items which are produced, received and/or shipped to any parties:<br><ul style="list-style-type: none"> <li>- Shipment identification number (shipment only)</li> <li>- Logistic unit number or SSCC for logistic units</li> <li>- Trade item number or GTIN</li> <li>- Production batch/lot code (consumer unit, trade unit, case, pallet)</li> <li>- Serial number (consumer unit, trade unit, case, pallet)</li> </ul> Each of the traceable items identified by one of the identification numbers and where applicable the associated identification number extension, must or may be further described by attribute fields such as:<br><ul style="list-style-type: none"> <li>- quantity</li> <li>- code date (e.g. 'sell-by date', 'best-before date', 'expiry date', 'packed-at date', 'production date')</li> <li>- recipient and/or supplier of the traceable item</li> <li>- despatched date and when applicable despatched time</li> </ul> For each party identification number or GLN must or may be attribute information associated, such as address and/or telephone number |
|                                 | 6.9 - 6.10     | Internal management of traceability information linkages (electronic or paper) between inputs and outputs (all hierarchy levels of traceable items)   |
|                                 | 6.11 - 6.13    | External management of traceability information linkages (electronic or paper) including the sharing of traceability related information for traceable items  |
| 7. Documentation Requirements   | 7.1 - 7.2      | Documentation of roles, responsibilities, organisational structure and recording processes associated with traceability to support all traceability related activities  |
|                                 | 7.3 - 7.5      | Maintenance of traceability documentation and traceability records  |
| 8. Structure & Responsibilities | 8.1 - 8.3      | Traceability team in place with appropriate knowledge of traceability procedures  |

| Section                          | Control Points | Description  |
|----------------------------------|----------------|--|
| 9. Training                      | 9.1 - 9.2      | Training program and records for those responsible for traceability activities   |
| 10. Supply Chain Coordination    | 10.1           | Ability to obtain traceability information from trading partners, including the following: <ul style="list-style-type: none"> <li>- Trade item number (e.g., GTIN/ UPC)</li> <li>- Quantity</li> <li>- Batch/lot number and/or serial number</li> <li>- Code date</li> <li>- Transporter name</li> </ul> |
|                                  | 10.2 - 10.6    | Documentation of team structure, responsibilities and procedures associated with addressing a potential safety hazard crisis, including communications and contact information   |
| 11. Monitoring                   | 11.1 - 11.2    | Existence of monitoring and control plan for reviewing effectiveness of traceability procedures  |
| 12. Internal and External Audits | 12.1 - 12.2    | Definition of all produced and received trade items in specifications or other similar document  |
|                                  | 12.3           | Documentation of corrective action plans to address Traceability Non-Conformities  |

## 2 Control Points

### 2.1 Choice of objectives

| N°  | CONTROL POINTS  | COMPLIANCE CRITERIA   | LEVEL     | RATIONALE  |
|-----|---|---|-----------|--|
| 1.1 | Is the Organisation aware of traceability regulations, standards and implementation guidance (global or country specific) to which its trade items are delivered /despatched/exported and/or sold?(BRU28) | The Organisation's management and responsible persons are updated with traceability regulations, standards and/or implementation guidance (global or country specific) to which its trade items are delivered/despached/exported and/or sold. | Mandatory | Organisations are not able to sell goods to markets without being compliant with the relevant traceability requirements.   |
| 1.2 | Is the Organisation aware of all their customer's traceability requirements to which its trade items are sold? (BRU28)  | The Organisation should have a system to ensure that the site has an updated register of the applicable customer's traceability requirements to which its trade items are sold.   | Mandatory | Organisations should keep a record of their customer's traceability requirements in order to avoid missing any of the requirements leading to failure to comply. |

| N°  | CONTROL POINTS   | COMPLIANCE CRITERIA   | LEVEL     | RATIONALE   |
|-----|--|---|-----------|---|
| 1.3 | Is there a document (paper based/ electronically based) defining the Organisation's objectives, methodology and scope of its Traceability System, with a designated person responsible for it? | <p>The Organisation must have appropriate documentation on:</p> <ul style="list-style-type: none"> <li>a) Description of scope, objectives and relevant steps in a traceability system, i.e. traceability plan</li> <li>b) Description of links management within the traceability system</li> <li>c) Description of management responsibilities and personnel within the scope of the traceability system</li> </ul> <p>No N/A</p> | Mandatory | This document is meant to be the reference document for traceability information and personnel management.  |
| 1.4 | Is the management team aware of the objectives and scope of the organisation's Traceability System?  | <p>The management team demonstrates competency in explaining the scope and objectives of the organisation's Traceability System.</p> <p>Documents containing scope and defined objectives of the traceability system have been signed off by management.</p> <p>No N/A</p>  | Mandatory | The management team should have strong knowledge of the scope, objectives, projects and any important information regarding the organisation's Traceability System. |

## 2.2 Product Definitions

| N°  | CONTROL POINTS   | COMPLIANCE CRITERIA  | LEVEL                   | RATIONALE   |
|-----|--|--|-------------------------|---|
| 2.1 | Are all trade items <u>received</u> by the Organisation identified with a <u>unique identification number</u> and described in a Master Data record for each product hierarchy level that needs to be traced?                          | A Master Data record with a unique identification number and description must exist for all trade items received by the Organisation, that need to be traced. This applies to any level of the Product Hierarchy.  | Mandatory (conditional) | Identifications numbers and master data records decrease human mistakes in the process of receiving goods.                    |
| 2.2 | Are trade items <u>received</u> by the Organisation identified with a Global Trade Item Number (GTIN) and described in a Master Data record for each product hierarchy level that needs to be traced?<br>(BR3, BR7, BR13, BRU4, BRU16) | A Master Data record using the Global Data Synchronisation Network (GDSN) with a Global Trade Item Number (GTIN) and description must exist for all trade items received by the Organisation that need to be traced. This applies to any level of the Product Hierarchy. | Optional                | GTIN and the corresponding master data are used to uniquely identify trade items for the purpose of being able to trace them. |

| N°  | CONTROL POINTS   | COMPLIANCE CRITERIA  | LEVEL                   | RATIONALE   |
|-----|--|--|-------------------------|---|
| 2.3 | Are intermediate items <u>manufactured</u> by the Organisation that are critical to be traced, identified with unique identification numbers and recorded?   | A document or record with unique identification numbers and description must exist for such intermediate items, manufactured by the Organisation.  | Mandatory (conditional) | Well performed traceability is only possible by having correctly identified all traceable items.  |
| 2.4 | Are all trade items, <u>despatched</u> by the Organisation, identified with a Global Trade Item Number (GTIN) and described in a Master Data record for each product hierarchy level that needs to be traced? (BR3, BR7, BR 13, BRU4, BRU16) | A Master Data record with a Global Trade Item Number (GTIN) and a description must exist for all trade items distributed by the Organisation, at all levels of the product hierarchy that need to be traced. | Mandatory (conditional) | GTIN and the corresponding master data are used to uniquely identify trade items for the purpose of being able to trace them.                               |
| 2.5 | Are all assets that need to be traced identified in a Master Data record with a Global Returnable Asset Identifier (GRAI) and/or Global Individual Asset Identifier (GIAI)? (BR4)  | A Master Data record with a GS1 identification key must exist for all assets that need to be traced (GRAI or GIAI).  | Optional                | Identifying assets moving along the supply chain using open standards enables parties with different systems to share information on the assets seamlessly. |

### 2.3 Supply chain placement

| N°  | CONTROL POINTS   | COMPLIANCE CRITERIA  | LEVEL       | RATIONALE  |
|-----|--|--|-------------|--|
| 3.1 | Are all <u>personnel</u> directly involved within the Organisation (production and distribution area) recognised and identified with a description and an identification number in a Master Data record? | A Master Data record with a description and an identification number must exist for all the personnel involved in the production and distribution chain. The description must include at least: <ul style="list-style-type: none"> <li>• Name</li> <li>• ID number (or Badge Card)</li> <li>• Position</li> </ul> No N/A | Recommended | Human activities might be a risk in the operation. The Organisation needs to know which persons are directly involved in each process. |

| N°  | CONTROL POINTS   | COMPLIANCE CRITERIA  | LEVEL                   | RATIONALE   |
|-----|--|--|-------------------------|---|
| 3.2 | Are all trading partners assigned an identification number and have a description in a Master Data record?   | A Master Data record with description and an identification number must exist for all trading partners. The description must include at least: <ul style="list-style-type: none"> <li>• Organisation name*</li> <li>• Address*</li> <li>• Contact person**</li> <li>• Telephone number**</li> <li>• Fax**</li> <li>• E-mail**</li> </ul> (All marked with * are mandatory outside the US. All marked with ** are mandatory for US Bioterrorism Act).<br>No N/A         | Mandatory               | The identification of trading partners and keeping master data records helps the organisation with communication and to track or retrieve its trade items. This becomes very important in the case of recall or withdrawal. |
| 3.3 | Are all trading partners identified with a Global Location Number (GLN) and have a description in a Master Data record? (BR2, BRU4, BRU12)                       | A Master Data record with a Global Location Number (GLN) and a description must exist for all trading partners. The description must include at least: <ul style="list-style-type: none"> <li>• Organisation name*</li> <li>• Address*</li> <li>• Contact person**</li> <li>• Telephone number**</li> <li>• Fax**</li> <li>• E-mail**</li> </ul> (All marked with * are mandatory outside the US. All marked with ** are mandatory for US Bioterrorism Act).<br>No N/A | Optional                | GLN and the corresponding master data are used to uniquely identify companies.  |
| 3.4 | Are all internal <u>locations</u> , that need to be traced, identified with an identification number and have a description in a Master Data record? (BR1, BRU4) | A Master Data record with an identification number and a description must exist for all internal locations of the Organisation that need to be traced. (E.g. working position location, production lines, warehousing location)  | Mandatory (conditional) | The identification of locations and keeping master data records helps the organisation know the internal whereabouts of their trade items.  |

| N°  | CONTROL POINTS   | COMPLIANCE CRITERIA   | LEVEL                   | RATIONALE   |
|-----|--|---|-------------------------|---|
| 3.5 | <p>Are all internal <u>locations</u> that need to be aligned with the trading partners, identified with a Global Location Number (GLN) and have a description in a Master Data record? (BR1, BR2, BRU4)</p>                                    | <p>A Master Data record with a GS1 identification key (GLN) and description must exist for all internal locations of the Organisation that need to be aligned with the trading partners (e.g. Distribution Centre, Point of Receiving, Point of Distribution, Manufacturing Facility, Farm). <u>Every Organisation should identify at minimum the location of its legal entity.</u></p> <p>The description must include at least:</p> <ul style="list-style-type: none"> <li>• Location name*</li> <li>• Address*</li> <li>• Telephone number**</li> <li>• Fax**</li> <li>• E-mail**</li> </ul> <p>(All marked with * are mandatory outside the US. All marked with ** are mandatory for US Bioterrorism Act).<br/>No N/A</p> | Mandatory               | <p>GLN and the corresponding master data are used to uniquely identify locations.</p>   |
| 3.6 | <p>Are all external <u>locations</u>, (e.g., storage warehouses, distribution centres, trading partners) that need to be traced, identified with an identification number and have a description in a Master Data record? (BR1, BR2, BRU4)</p> | <p>A Master Data record with an identification number and a description must exist for all trading partners' locations that need to be traced (e.g. storage warehouses, distribution centres). The location must be a legal or physical entity involved in the supply chain.</p> <p>The description must include at least:</p> <ul style="list-style-type: none"> <li>• Location name*</li> <li>• Address*</li> <li>• Telephone number**</li> <li>• Fax**</li> <li>• E-mail**</li> </ul> <p>(All marked with * are mandatory outside the US. All marked with ** are mandatory for US Bioterrorism Act).</p>   | Mandatory (conditional) | <p>The identification of locations and keeping master data records helps the organisation know the external whereabouts of their trade items.</p> |

| N°  | CONTROL POINTS   | COMPLIANCE CRITERIA  | LEVEL    | RATIONALE  |
|-----|--|--|----------|--|
| 3.7 | Are all external <u>locations</u> , (e.g. storage warehouses, distribution centres, trading partners) that need to be traced identified with a Global Location Number (GLN) and have a description in a Master Data record? (BR1, BR2, BRU4) | <p>A Master Data record with a Global Location Number (GLN) and description must exist for all trading partner's locations that need to be traced. The location must be a legal or physical entity involved in the supply chain.</p> <p>The description must include, at least:</p> <ul style="list-style-type: none"> <li>• Location name*</li> <li>• Address*</li> <li>• Telephone number**</li> <li>• Fax**</li> <li>• E-mail**</li> </ul> <p>(All marked with * are mandatory outside the US. All marked with ** are mandatory for US Bioterrorism Act).</p> | Optional | GLN and the corresponding master data are used to uniquely identify locations. |

## 2.4 Establishment of Procedures

| N°  | CONTROL POINTS   | COMPLIANCE CRITERIA  | LEVEL                   | RATIONALE   |
|-----|--|--|-------------------------|---|
| 4.1 | Are there procedures being defined to describe and record traceable trade items <u>received, produced</u> and <u>despatched</u> by the Organisation?                   | <p>A documented procedure exists describing in detail each traceable trade item the Organisation receives, produces and despatches.</p> <p>The document must include:</p> <ul style="list-style-type: none"> <li>• Document number for procedures/procedure code or ID</li> <li>• Product name</li> <li>• Composition</li> <li>• Quantity</li> <li>• Packaging</li> <li>• Method(s) of distribution</li> </ul> | Mandatory (conditional) | This document describes all intern processes and helps identifying critical points CTE and critical data KDE for traceability events. This document should include all key processes performed  |
| 4.2 | Does a documented procedure exist that details the definition for the production batch/lot and/or serial number of each <u>trade item</u> created by the Organisation? | A documented procedure exists in the Organisation which describes in detail the definition for the production batch/lot and/or serial number of each trade item created by the Organisation.   | Mandatory (conditional) | The batch/lot and/or serial number definition helps organisations identify all traceable items and in turn improve the recall procedure.  |
| 4.3 | Does the Organisation have a process to review barcoding and assignment of numbers in compliance with GS1 Standards? (BR11, BR13)                                      | A documented procedure must exist to prove compliance with GS1 Standards for barcoding quality, allocation of numbers and maintenance of GTINs assignments for every trade item the Organisation distributes.  | Mandatory (conditional) | Quality of barcode must be checked before the item leaves for the open supply chain, to make sure it can be scanned at each point of the supply chain. GTIN allocation rules must be applied so that uniqueness can be guaranteed in the open supply chain. |

| N°    | CONTROL POINTS   | COMPLIANCE CRITERIA  | LEVEL                   | RATIONALE  |
|-------|--|--|-------------------------|--|
| 4.4   | Are there procedures for describing and recording critically traceable intermediate items <u>produced</u> by the Organisation?   | <p>A documented procedure exists describing in detail critically traceable intermediate items produced by the Organisation.</p> <p>The document must include:</p> <ul style="list-style-type: none"> <li>• Document number for procedures/procedure code or ID</li> <li>• Product name</li> <li>• Composition</li> <li>• Quantity</li> <li>• Packaging</li> <li>• Method(s) of distribution</li> </ul> | Recommended             | Describing and recording intermediate items helps the organisation connect inputs and outputs of production processes.   |
| 4.5   | Does a procedure exist within the Organisation for the production batch/lot and/or serial number of each <u>inventoried intermediate item</u> and/or reworked item which needs to be traced? | <p>A documented procedure exists within the Organisation for the production batch/lot and/or serial number of <u>each inventoried intermediate item</u> which needs to be traced.</p>  | Recommended             | Connecting intermediate items to production batch/lot and/or serial number helps the organisation create the link between inputs and outputs.                                |
| 4.5 a | Does a procedure exist within the organisation to describe the mass balance calculations for the various production processes?   | <p>A documented procedure exists within the organisation for any given production process that</p> <ul style="list-style-type: none"> <li>• records inputs and outputs from each production process.</li> <li>• describes how target yield was calculated and how often it is reviewed</li> </ul>  | Mandatory (conditional) | This is needed in order to ensure that all traceable products are accounted for.   |
| 4.6   | Does the Organisation have a procedure to align critical Master Data for traceability with its trading partners? (BR12, BR19)  | <p>A documented procedure exists in the Organisation which describes in detail how to align critical Master Data for traceability with trading partners. The Master Data must include:</p> <ul style="list-style-type: none"> <li>• Parties</li> <li>• Physical locations</li> <li>• Assets</li> <li>• Traceable trade items</li> </ul> <p>No N/A</p>  | Mandatory               | The quality of master data and its consistency across trading partners and throughout the supply chain are critical for seamless business processes successful trade         |
| 4.7   | Does the Organisation have an effective synchronisation process with its trading partners using the Global Data Synchronisation Network (GDSN)? (BR12, BR19)                                 | <p>An effective process for synchronising Master Data using GDSN with trading partners exists in the Organisation and is documented in detail.</p> <p>The Master Data synchronised must include:</p> <ul style="list-style-type: none"> <li>• Parties,</li> <li>• Physical locations</li> <li>• Assets</li> </ul> <p>Traceable trade items</p>   | Optional                | Global Data Synchronisation Network helps the organisation exchange quality master data and ensures its consistency across trading partners and throughout the supply chain. |

| N°  | CONTROL POINTS  | COMPLIANCE CRITERIA  | LEVEL     | RATIONALE  |
|-----|---|--|-----------|--|
| 4.8 | <p>Is there a procedure or defined mechanism (digital or paper) at each stage of the traceability flow for the <u>collection of accurate and timely data, recording and sharing of information</u> between trading partners and the identification of the responsible person for the recorded information? (BR11, BR13, BR14, BRU4, BRU 10, BRU11, BRU 18, BRU22)</p> | <p>Digital or paper forms and/or mechanisms detailing procedures for the <u>collection, recording and sharing of traceability information</u> at each stage of traceability flow, identifying each person responsible for the recorded information.</p> <p>No N/A</p>  | Mandatory | <p>Defining how traceability data is captured, stored and shared allows the organisation to have effective and efficient processes as well as having personnel aware of their responsibilities at each traceability event.</p>                           |
| 4.9 | <p>Is there an <u>internal and external trace request process</u> in place? (BR17, BR18)</p>  | <p>The Organisation has a documented procedure defining the request process for traceability information in an event of a crisis. It should contain:</p> <ul style="list-style-type: none"> <li>• List of internal and external partners</li> <li>• Identification of key personnel for crisis management (e.g. recall) with defined responsibilities</li> <li>• Communication plan to internal and external trace request</li> <li>• Key product attributes such as product identification number, batch/lot and/or serial number, quantity, composition,</li> <li>• Material type, batch/lot/manufacturing date</li> <li>• Location identification (or location attributes) within the organisation and between trading partners</li> <li>• List of documentation to be provided to internal and external parties</li> </ul> <p>No N/A</p> | Mandatory | <p>This document helps the organisation take immediate action at the event of a crisis with clear responsibilities and information about how to handle the situation as fast and as efficient as possible. It is a common requirement in regulation.</p> |

| N°   | CONTROL POINTS  | COMPLIANCE CRITERIA  | LEVEL                   | RATIONALE   |
|------|---|--|-------------------------|---|
| 4.10 | Is there a procedure for communicating to key internal and external parties in an event of a recall/withdrawal/food safety crisis? (BRU24, BRU26, BRU28)  | <p>A documented procedure exists describing precisely on how to communicate to key stakeholders in an event of a recall and/or withdrawal:</p> <ul style="list-style-type: none"> <li>• Quality &amp; safety team (Internal)</li> <li>• Production Manager (Internal)</li> <li>• Brand owner</li> <li>• Suppliers</li> <li>• Manufacturers</li> <li>• Specialist laboratories</li> <li>• Regulatory authorities</li> <li>• Legal expertise</li> <li>• Market surveillance &amp; consumer groups</li> </ul> <p>No N/A</p> | Mandatory               | This document helps the organisation take immediate action at the event of a crisis with clear and precise communication to key stakeholders in order to handle the situation as fast and as efficient as possible.   |
| 4.11 | Is there a procedure or defined process to store multiple representative traceable item samples of the manufacturing batch/lot and kept until expiration of the "Use by" or "Best before" date and, if necessary, for a determined period beyond this date? | If required by the customer, identified representative samples of the manufacturing lot or batch number shall be appropriately time stamped, stored and kept until expiration of the "Use by" or "Best before" date of the finished products and, if necessary, for a determined period beyond this date.  | Mandatory (conditional) | In case of recall or withdrawal, the organisation will be able to substantiate the original characteristics of the product. Having the possibility to re-test or re-check the characteristics of the stored item allows the organisation to prove that the item produced in a particular batch is correct. Or where it is not correct, to find out the possible reasons for that so that it can take corrective actions |

## 2.5 Flow of materials

| N°  | CONTROL POINTS   | COMPLIANCE CRITERIA  | LEVEL                   | RATIONALE  |
|-----|--|--|-------------------------|--|
| 5.1 | Are shipments <u>received</u> by the Organisation that needs to be traced, physically identified with an identification number? (BR6, BR7, BRU4) | The shipments received by the Organisation must have an identification number on the item or if not possible at least on the asset containing it or on an accompanying document. | Mandatory (conditional) | Physical identification of shipments enables organisations to connect the shipments to traceability data whether they are paper based or stored in a digital system. |
| 5.2 | Are shipments <u>received</u> by the Organisation identified with a GS1 Global Shipment Identification Number (GSIN AI 402)? (BR6, BR7, BRU4)    | The shipments received by the Organisation must have standard identification on the item or if not possible at least on the asset containing it or on an accompanying document.  | Optional                | Global Shipment Identification Number uniquely identifies shipments comprised of one or more logistic units enabling parties to trace the shipment as one item.      |

| N°  | CONTROL POINTS  | COMPLIANCE CRITERIA  | LEVEL                   | RATIONALE  |
|-----|---|--|-------------------------|--|
| 5.3 | Are logistic units <u>received</u> by the Organisation physically identified with an identification number? (BRU4)  | The logistic units received by the Organisation must have an identification number on the item or if not possible at least on the asset containing it or on an accompanying document.  | Mandatory (conditional) | Physical identification of logistic units enables organisations to connect the logistic units to traceability data whether they are paper based or stored in a digital system.   |
| 5.4 | Are logistic units <u>received</u> by the Organisation physically identified with a Serial Shipping Container Code (SSCC) and a GS1 Data Carrier (GS1-128 or EPC tag)?<br>(BR3, BR6, BR7, BR11, BR12, BRU4) | The logistic units received by the Organisation must have a Serial Shipping Container Code (SSCC) and a GS1-128 or EPC/RFID tag on the outer wrapping/packaging or at least on the asset containing it or on an accompanying document.   | Optional                | SSCC enables organisations to create serialised and unique identification of logistic units. Physical identification (use of GS1-128 or EPC/RFID) of items enables organisations to connect them to traceability data whether they are paper based or stored in a digital system |
| 5.5 | Are trade items <u>received</u> by the Organisation, that need to be traced, physically identified with a Global Trade Item Number (GTIN) and a GS1 Data Carrier?<br>(BR3, BR6, BR7, BR11, BRU4)            | The trade items received by the Organisation must have a GTIN and a GS1 Data Carrier on the packaging or at least on the asset containing it or on an accompanying document.<br>The corresponding GS1 Standards for data carriers are: <ul style="list-style-type: none"> <li>For trade item crossing the point of sale (consumer unit): EAN-13, EAN- 8, UPC-A, UPC-E, GS1 DataBar, GS1 DataMatrix*, GS1 QR Code*</li> <li>For trade item not crossing the point of sale (grouping of trade items): EAN-13, ITF-14, GS1-128, GS1 DataMatrix*, GS1 DataBar, EPC/RFID tag</li> </ul> (*Refer to <a href="#">GS1 General Specifications</a> where 2D may be allowed depending on the application standard.) | Optional                | GTIN enables organisations to create unique identification of trade items. Physical identification (use of GS1 Data Carrier) of items enables organisations to connect them to traceability data   |
| 5.6 | Are intermediate items ( <u>received and/or distributed</u> ) by the organisation identified physically with an identification number and/or the production batch/lot or serial number?                     | All inventoried intermediate items should have an identification number and/or production batch/lot and/or serial number on packaging or if not possible at least on the asset containing it or on an accompanying document.   | Mandatory (conditional) | Physical identification of intermediate items enables organisations to connect them to traceability data in systems or paper based whether they are paper based or stored in a digital system.   |

| N°  | CONTROL POINTS  | COMPLIANCE CRITERIA  | LEVEL                   | RATIONALE  |
|-----|---|--|-------------------------|--|
| 5.7 | <p>Are shipments <u>despatched</u> by the Organisation that need to be traced, physically identified with a Global Shipment Identification Number (GSIN AI 402)?</p> <p>(BR3, BR6, BR7, BRU4)</p>                       | <p>The shipments despatched by the Organisation must have a GSIN with a GS1-128, GS1 DataMatrix, GS1 QR Code on the shipment or at least on the asset containing it or on an accompanying document.</p>  | Mandatory (conditional) | <p>Global Shipment Identification Number uniquely identifies shipments comprised of one or more logistic units enabling parties to trace the shipment as one item.</p>   |
| 5.8 | <p>Are logistic units <u>despatched</u> by the Organisation physically identified with a Serial Shipping Container Code (SSCC) and carrying a GS1 Data Carrier (GS1- 128 or EPC tag)?</p> <p>(BR6, BR7, BR11, BRU4)</p> | <p>The logistic units despatched by the Organisation must have a SSCC and a GS1-128 or EPC/RFID tag attached on the item/packaging or at least on the asset containing it or on an accompanying document.</p> <p>No N/A</p>  | Mandatory               | <p>SSCC enables organisations to create serialised and unique identification of logistic units. Physical identification (use of GS1-128 or EPC/RFID) of items enables organisations to connect them to traceability data whether they are paper based or stored in a digital system.</p> |
| 5.9 | <p>Are trade items <u>despatched</u> by the Organisation identified physically with a Global Trade Item Number (GTIN) and a GS1 Data Carrier?</p> <p>(BR3, BR6, BR7, BR11)</p>  | <p>The trade items despatched by the Organisation must have a GTIN with a GS1 Data Carrier attached on the packaging or at least on the asset containing it or on an accompanying document.</p> <p>The corresponding GS1 Standards for data carriers are:</p> <ul style="list-style-type: none"> <li>For trade item crossing the point of sale (consumer unit): EAN-13, EAN- 8, UPC-A, UPC-E, GS1 DataBar, GS1 DataMatrix* GS1 QR Code*,</li> <li>For trade item not crossing the point of sale (grouping of trade items such as a case): EAN-13, ITF-14, GS1- 128, GS1 DataMatrix*, GS1 DataBar, EPC/RFID tag</li> </ul> <p>(*Refer to <a href="#">GS1 General Specifications</a> where 2D may be allowed depending on the application standard.)</p> <p>No N/A</p> | Mandatory               | <p>GTIN enables organisations to create unique identification of trade items. Physical identification (use of GS1 Data Carrier) of items enables organisations to connect them to traceability data</p>  |

| N°   | CONTROL POINTS  | COMPLIANCE CRITERIA  | LEVEL                          | RATIONALE  |
|------|---|--|--------------------------------|--|
| 5.10 | <p>Are trade items <u>despatched</u> by the Organisation identified with the production batch/lot or serial number or SGTIN? (BR6, BRU4)</p>  | <p>The trade items distributed by the Organisation must be identified with the production batch/lot and/or serial number or SGTIN on the packaging or on the asset containing it or on an accompanying document.</p>   | <p>Mandatory (conditional)</p> | <p>Depending on the level of traceability system of the company, items or groups of items must be identified so that they can be separated from other items or groups of items. This enables the company the most accurate definition of items or groups of items in case of a crisis. Physical identification of items enables organisations to connect them to traceability data whether they are paper based or stored in a digital system.</p> |
| 5.11 | <p>Is there a diagram/traceability link scheme that reflects the Organisation's manufacturing operation from the point at which the product supplies, packaging and raw materials arrive until the trade item is delivered to the customer? (BRU4, BRU21)</p> | <p>A schematic and systematic flowdiagram must exist for the processes involved in the manufacture of trade items, from the point at which the products, product supplies, packaging and raw materials arrive until the trade item is delivered to the customer.</p> | <p>Mandatory</p>               | <p>This diagram/scheme provides information for the organisation's staff on the processes involved and how inputs and outputs are linked together in the traceability system.</p>  |
| 5.12 | <p>Is there a process flow diagram that illustrates the internal trace request process?</p>   | <p>A schematic and systematic flowdiagram must exist to link trace request processes with the Organisation's production flows for its trade items and/or non-conforming products.</p>  | <p>Mandatory</p>               | <p>This flow diagram provides information for the organisation's staff on the connection between trace requests and traceability data on production, linking all systems and data registers.</p>   |

## 2.6 Information Requirements

| N°  | CONTROL POINTS  | COMPLIANCE CRITERIA  | LEVEL                   | RATIONALE   |
|-----|---|--|-------------------------|---|
| 6.1 | <p>Is the information of all shipments and logistic units <u>received</u> by the Organisation that needs to be traced described in a record?</p> <p>1 (BR6, BR13, BRU4, BRU18)<br/>(Although this Control Point doesn't ask for GS1 standard, it is "Mandatory Conditional". This is necessary to ensure traceability links are managed, even if the Organisation doesn't use global standards for this control point.)</p> | <p>A registry with a description must exist in one or more systems (electronic or physical) for each traceable shipment and logistic unit received by the Organisation. The description must include at least:</p> <ul style="list-style-type: none"> <li>• Shipment identification number (for shipments)</li> <li>• Logistic unit number (for logistic units)</li> <li>• Supplier Identification (GLN if used)</li> <li>• Receipt date</li> </ul>          | Mandatory (conditional) | Having a record of all shipments and logistic units allows traceability data to be available for trace request and be stored according to legal requirements.   |
| 6.2 | <p>Is the information of all globally unique shipments and logistic units <u>received</u> by the Organisation that needs to be traced described in a record?</p> <p>(BR3, BR6, BRU4)</p>  | <p>A registry with a description must exist in one or more systems (electronic or physical) for each globally unique shipment and logistic unit received by the Organisation. The description must include at least:</p> <ul style="list-style-type: none"> <li>• Global Shipment Identification number with AI 402 (for shipments)</li> <li>• SSCC (for logistic units)</li> <li>• Supplier Identification (GLN if used)</li> <li>• Receipt date</li> </ul> | Optional                | Having a record of all shipments and logistic units that are uniquely identified using GS1 identification keys, allows traceability data to be available for trace request and be stored according to legal requirements. |

| N°  | CONTROL POINTS  | COMPLIANCE CRITERIA  | LEVEL                   | RATIONALE  |
|-----|---|--|-------------------------|--|
| 6.3 | <p>Is the delivery information of all traceable trade items <u>received</u> by the Organisation described in a record?<br/>(BR13, BRU3, BRU4, BRU22)</p>  | <p>A delivery record with the trade item received must exist with the following details:</p> <ul style="list-style-type: none"> <li>• Trade Item Identification (GTIN if used)*</li> <li>• Batch/lot and/or serial number (if used)</li> <li>• Quantity*</li> <li>• Supplier (GLN if used)*</li> <li>• Importer (for imports) (GLN if used) **</li> <li>• Despatch documentation*</li> <li>• Transporter information (GLN if used) **, address, telephone number, and fax number and email address (if available)</li> <li>• Receipt date*</li> </ul> <p>(All marked with * are mandatory outside the US. All marked with ** are mandatory for US Bioterrorism Act).</p> | Mandatory (conditional) | Having a record of all received trade items allows traceability data to be available for trace request and be stored according to legal requirements.                          |
| 6.4 | <p>Is information to determine whether a batch/lot and/or serial number of a trade item was <u>despatched</u> or is <u>still</u> within the vicinity of the organisation available?<br/>(BR14, BRU3, BRU4, BRU7, BRU18)</p>   | <p>There is a registry that documents whether a batch/lot and/or serial number of a trade item was despatched or is still within the Organisation's vicinity<br/>No N/A</p>  | Mandatory               | The documentation of the despatch of a specific batch/lot or serial number of a trade item helps the organisation immediately locate the item in case of recall or withdrawal. |
| 6.5 | <p>Is the information of all shipments and logistic units <u>despatched</u> by the Organisation that needs to be traced described in a record?<br/>(BR6, BR13, BRU4, BRU18)<br/><br/>(Although this Control Point doesn't ask for GS1 standard, it is "Mandatory Conditional". This is necessary to ensure traceability links are managed, even if the Organisation doesn't use global standards for this control point.)</p> | <p>A record with a description must exist in one or more systems (electronic or physical) for each traceable shipment and logistic unit delivered by the Organisation. The description must include at least:</p> <ul style="list-style-type: none"> <li>• Shipment identification number (for shipments)</li> <li>• Logistic unit number (for logistic units)</li> <li>• batch/lot and/or serial number Recipient Identification (GLN if used)</li> </ul> <p>Despatched date</p>  | Mandatory (conditional) | Having a record of all despatched shipments and logistic units allows traceability data to be available for trace request and be stored according to legal requirements.       |

| N°  | CONTROL POINTS   | COMPLIANCE CRITERIA  | LEVEL                   | RATIONALE  |
|-----|--|--|-------------------------|--|
| 6.6 | Is the information of all globally unique shipments and logistic units <u>despatched</u> by the Organisation that needs to be traced described in a record? (BR3, BR6, BRU4) | <p>A record with a description must exist in one or more systems (electronic or physical) for each globally unique shipment and logistic units delivered by the Organisation</p> <p>The description must include at least:</p> <ul style="list-style-type: none"> <li>• Global Shipment Identification number with AI 402 (for shipments)</li> <li>• SSCC</li> <li>• Recipient Identification (GLN if used)</li> <li>• Despatched date</li> </ul> <p>No N/A</p>  | Mandatory               | Having a record of despatched shipments and logistic units that are uniquely identified using GS1 identification keys, allows traceability data to be available for trace request and be stored according to legal requirements. |
| 6.7 | Is the information of all traceable trade items <u>despatched</u> by the Organisation described in a record? (BR13, BRU3, BRU4, BRU23)                                       | <p>A record with the traceable trade item identification must exist with the following details:</p> <ul style="list-style-type: none"> <li>• Trade Item Identification (GTIN if used)*</li> <li>• Batch/lot and/or serial number (if used)</li> <li>• Quantity*</li> <li>• Possible Customers (GLN if used)*</li> <li>• Purchasing company (for exports) (GLN if used)**</li> <li>• Possible Recipients (GLN if used)*</li> <li>• Transporter information (GLN if used)</li> </ul> <p>** , address, telephone number, and fax number and email address (if available)</p> <ul style="list-style-type: none"> <li>• Dispatch documentation*</li> <li>• Despatched date*</li> </ul> <p>(All marked with * are mandatory outside the US. All marked with ** are mandatory for US Bioterrorism Act).</p> | Mandatory (conditional) | Having a record of all despatched trade items allows traceability data to be available for trace request and be stored according to legal requirements.  |

| N°  | CONTROL POINTS   | COMPLIANCE CRITERIA  | LEVEL     | RATIONALE   |
|-----|--|--|-----------|---|
| 6.8 | Is the information of all globally unique trade items <u>despatched</u> by the Organisation that needs to be traced described in a record? (BR3, BR6, BR13, BRU4, BRU18) | <p>A record with a description must exist in one or more systems (electronic or physical) for each globally unique traceable trade item <u>despatched</u> by the Organisation. The description must include at least:</p> <ul style="list-style-type: none"> <li>• GTIN (for trade items crossing point of sale)</li> <li>• Batch/lot and/or serial number Quantity*</li> <li>• Possible Customers (GLN if used)*</li> <li>• Recipients information(GLN if used)*</li> <li>• Transporter information (GLN if used), address, telephone number, and fax number and email address (if available)**</li> <li>• Despatch documentation*</li> <li>• Despatched date*</li> </ul> <p>(All marked with * are mandatory outside the US. All marked with ** are mandatory for US Bioterrorism Act).<br/>No N/A</p> | Mandatory | <p><u>Having a record of despatched trade items that are uniquely identified using GS1 identification keys, allows traceability data to be available for trace request and be stored according to legal requirements.</u></p> |

| N°   | CONTROL POINTS   | COMPLIANCE CRITERIA   | LEVEL                   | RATIONALE  |
|------|--|---|-------------------------|--|
| 6.9  | <p>Is it possible to link the information of inputs with outputs (one to many, many to one, many to many) at all hierarchy levels?<br/>(BR13, BR14, BRU4, BRU6, BRU18)</p>   | <p>There is a possibility to link the information of the following inputs and outputs through documentation:</p> <ul style="list-style-type: none"> <li>Information for each logistic unit (e.g. pallet no, supplier identification) received is linked with the production batch/lot and/or serial number of the trade items</li> <li>Information for each production batch/lot and/or serial number of a trade item (e.g. Product code, Best before date) is linked to the transformation of the trade item (e.g. Manufacturing time, date).</li> <li>Information for each batch/lot and/or serial number of the trade item received (e.g. case number) is linked to the logistic units (e.g. pallet no.), shipment (e.g. shipment identification) and batch/lot and/or serial number of the trade items distributed (e.g. product number, despatched date, location name)</li> <li>Information for each batch/lot and/or serial number of the trade item despatched is linked to the logistics units and shipment being delivered</li> </ul> | Mandatory (conditional) | Having a a hierarchy linking inputs with outputs are important for the organisation to be able to trace items individually or collectively.  |
| 6.10 | <p>Is it possible to link information of logistic units and Batch/Lot and/or serial number of trade items within the Organisation using globally unique identification numbers?<br/>(BR14, BRU4, BRU6, BRU18)</p>          | <p>There is a possibility to link the information of the outputs using globally unique identification numbers:</p> <ul style="list-style-type: none"> <li>For each logistic unit distributed by the Organisation, its SSCC number is linked with the GTIN and production batch/lot and/or serial number of the trade items</li> </ul> <p>For each trade item distributed, it's GTIN and batch/lot and/or serial number is linked to the SSCC of the logistic units involved</p>   | Mandatory (conditional) | Having a a hierarchy linking logistic units and batch/lot or serial number or trade items that are uniquely identified using GS1 keys helps the organisation to be able to trace items individually or collectively. |
| 6.11 | <p>Is it possible to link information of each <u>despatched</u> trade item batch/lot and/or serial number and logistic unit with the customer/destination using available documentation?<br/>(BR14, BRU4, BRU6, BRU18)</p> | <p>There is a registry linking information of each despatched trade item batch/lot and/or serial number with the customer number, destination and despatched date</p>   | Mandatory (conditional) | Linking information of despatched items with customer or destination helps the organisation to trace items to their destinations.  |

| N°   | CONTROL POINTS   | COMPLIANCE CRITERIA   | LEVEL     | RATIONALE   |
|------|--|---|-----------|---|
| 6.12 | <p>Can detailed traceability information of trade items distributed by the Organisation be shared with trading partners in an event of a trace request or commercial need? (BR13, BR15, BRU14, BRU15, BRU17)</p> | <p>There are documents available with traceability information that can be shared with trading partners for each batch/lot and/or serial number of trade items distributed by the Organisation:</p> <ul style="list-style-type: none"> <li>• Trade Item identification (GTIN if used)*</li> <li>• Quantity*</li> <li>• Despatch date*</li> <li>• Possible Customers to which the batch/lot and/or serial number was despatched (GLN if used)*</li> <li>• Transporter utilised in the despatch (GLN if used), address, telephone number, and fax number and email address (if available)**</li> <li>• Despatch documentation*</li> <li>• Batch/lot and/or serial number and supplier of trade items used as inputs*</li> <li>• Receipt dates of batch/lot and/or serial number of trade items used as inputs*</li> <li>• Transporter (GLN if used), address, telephone number, and fax number and email address (if available) used in the delivery of trade items used as inputs**</li> </ul> <p>(All marked with * are mandatory outside the US. All marked with ** are mandatory for US Bioterrorism Act).<br/>No N/A</p> | Mandatory | <p>Sharing traceability information with trading partners are important for the organisation in order to meet customer needs and the legal requirements of 'one-step-up - one-step-down'.</p> |
| 6.13 | <p>Is the GS1 electronic document "Despatch Advise" (DESADV) used to send information of trade items to the trading partners prior to physical delivery? (BR13)</p>  | <p>Prior to the delivery of a trade item, an electronic message that includes the information of the despatched trade item is sent to the trading partners. The corresponding GS1 Standards are EANCOM or GS1 XML.</p>  | Optional  | <p>DESADV enables the organisation to effectively share traceability data of a shipment as well as the receipt for collection.</p>  |

## 2.7 Documentation Requirements

| N°  | CONTROL POINTS  | COMPLIANCE CRITERIA  | LEVEL       | RATIONALE   |
|-----|---|--|-------------|---|
| 7.1 | Are there records existing within the Organisation which validate all relevant process stages from the time trade items are received to the time trade items are delivered to trading partners? | Records and logs must exist to validate all the processes of the Organisation, from reception of trade item to the point in which the trade item is delivered to the trading partners.<br>No N/A   | Mandatory   | Invalid records and logs may lead the organisation to take wrong steps in a crisis resulting in business and financial damages.   |
| 7.2 | Are there documents describing administration of traceability information such as the organisational structure, operational responsibilities and traceability system capabilities?              | Documentation must exist describing the organisational structure, operational responsibilities and system capabilities for traceability such as: <ul style="list-style-type: none"> <li>• Organisation structure</li> <li>• Dependency</li> <li>• Roles</li> <li>• Personnel</li> <li>• Infrastructure</li> <li>• Documentation methods</li> <li>• Software used (if applicable)</li> </ul> No N/A | Mandatory   | These documents are the basis of Information sharing within the organisation on the traceability system, and they help personnel understand their roles and responsibilities.               |
| 7.3 | Are documents related to traceability information of the trade item maintained until the end of its life cycle and stored for a minimum period of 1 year? (BR8)                                 | All records must be kept up to date for a minimum period of one year, in accordance with regulations, standards or commercial requirements defined in the objectives of the Organisation's traceability system.<br>No N/A  | Mandatory   | Keeping up to date records helps the organisation meeting legal requirements and make traceability data available in case of recall/withdrawal.   |
| 7.4 | Are all documents on the traceability system kept up to date (at least annually), reflecting current processes and procedures?  | There is concurrence between the current traceability processes and documentation. It must be confirmed that what occurs in the production line is reflected in its documentation.<br>No N/A   | Mandatory   | These documents are the basis of Information sharing within the organisation on the traceability system thus must be kept up to date.   |
| 7.5 | Are documents related to traceability (traceability data) kept in a restricted area/location with only authorisation by appointed personnel?  | The Organisation has an area with restricted access and authorisation of controlled documents where all traceability data is recorded, stored and/or administered.<br>No N/A   | Recommended | Traceability documents contain sensitive information therefore the organisation must keep them safe and confidential to avoid their misuse.<br>Documents can be in physical or digital way. |

## 2.8 Structure & responsibilities

| N°  | CONTROL POINTS  | COMPLIANCE CRITERIA   | LEVEL     | RATIONALE   |
|-----|---|---|-----------|---|
| 8.1 | Does an operational traceability team exist and are their roles and responsibilities defined and documented?  | The Organisation has an operational traceability team with their roles and responsibilities defined and documented. No N/A  | Mandatory | Having a dedicated team with clearly defined roles and responsibilities in an organisation allows it to act swiftly upon any case of crisis.  |
| 8.2 | Does the traceability team have the necessary resources in order to maintain the Traceability System? Resources include HR, IT and budget.                      | The Organisation must ensure a direct relation between HR assigned to traceability, the technology used and the budget assigned to these items.<br>No N/A                           | Mandatory | By making resources available, the organisation ensures that the operations of the traceability team will be maintained.  |
| 8.3 | Are the personnel aware of the traceability procedures and instructions applicable to their functions and know where to find them and when and how to use them? | The personnel are aware of the current traceability procedures and instructions applicable to their functions. They know where to find them and when and how to use them.<br>No N/A | Mandatory | A Traceability system is run by staff from different functions/divisions within the organisation. All staff must understand the applicable procedures for their specific roles in order to have successful traceability operations. |

## 2.9 Training

| N°  | CONTROL POINTS  | COMPLIANCE CRITERIA  | LEVEL                   | RATIONALE   |
|-----|---|--|-------------------------|---|
| 9.1 | Has training on the Organisation's traceability system been provided to personnel and are these trainings updated and given periodically?                     | Records should indicate when (training dates) those instructions and/ or training on the Organisation's traceability system has been given to personnel responsible in traceability.<br>No N/A   | Mandatory               | Training about the traceability system must be held on regular basis to the traceability team in the organisation to ensure that the team has the necessary knowledge to properly perform their jobs. |
| 9.2 | Have personnel, who are responsible for the Organisation's traceability system, received training on the GS1 Global Traceability Standard and the GS1 System? | Records should indicate that personnel responsible in supporting the Organisation's traceability system should be trained in the GS1 Global Traceability Standard and the GS1 System. Copies of certificates of attendance or attendance registers can be evidence of the training participation<br>No N/A | Mandatory (conditional) | When the organisation uses GS1 Standards, personnel should receive training on GS1 Global Traceability Standard and the GS1 System in order to perform the related work appropriately.                |

## 2.10 Supply chain coordination

| N°   | CONTROL POINTS  | COMPLIANCE CRITERIA  | LEVEL                   | RATIONALE   |
|------|---|--|-------------------------|---|
| 10.1 | <p>Is it possible to obtain traceability information of all Trade Items received from all Trading Partners in a timely manner?</p> <p>(BR18, BR19, BRU17, BRU23, BRU25, BRU26)</p>                                      | <p>From each trading partner of a batch/lot and/or serial number of a traceable trade item, it is possible to obtain at least the following traceability information:</p> <ul style="list-style-type: none"> <li>• Product Identification (GTIN if used)*</li> <li>• Quantity*</li> <li>• Manufacture Date*</li> <li>• Despatch Date*</li> <li>• Transporter (GLN if used), address, telephone number, and fax number and email address (if available)**</li> </ul> <p>(All marked with * are mandatory outside the US. All marked with ** are mandatory for US Bioterrorism Act).</p> | Mandatory (conditional) | Capturing and sharing traceability information in a timely manner is key to take actions in case of crisis.         |
| 10.2 | <p>Is it possible to provide detailed traceability information to parties requesting it in a timely fashion as well as obtaining information from trading partners, in accordance with industry agreements? (BRU25)</p> | <p>For each trading partner of a batch/lot and/or serial number of a trade item, that needs to be traced, it is possible to obtain traceability information in a timely manner according to industry agreement (i.e. US Bioterrorism Act ask 4 business hours).</p>  | Recommended             | Capturing and sharing traceability information in a timely manner is key to take actions in case of crisis.         |
| 10.3 | <p>Does a documented management procedure exist detailing how to manage a traceability crisis?</p>  | <p>Documentation must exist defining when a crisis is to be activated and indicate all the actions that are to be taken in order to manage the crisis.</p>   | Recommended             | Documented procedures help dedicated teams act as accurately and as swiftly as possible in case of crisis.          |
| 10.4 | <p>Does a safety hazard crisis team exist within the Organisation and are their respective roles and responsibilities assigned?</p>   | <p>The Organisation must have a team with authority to manage a crisis. This team must have a detailed definition of responsibilities and roles.</p>   | Recommended             | Having a dedicated team for safety hazard crisis ensures readiness and swift response in case of crisis.            |
| 10.5 | <p>Does a documented plan exist for the recall of affected products?</p>  | <p>Documentation exists detailing how affected products are to be recalled.</p> <p>No N/A</p>  | Recommended             | Documented plan helps dedicated teams act as accurately and as swiftly as possible in case of recall.               |
| 10.6 | <p>Is the safety hazard management or recall procedure capable to operate at any time?</p>  | <p>It can be proven that the hazard management or recall procedure operates 24/7.</p> <p>No N/A</p>  | Recommended             | The readiness of the organisation to initiate a recall is crucial to avoid putting the safety of consumers at risk. |

## 2.11 Monitoring

| N°   | CONTROL POINTS   | COMPLIANCE CRITERIA  | LEVEL       | RATIONALE  |
|------|--|--|-------------|--|
| 11.1 | Does a monitoring and control plan exist for the traceability system and is this plan executed periodically?                           | A monitoring and control plan exists for the Traceability System that periodically verifies the current operation in accordance to the scope and objectives.<br>No N/A | Mandatory   | The Traceability system must be tested on regular basis to ensure the alignment of the operations with the scope and objectives of the Traceability system. This will highlight any issues in time and avoid unwanted surprises during crisis. |
| 11.2 | From the monitoring and control plans in place, does the Organisation have feedback or results from their traceability system reviews? | The Organisation must provide evidence of results of monitoring and control of the Traceability System in accordance with the monitoring plan.<br>No N/A               | Recommended | The Traceability system must be tested on regular basis to ensure the alignment of the operations with the scope and objectives of the Traceability system. This will highlight any issues in time and avoid unwanted surprises during crisis. |

## 2.12 Internal and external audits

| N°   | CONTROL POINTS  | COMPLIANCE CRITERIA   | LEVEL                   | RATIONALE  |
|------|---|---|-------------------------|--|
| 12.1 | Does the Organisation maintain a register of internal or external audits to ensure compliance to the Traceability standard, and are these audits carried out at least on an annual basis? | Documentation is recorded indicating that internal or external audits have been carried out on an annual basis.<br>No N/A | Mandatory               | Accurate documentation of audits, reviews and corrective actions helps the organisation in monitoring the traceability system. |
| 12.2 | Are there records of past traceability reviews and audits?  | There are records of past results of traceability reviews and audits within the Organisation<br>No N/A                    | Mandatory               | Accurate documentation of audits, reviews and corrective actions helps the organisation in monitoring the traceability system. |
| 12.3 | Are there corrective action plans shown in internal and external (3rd party) audits performed to resolve Non-Conformities involving traceability system requirements?                     | There are documents which describe actions taken to resolve the Non-Conformities of the traceability system requirements  | Mandatory (conditional) | Accurate documentation of audits, reviews and corrective actions helps the organisation in monitoring the traceability system. |

## 3 Business Requirements and Business Rules

### 3.1 Business Requirements

A business requirement is a statement of need concerning the business area or business process under study. It is something that the system must do or a quality that the system must have. A requirement exists either because the type of product demands certain functions or qualities, or the client wants the requirement to be part of the delivered product.

To keep consistent with the three major activities the following abbreviations are used in the number column for the Business Requirements.

**AMD:** Align Master Data

**RTD:** Record Traceability Data

**RT:** Request Trace

#### Key Words

**MUST = Mandatory** - This word, or the terms "REQUIRED" or "SHALL" means that the definition is an absolute requirement of the specification.

**MAY= Optional** - This word, or the adjective "OPTIONAL", means that an item is truly optional.

| Number               | Business Requirement   | Rationale   | Corresponding Standard(s)  |
|----------------------|--|---|--|
| <i>BR 1</i><br>(AMD) | Any internal or external location which needs to be traced <b>MUST</b> be globally and uniquely identified.<br><br>This may be at a high level (warehouse location) but could be at the detail level (precise bin location) within a warehouse.<br><br>It is the choice of the Traceability Partner which location level they uniquely identify. | For unique identification of location.  | [Ref 1] GS1 General Specifications GLN   |
| <i>BR 2</i><br>(RTD) | Trading Partners <b>MUST</b> be globally and uniquely identified.<br><br>It is the choice of the Traceability Partner which actor level they uniquely identify, e.g. the Legal Entity.   | Identifying the actor to whom a trace request must be directed, will expedite the collection of the traceability information. | [Ref 1] GS1 General Specifications GLN<br>Party role list for messages   |
| <i>BR 3</i><br>(AMD) | Any traceable item, which needs to be tracked forward or traced back between traceability partners, <b>MUST</b> be globally and uniquely identified.<br><br>This applies to any level of the Product Hierarchy for example, Consumer Unit or a traceable Item not crossing the point of sale   | For unique identification of a traceable item   | [Ref 1] GS1 General Specifications GTIN  |
| <i>BR 4</i><br>(AMD) | Any asset, which needs to be tracked forward or traced back, <b>MUST</b> be globally and uniquely identified.  | For unique identification of the asset  | [Ref 1] GS1 General Specifications,<br>GRAI (Global Returnable Asset Identifier) and GIAI (Global Individual Asset Identifier) |

| Number            | Business Requirement  | Rationale  | Corresponding Standard(s)  |
|-------------------|---|--|--|
| <i>BR 5 (RTD)</i> | <p>The identification of the traceable item MUST be assigned, at the latest, when physically created.</p> <p>When the traceable item is a trade item, the trade item identification MUST at a minimum be identified with a GTIN. For the purpose of traceability, this may not be sufficient, requiring additional information to uniquely identify a product or grouping of products such as a batch/lot number or where appropriate, a serial number.</p> <p>When the traceable item is a logistic unit, it MUST be uniquely identified.</p> <p>It is the choice of the Traceability Partner which identification level to use for the traceable item</p> | For unique identification of the traceable item  | <p>[Ref 1] GS1 General Specifications</p> <p>GTIN<br/>           GTIN + batch/Lot number<br/>           GTIN + serial number/SGTIN<br/>           Logistic Unit – SSCC</p> <p>Best Practice At minimum this information must be displayed in human readable form. For example printed on the product/label or accompanying document or electronic record.</p>  |
| <i>BR 6 (RTD)</i> | All instances of a traceable item must carry a globally unique identification directly on the traceable item or, if not possible, at least on the asset containing it or in an accompanying document.   | To carry the globally unique identification.   | <p>[Ref 1] GS1 General Specifications</p> <p>If the traceable item is Trade Item: GTIN batch/lot of trade item:<br/>           GTIN + batch/lot number<br/>           Serialised Trade Item: GTIN + serial number, SGTIN<br/>           Logistic Unit: SSCC<br/>           Shipment: Shipment Identification Number<br/>           Best Practice :<br/>           The traceable item identification should be at least one of the following:<br/>           electronically held<br/>           electronically transmitted<br/>           Machine readable on the identification carrier.</p> |
| <i>BR 7 (RTD)</i> | The Brand Owner MUST ensure the unique identification of the traceable item.  | The Brand Owner is the party responsible for allocating GS1 System numbering and barcode symbols or EPC tag to a given item. | [Ref 1] GS1 General Specifications   |
| <i>BR 8 (RTD)</i> | The identification carrier MUST remain on or attached to the traceable item <i>until the end of life of the traceable item.</i>   | For unique identification of the traceable item throughout its life cycle.   | [Ref 1] GS1 General Specifications<br>Allocation Rules and Labelling   |

| Number         | Business Requirement  | Rationale  | Corresponding Standard(s)   |
|----------------|---|--|---|
| BR 9<br>(RTD)  | The identification carrier MUST remain on or attached to the traceable item when it is packed in an upper level of packaging.   | For unique identification of the traceable item throughout the packaging hierarchy.  | [Ref 1] GS1 General Specifications<br>Allocation Rules and Labelling  |
| BR 10          | The identification carrier MUST carry some information to link with at least one Traceability Data Source (e.g. Brand Owner, importer,).                                    | This allows a traceability partner to identify a data source so that a trace request can be directed to it.  | GS1 Logistics Label   |
| BR 11<br>(RTD) | All Traceable Item Sources and Traceable Item Recipients MUST collect the identification of the traceable item or asset containing it from the identification carrier.      | To follow the path of a traceable item   |   |
| BR 12<br>(RTD) | Traceability Partners MUST agree on at least one common level of traceable item and for this common level agree on the set of consistent traceability data to be exchanged. | The traceability Partners will exchange traceable items with each other and ensure that these goods are uniquely identified to manage links between inputs, internal processes, and outputs. | With Bar-Codes:<br>If the traceable item is a trade item crossing the point of sale (consumer unit): EAN/UPC, GS1 DataBar*<br>If the traceable item is a trade item not crossing the point of sale (grouping of trade items): GS1-128, ITF- 14, GS1 DataMatrix, GS1 DataBar*, EAN/UPC (excluding EAN-8), according to the application guidelines described in the GS1 General Specifications.<br>If the traceable item is a batch/lot of trade items not crossing the point of sale: GS1-128, ITF-14, GS1 DataBar*, EAN/UPC (excluding EAN-8)<br>If the traceable item is a serialised trade item not crossing the point of sale: GS1-128, ITF-14, GS1 DataBar*, EAN/UPC (excluding EAN-8)<br>If the traceable item is a logistic unit: GS1-128, GS1 DataBar*<br>If the traceable item is a |

### 3.2 Technical Requirements

Technical requirements are technical constraints or capabilities around business requirements (e.g. "claim reports must be sent via xml"). Technical Requirements include User Interface, Security, Performance, Quality and Backward Compatibility. As this is a *process standard* technical requirements are out of the scope of this document.

### 3.3 Business Rules

Business rules are statement of **fact** concerning the business area or business process under study that must survive changes to process or data. Business rules are a constraint, in the sense that a business rule lays down what must or must not be the case

Business rules define **what** must be the case rather than **how** it comes to be.

| Number | Business Rule  | Details   |
|--------|--|---|
| BRU 1  | Traceability systems and procedures serve the purpose of meeting business, regulatory, and legal requirements by providing access to relevant party and product traceability information.  | Rule Type: Definition   |
| BRU 2  | A traceable item must be one of the following: Shipment<br>Logistic unit Trade item<br>Batch/lot of trade items Serialised trade item<br>Any item that traceability partners agree is a traceable item   | Rule Type: Definition   |
| BRU 3  | Traceability data includes information about: What is it? (i.e., the traceable item)<br>Who has been involved? (i.e., the traceability partner(s))<br>Where did it happen? (i.e., location)<br>When did it happen? (i.e., date / time, period of time)<br>What happened? (i.e., process or event)<br>The following information is NOT within the scope of an external traceability system:<br>full recipes or formulas financial or pricing data, employee personal data, patient personal data or research and development data | Rule Type: Definition Rationale<br>Key questions for traceability |
| BRU 4  | Key traceability principles are:<br>Unique identification of traceable items Capturing and recording traceability data<br>Sharing traceability data between traceability partners<br>Linking inputs through changes or processing to outputs, be that the same traceable item or a new traceable item  | Rule Type: Definition   |
| BRU 5  | Traceability is an integral part of the business process. It is not separate from logistical processes and/or product safety / quality programs.   | Rule Type: Definition   |
| BRU 6  | A traceable item may be related to another traceable item.   | Rule Type: Definition   |
| BRU 7  | Instances of a traceable item may exist in multiple locations at the same time.  | Rule Type: Definition   |



| Number | Business Rule   | Details               |
|--------|---|-----------------------|
| BRU 8  | There may be several levels of traceable items at the same time in one shipment with regards to the traceable item hierarchy.   | Rule Type: Definition |
| BRU 9  | Traceability data may be master data, constant across time (e.g. GTIN) or event data, changing with each case or shipment (e.g., batch/lot).  | Rule Type: Definition |
| BRU 10 | All Traceability Partners must have internal and external traceability to achieve traceability across the supply chain.   | Rule Type: Guideline  |
| BRU 11 | Every Traceability Partner may decide on HOW to implement internal traceability systems. It is essential that they be able to collect, record, and share the necessary information with upstream and downstream Traceability Partners in an accurate and timely manner.   | Rule Type: Guideline  |
| BRU 12 | Traceability Partners use GS1 standards to ensure fast and accurate flow of information between traceability partners.  | Rule Type: Guideline  |
| BRU 13 | Traceability Partners should not impose proprietary practices on other Traceability Partners.   | Rule Type: Guideline  |
| BRU 14 | It is not necessary for ALL Traceability Partners to store and share ALL traceability information, but they must be able to access and share relevant and agreed information.   | Rule Type: Guideline  |
| BRU 15 | The minimum information shared between Traceability Partners should be the greater of: minimum requirements defined in this GS1 Global Traceability Standard<br><br>What is needed for day to day business transactions with traceability partners?   | Rule Type: Guideline  |
| BRU 16 | Each Traceability Partner must define at least one level of traceable item for each shipment.   | Rule Type: Guideline  |
| BRU 17 | The Brand Owner and / or Traceable Item Creator must know the details of the traceable item and be able to reply to a trace request.  | Rule Type: Guideline  |
| BRU 18 | A Traceable Item Source must know what has happened to the traceable item during its internal process and when, where, and to whom it has despatched the traceable item.<br><br>Each Traceability Partner must store the data links between what is received, produced, packed, stored and shipped.<br><br>When the Traceable Item is mixed with similar items from many locations or batches, e.g. in a grain silo, the Traceability Partner must store records of all inputs and outputs in order to provide fair estimates of where the Traceable Item has gone. | Rule Type: Guideline  |
| BRU 19 | A Traceable Item Recipient must know the Traceable Item Source that supplied the traceable item.  | Rule Type: Guideline  |

| Number        | Business Rule   | Details              |
|---------------|---|----------------------|
| <i>BRU 20</i> | As long as a traceable item is contained within another traceable item and parent/child relationships are maintained, traceability partners MAY store only records of the movements and location of the higher level traceable item. (Refer to Business Requirement 13)   | Rule Type: Guideline |
| <i>BRU 21</i> | Traceability Partners must link physical movement of traceable items to the information movement, both between the Traceable Item Source and themselves, and between Traceable Item Recipient and themselves. This event flow of information must exactly reflect the physical movement.<br>This linkage is necessary for the traceable item to be traced from point of origin or manufacture to the point of sale or use or user (if relevant).<br>Conversely, this linkage must also ensure that product can be traced back through the supply chain. | Rule Type: Guideline |
| <i>BRU 22</i> | The Traceable Item Recipient may collect information from both the previous Traceable Item Source and the previous Transporter source (land, ocean, rail or air).   | Rule Type: Guideline |
| <i>BRU 23</i> | The Traceable Item Source may communicate information to both the Traceable Item Recipient and the subsequent Transporter (land, ocean, rail or air).   | Rule Type: Guideline |
| <i>BRU 24</i> | A Trace Request Initiator must contact its Traceability Partners, including the Brand Owner where appropriate   | Rule Type: Guideline |
| <i>BRU 25</i> | The Traceability Data Source must reply as quickly as possible to the party requesting traceability information. The time period allowed may be defined in local regulations or commercial agreements.  | Rule Type: Guideline |
| <i>BRU 26</i> | A Trace Request may trigger subsequent trace requests up or down the supply chain in order to fulfil the original request.  | Rule Type: Guideline |
| <i>BRU 27</i> | A traceability system is only as good as its weakest link. If failure occurs at any point, traceability breaks down.  | Rule Type: Guideline |
| <i>BRU 28</i> | Various industries, regions or countries may have additional Business Requirements beyond this generic GS1 Global Traceability Standard. These should be addressed by defining specific extensions.   | Rule Type: Guideline |
| <i>BRU 29</i> | Access to and sharing of information does NOT include intellectual property of each traceability partner  | Rule Type: Guideline |
| <i>BRU 30</i> | Traceability Partners MAY choose a specific, key data element, e.g. purchase order number, to enable access to data and/or information related to an event of a traceable item.   | Rule Type: Guideline |

## 4 Glossary of Business Terms

Please refer to [www.gs1.org/glossary](http://www.gs1.org/glossary) for the latest version

| Term   | Description   |
|--|---|
| Assessment team leader                       | One of whom is appointed to be the assessment leader from an assessment team  |
| Batch/lot                                    | [GS1 GTS] The batch or lot number associates a trade item with information the manufacturer considers relevant for traceability of the item. The data may refer to the trade item itself or to items contained in it.<br>GDD Implementation Notes: A typical batch/lot code might include a plant location, production line, date of production and shift. The format and structure will vary by organisation.        |
| Compliance Criteria                          | Are the facts that must be monitored and documented by the Organisation in order to maintain traceability over a certain Control Point  |
| Consumer                                     | [GS1 GTS] The end user of a trade item or a service.  |
| Consumer Unit                                | [EANCOM Glossary] The package size of a product or products agreed by trading partners as the size sold at the retail point of sale.  |
| Correction                                   | Action to eliminate a detected nonconformity.   |
| Corrective Action                            | Action to be taken to eliminate the cause of a detected non conformity or other undesirable situation in a traceability system.   |
| Customer                                     | [GS1 General Specification] The party that receives, buys, or consumes an item or service.  |
| Data Matrix symbology                        | [GS1 General Specification] A standalone, two-dimensional matrix symbology that is made up of square modules arranged within a perimeter finder pattern. Data Matrix using ECC 200 error correction is the only version that supports GS1 system identification keys, including the Function 1 Symbol Character (FNC1). Data Matrix symbols are read by two-dimensional imaging scanners or vision systems.           |
| EANCOM                                       | [GS1 General Specification] The GS1 standard for Electronic Data Interchange (EDI) is a detailed implementation guideline of the UN/EDIFACT standard messages using the GS1 Identification Keys.  |
| EAN-13                                       | [GS1 General Specification] A barcode symbol of the EAN/UPC Symbology that encodes GTIN-13 and RCN-13.  |
| Electronic Product Code                      | [GS1 General Specification] An identification scheme for universally identifying physical objects (e.g. trade items, assets, and locations) via RFID tags and other means. The standardised EPC data consists of an EPC (or EPC Identifier) that uniquely identifies an individual object, as well as an optional Filter Value when judged to be necessary to enable effective and efficient reading of the EPC tags. |
| EU   | European Union  |
| Flow Diagram                                 | Schematic and systematic presentation of the sequence and interactions of steps.  |
| GIAI (Global Individual Asset Identifier)    | [GS1 General Specification] The GS1 identification key used to identify an individual asset. The key comprises a GS1 Company Prefix and individual asset reference.   |
| GLN (Global Location Number)                 | [GS1 General Specification] The GS1 identification key used to identify physical locations or parties. The key comprises a GS1 Company Prefix, location reference, and check digit.   |
| GRAI (Global Returnable Asset Identifier)    | [GS1 General Specification] The GS1 identification key used to identify returnable assets. The key comprises a GS1 Company Prefix, asset type, check digit, and optional serial number.   |
| GSIN (Global Shipment Identification Number) | [GS1 General Specification] The GS1 identification key used to identify a logical grouping of logistic or transport units that are assembled by the consignor (seller) for a transport shipment from that consignor to one consignee (buyer) referencing a despatch advice and/or BOL. The key comprises a GS1 Company Prefix, shipper reference and check digit.   |
| GTIN (Global Trade Item Number)              | [GS1 General Specification] The GS1 identification key used to identify trade items. The key comprises a GS1 Company Prefix, an item reference and check digit.   |

| Term                                  | Description  |
|---------------------------------------|--|
| GS1 Application Identifier (AI)       | [GS1 General Specification] The field of two or more digits at the beginning of an element string that uniquely defines its format and meaning.  |
| GS1-128 Symbology                     | [GS1 General Specification] A subset of the Code 128 that is utilised exclusively for GS1 System data structures.  |
| GS1 DataBar                           | [GS1 General Specification] A family of barcodes, including GS1 DataBar Omnidirectional; GS1 DataBar Stacked Omnidirectional; GS1 DataBar Expanded; GS1 DataBar Expanded Stacked GS1 DataBar Truncated, GS1 DataBar Limited, and GS1 DataBar Stacked symbols.  |
| GS1 DataMatrix                        | [GS1 General Specification] A subset of Data Matrix which uses the function that allows the encoding of element strings.   |
| GS1 identification key                | [GS1 General Specification] A unique identifier for a class of objects (e.g. a trade item) or an instance of an object (e.g. a logistic unit).   |
| GS1 XML                               | [GS1 General Specification] The GS1 standard for extensible markup language (XML) schemas providing users with a global business messaging language of e-business to conduct efficient internet-based commerce.  |
| Identification number                 | A numeric or alphanumeric string that is used for identification.  |
| Identify physically                   | It is related to the identification of products with a number but not necessarily converted into a barcode symbology.  |
| Intermediate Item                     | [GS1 GTS] Partly processed product that must undergo further manufacturing steps before it becomes a bulk finished product.  |
| Location                              | A place where a traceable item is or could be located [ISO / CD 22519]. A place of production, handling, storage and / or sale. (Examples include Farms, Processing Plants, Distribution Centres and Warehouses. The internal and external locations shall be defined in the declaration of the objectives at the beginning of the assessment process).  |
| Logistic Unit                         | [GS1 General Specification] An item of any composition established for transport and/or storage that needs to be managed through the supply chain. It is identified with a Serial Shipping Container Code (SSCC).  |
| Master Data                           | [GS1 GTS] Master Data describes each item and party involved in supply chain processes. Master Data is defined as data having the following characteristics:<br>Permanent or lasting nature<br>Relatively constant across time, not being subject to frequent change<br>Accessed / used by multiple business processes and system applications Can either be neutral or relationship dependent |
| Monitoring                            | Conducting a planned sequence of observations and measurements to assess whether control measures are operating as intended.   |
| Party                                 | [GS1 GTS] A Party (or) Location is any legal or physical entity involved at any point in any supply chain and upon which there is a need to retrieve pre-defined information. A Party is uniquely identified by a Global Location Number (GLN).  |
| point-of-sale (POS)                   | [GS1 General Specification] Refers to the retail checkout where omnidirectional linear barcodes must be used to support high-volume laser-based scanning or low volume checkout where linear barcodes (or for regulated healthcare trade items, GS1 DataMatrix) are used with image-based scanners.  |
| Process                               | [GS1 GTS] A series of actions or steps towards achieving a particular end. Examples of common processes include Production, Transformation, Quality Control, Storage, Transportation, Movement, Recycle, Return, Packing, Receiving and Traceability.  |
| Safety Hazard                         | Chemical, biological or physical agent in product, or condition of product, with the potential to cause an adverse health effect.  |
| Shipment                              | [GS1 General Specification] A grouping of logistics and transport units assembled and identified by the seller (sender) of the goods travelling under one despatch advice and/or Bill of Lading to one customer (recipient).   |
| SSCC (Serial Shipping Container Code) | [GS1 General Specification] The GS1 identification key used to identify logistics units. The key comprises an extension digit, GS1 Company Prefix, serial reference, and check digit.  |



| Term  | Description   |
|---|---|
| SGTIN (Serialised Global Trade Item Number) | [GS1 GTS] SGTIN is a method of identifying items at the unit or retail level as well as at the case and carton levels. It is composed of a GS1 assigned Company Prefix & Item Reference (GTIN), combined with a serial number. Where GS1 barcodes have traditionally been used, the SGTIN specification combined with an EPC tag can give visibility beyond the Item Reference right down to the exact serial number of the item.   |
| supplier                                    | [GS1 General Specification] The party that produces, provides, or furnishes an item or service.   |
| Traceability                                | [GS1 GTS] Traceability is the ability to track forward the movement through specified stage(s) of the extended supply chain and trace backward the history, application or location of that which is under consideration.   |
| Traceability System                         | [GS1 GTS] The tools and organisation necessary to implement the traceability process in a given environment, party or group or parties  |
| Traceable Item                              | [GS1 GTS] A physical object where there may be a need to retrieve information about its history, application, or location. The level at which the traceable item is defined within a product packaging or logistical hierarchy is dependent on the industry and degree of control required. Could be tracked, traced, recalled or withdrawn. Could exist in multiple locations at the same time (for example, if identified at the trade item and Batch level). A traceable item may be related to another traceable item. It is the choice of the Traceability Partner which identification level (e.g. GTIN or batch/lot or serial level) to use for the traceable item. See also definition for process. |
| Traceable Item Recipient                    | [GS1 GTS] The Partner that receives the traceable item.   |
| Trade Item                                  | [GS1 General Specification] Any item (product or service) upon which there is a need to retrieve pre-defined information and that may be priced, or ordered, or invoiced at any point in any supply chain.  |
| Trading Partner                             | [GS1 GTS] Any Supply Chain Partner that has a direct impact on the flow of goods through the supply chain. Examples include Third Party Logistics Provider, Manufacturer, Retailer, and Grower.   |
| Transporter                                 | [GS1 GTS] The Traceability Partner that receives, carries, and delivers one or more traceable items from one point to another without transforming the traceable item(s). Typically only has possession, custody, or control of a traceable item, but may have ownership.   |
| US  | United States of America  |

## A Relationship between the GTC Checklist and other Standards

### A.1 The GTC and its Relationship with Traceability Standards and Best Manufacture Practices (BMP) Standards

There are several Control Points in the GS1 GTC Checklist that relate to certain traceability requirements of other relevant standards and regulations. This Appendix cross references the Control Points in the GS1 GTC Checklist and the traceability requirements of the following (non-GS1) standards and regulations:

1. ISO 22005-2007
2. ISO 9001-2015
3. ISO 22000-2018
4. BRC (British Retail Consortium) Global Standard issue 8 - Food
5. IFS (International Featured Standard) version 7 - Food
6. GlobalG.A.P version 5.2
7. GFSI Benchmarking Requirements
8. ISO 10377
9. ISO 10393
10. ISO 14001-2015
11. ISO 22095-2020
12. IFS Logistics 2.2
13. IFS Global Markets Logistics
14. IFS HPC
15. HL7 Implementation Guide for Clinical Notes
16. HL7 Implementation Guide for UDI
17. US DSCSA
18. EU Falsified Medicine Directive and Regulation



**Important:** In this Appendix, the cross references between Control Points of the GS1 GTC Checklist and the above non-GS1 standards and regulations have been prepared by GS1 and does NOT in any case imply compliance with the traceability requirements of such non-GS1 standards and regulations. These cross references have not been validated by the Standard Bodies or Regulators that own the standards presented in this Appendix and are provided as a reference guide to help organisations understand their traceability requirements.

### A.2 Cross Reference between the GS1 GTC Checklist and Traceability Standards and Best Manufacture Practices (BMP) Standards

#### A.2.1 ISO 22005-2007

The GS1 GTC Checklist has been benchmarked against ISO 22005-2007, Traceability in the feed and food chain – General principles and basic requirements for system design and implementation. The following table presents the cross reference between the GS1 GTC Checklist and the traceability requirements and clauses of ISO 22005-2007 Standard:

| Standard reference | GTC Section                      | Related GTC Control Points | ISO 22005-2007 Clauses |
|--------------------|----------------------------------|----------------------------|------------------------|
| ISO 22005-2007     | 1.CHOICE OF OBJECTIVES           | 1.1, 1.3, 1.4              | 4, 5.1, 5.2, 5.3       |
|                    | 2. PRODUCT DEFINITIONS           | 2.1                        | 5.4                    |
|                    | 3. SUPPLY CHAIN PLACEMENT        | 3.2                        | 5.5.1                  |
|                    | 4. ESTABLISHMENT OF PROCEDURES   | 4.2                        | 5.6                    |
|                    | 5. FLOW OF MATERIAL              | 5.5, 5.8, 5.9, 5.11        | 5.5.2                  |
|                    | 6. INFORMATION REQUIREMENTS      | 6.9                        | 5.5.3                  |
|                    | 7. DOCUMENTATION REQUIREMENTS    | 7.3                        | 5.7                    |
|                    | 8. STRUCTURE & RESPONSIBILITIES  | 8.1, 8.2, 8.3              | 6.1, 6.3               |
|                    | 9. TRAINING                      | 9.1                        | 6.4                    |
|                    | 10. SUPPLY CHAIN COORDINATION    | 10.1, 10.2, 10.3           | 5.8                    |
|                    | 11. MONITORING                   | 11.1                       | 6.5, 6.6, 8            |
|                    | 12. INTERNAL AND EXTERNAL AUDITS | 12.1                       | 7                      |
|                    | TOTAL REFERENCE POINTS           | 21                         | 18                     |

### A.2.2 ISO 9001-2015

ISO 9001-2015, Quality management systems - Requirements. This standard specifies requirements for a quality management system where an Organisation needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements, and aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements. The following table presents the cross reference between the GS1 GTC Checklist and the traceability requirements and clauses of the ISO 9001-2015 Standard:

| Standard reference | GTC Section                    | Related GTC Control Points                   | ISO 9001-2015 Clauses |
|--------------------|--------------------------------|--|-----------------------|
| ISO 9001-2015      | 1.CHOICE OF OBJECTIVES         | 1.1, 1.2, 1.3, 1.4                           | 4.2, 4.3              |
|                    | 2. PRODUCT DEFINITIONS         | 2.1, 2.2, 2.3, 2.4, 2.5                      | 8.5.2                 |
|                    | 3. SUPPLY CHAIN PLACEMENT      | 3.1, 3.2, 3.3, 3.4, 3.6, 3.7                 | 8.5.2                 |
|                    | 4. ESTABLISHMENT OF PROCEDURES | 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 4.9, 4.10 | 8.5.1, 8.7            |
|                    | 5. FLOW OF MATERIAL            | 5.5, 5.6, 5.7, 5.10, 5.11                    | 8.5.2, 8.5.1          |

| Standard reference | GTC Section                      | Related GTC Control Points                    | ISO 9001-2015 Clauses |
|--------------------|----------------------------------|---|-----------------------|
|                    | 6. INFORMATION REQUIREMENTS      | 6.1, 6.2, 6.3, 6.4, 6.5, 6.6, 6.7, 6.11, 6.12 | 8.5.1, 8.5.2          |
|                    | 7. DOCUMENTATION REQUIREMENTS    | 7.1, 7.2, 7.3, 7.4                            | 8.5.1, 7.5.3          |
|                    | 8. STRUCTURE & RESPONSIBILITIES  | 8.2, 8.3                                      | 5.3, 7.1.2            |
|                    | 9. TRAINING                      | 9.1, 9.2                                      | 5.3, 7.1.2            |
|                    | 10. SUPPLY CHAIN COORDINATION    | 10.1, 10.3, 10.5, 10.6                        | 7.5.3, 8.7, 6.1       |
|                    | 11. MONITORING                   | 11.1, 11.2                                    | 9.1                   |
|                    | 12. INTERNAL AND EXTERNAL AUDITS | 12.1, 12.2, 12.3                              | 9.2                   |
|                    | TOTAL REFERENCE POINTS           | 54  | 11                    |

### A.2.3 ISO 22000-2018

ISO 22000-2018 standard “Food safety management systems – Requirements for any Organisation in the food Chain”. The following table presents the cross reference between the GTC Checklist and the traceability requirements and clauses of ISO 22000-2018 Standard:

| Standard reference | GTC Section                      | Related GTC Control Points | ISO 22000-2018 Clauses                   |
|--------------------|----------------------------------|----------------------------|--|
| ISO 22000-2018     | 1. CHOICE OF OBJECTIVES          | 1.1, 1.2, 1.3, 1.4         | 4.1, 4.2, 4.3, 5.1, 5.2.1, 8.3           |
|                    | 2. PRODUCT DEFINITIONS           | 2.3                        | 8.3                                      |
|                    | 3. SUPPLY CHAIN PLACEMENT        | 3.1, 3.4, 3.6              | 5.1, 5.3.1, 7.1.2, 7.2, 8.5.1.5.3, 7.1.5 |
|                    | 4. ESTABLISHMENT OF PROCEDURES   | 4.4, 4.5, 4.9, 4.10        | 8.3, 8.5.1.5.3, 8.4.2                    |
|                    | 5. FLOW OF MATERIAL              | 5.6, 5.11, 5.12            | 8.3, 8.5.1.5.3, 8.5.1.5.1, 8.6           |
|                    | 6. INFORMATION REQUIREMENTS      | 6.3, 6.4, 6.7              | 8.2.4, 8.3, 8.6                          |
|                    | 7. DOCUMENTATION REQUIREMENTS    | 7.2, 7.4, 7.5              | 7.5.3.2, 8.3, 5.3.1, 8.1, 8.4.2          |
|                    | 8. STRUCTURE & RESPONSIBILITIES  | 8.3                        | 5.3.1, 5.3.2, 7.2                        |
|                    | 9. TRAINING                      | 9.1                        | 5.3.2, 7.2                               |
|                    | 10. SUPPLY CHAIN COORDINATION    | 10.1, 10.2, 10.5           | 8.3, 8.4.2, 8.9.5                        |
|                    | 11. MONITORING                   | 11.1, 11.2                 | 8.5.4, 9.1.1, 9.3.2, 10.1.1, 10.1.2      |
|                    | 12. INTERNAL AND EXTERNAL AUDITS | 12.1, 12.2, 12.3           | 9.1.2, 9.2.2, 9.3.2, 8.3, 10.1.2         |
|                    | TOTAL REFERENCE POINTS           | 31                         | 25                                       |

### A.2.4 BRC issue 8 (British Retail Consortium)

The BRC Global Standard – Food “was developed to assist retailers in their fulfilment of legal obligations and protection of the consumer, by providing a common basis for the audit of companies supplying retailer branded food products”. It requires the adoption and implementation of HACCP. The following table presents the cross reference between the GS1 GTC Checklist and the traceability requirements and clauses of the BRC issue 8 Global Food Standard:

| Standard reference | GTC Section                      | Related GTC Control Points    | BRC issue 8 Clauses   |
|--------------------|----------------------------------|-------------------------------|---|
| BRC issue 8        | 1.CHOICE OF OBJECTIVES           | 1.3, 1.4                      | 3.9.1, 3.9.3, 1.1.1, 1.1.2, 1.1.3   |
|                    | 2. PRODUCT DEFINITIONS           | 2.1, 2.3                      | 2.1.2, 3.9.2, 3.9.1   |
|                    | 3. SUPPLY CHAIN PLACEMENT        | 3.1, 3.4, 3.6                 | 1.2.1, 4.3.1, 4.2.3, 8.1.1, 2.5.1, 3.11.2, 9.5.1, 9.5.2, 3.5.1.4, 3.5.1.5 |
|                    | 4. ESTABLISHMENT OF PROCEDURES   | 4.4                           | 2.3.1, 2.5.1  |
|                    | 5. FLOW OF MATERIAL              | 5.1, 5.3, 5.6, 5.11           | 3.5.1.2, 3.5.1.6, 3.5.2.1, 3.9.2, 2.1.2, 2.5.1                            |
|                    | 6. INFORMATION REQUIREMENTS      | 6.1, 6.3, 6.4, 6.5, 6.7, 6.12 | 3.9.3, 9.5.1, 9.5.2, 2.2, 9.5.3, 5.4.4, 3.11.2                            |
|                    | 7. DOCUMENTATION REQUIREMENTS    | 7.2, 7.4                      | 3.9.1, 4.3.1, 3.11.1, 3.2.1, 3.11.2, 3.2, 3.11.3                          |
|                    | 8. STRUCTURE & RESPONSIBILITIES  | 8.1, 8.3                      | 1.2.1, 1.2.2, 2.1.1   |
|                    | 9. TRAINING                      | 9.1                           | 2.2.1, 7.1.1, 7.1.2, 7.1.3, 7.1.6, 7.1.7                                  |
|                    | 10. SUPPLY CHAIN COORDINATION    | 10.1, 10.2                    | 3.9.3, 5.4.4, 9.5.1, 9.5.2, 9.5.3   |
|                    | 11. MONITORING                   |                               |   |
|                    | 12. INTERNAL AND EXTERNAL AUDITS | 12.1, 12.2, 12.3              | 2.12.1, 3.4.1, 3.4.3, 1.1.4, 3.7.1, 3.7.2, 3.7.3, 2.3.2                   |
|                    | TOTAL REFERENCE POINTS           | 28                            | 45  |

### A.2.5 IFS (International Featured Standard) – Food Assessment Requirements (Part II)

IFS Food Version 7 is a norm created by the major German and French distribution Organisations that regulates the quality management systems in Organisations within the food and feeding sector, with the objective to obtain the maximum security in the manufacture processes and/or food manipulation. In this version of the standard, there is more emphasis on On-Site Evaluation. The Global Location Number (GLN), which is a GS1 Standard, became a mandatory field upon Retail and Wholesale Companies’ requests. The following table presents the cross reference between the GS1 GTC Checklist and the traceability requirements and clauses of the IFS version 7 (Part II) Food Standard:

| Standard reference | GTC Section            | Related GTC Control Points | IFS version 7 Clauses                                 |
|--------------------|------------------------|----------------------------|---|
| IFS version 7      | 1.CHOICE OF OBJECTIVES | 1.2, 1.3, 1.4*             | 1.1.1, 1.1.2, 1.2.5, 2.1.1.1, 2.1.1.2, 2.1.1.3, 2.2.2 |
|                    | 2. PRODUCT DEFINITIONS | 2.1, 2.3                   | 4.18.1  |

| Standard reference | GTC Section                      | Related GTC Control Points      | IFS version 7 Clauses   |
|--------------------|----------------------------------|---------------------------------|---|
|                    | 3. SUPPLY CHAIN PLACEMENT        | 3.1, 3.3*                       | 3.1   |
|                    | 4. ESTABLISHMENT OF PROCEDURES   | 4.1, 4.8, 4.11<br>4.9**, 4.10** | 2.2.1, 4.18.1, 4.18.7   |
|                    | 5. FLOW OF MATERIAL              | 5.1, 5.3, 5.6,<br>5.10, 5.11    | 4.18.1, 2.2.3.3, 2.2.3.4  |
|                    | 6. INFORMATION REQUIREMENTS      | 6.3, 6.7, 6.9,<br>6.11          | 4.18.1  |
|                    | 7. DOCUMENTATION REQUIREMENTS    | 7.1, 7.2, 7.3,<br>7.4, 7.5      | 5.3, 1.2, 2.1.2.2, 2.1.1.3, 2.2.3.3,<br>2.2.3.4, 2.1.2.1, 2.1.2.3 |
|                    | 8. STRUCTURE & RESPONSIBILITIES  | 8.1, 8.2, 8.3                   | 3.1.1, 3.1.2, 1.2.2, 1.1.2, 1.2.4                                 |
|                    | 9. TRAINING                      | 9.1                             | 3.3.1, 3.3.2  |
|                    | 10. SUPPLY CHAIN COORDINATION    | 10.2, 10.3,<br>10.4, 10.5       | 4.18.2, 5.9.1, 5.9.2  |
|                    | 11. MONITORING                   | 11.1, 11.2                      | 4.18.2, 4.18.3  |
|                    | 12. INTERNAL AND EXTERNAL AUDITS | 12.1, 12.2,<br>12.3             | 1.4.1, 1.4.2, 5.1.1, 5.1.2, 1.4.2,<br>5.11                        |
|                    | TOTAL REFERENCE POINTS           | 39                              | 32  |

\*The Global Location Number (GLN) is a mandatory field upon in IFS Food version 7.

\*\* These control points are covered in HACCP. IFS Food requires HACCP implementation.

### A.2.6 GlobalG.A.P version 5.2

GlobalG.A.P is a private sector body that sets voluntary standards for the certification of agricultural products around the globe. The aim is to establish a common approach for Good Agricultural Practice (G.A.P.) with different product applications capable of fitting to the whole of global agriculture. It consists of a set of normative documents. These documents cover the GLOBALGAP General Regulations and the GLOBALGAP Control Points and Compliance. The following table presents the cross reference between the GTC Checklist and the traceability requirements and clauses of the GlobalG.A.P version 5.2 Standard:

| Standard reference      | GTC Section                     | Related GTC Control Points | GlobalG.A.P V5.2 Clauses   |
|-------------------------|---------------------------------|----------------------------|--|
| GlobalG.A.P version 5.2 | 1.CHOICE OF OBJECTIVES          | 1.1, 1.2                   | II (2.2) (e), CPCC (1.1.2)                                       |
|                         | 2. PRODUCT DEFINITIONS          | 2.1, 2.2                   | II (8) (c), II (8) (d)   |
|                         | 3. SUPPLY CHAIN PLACEMENT       | 3.1, 3.4, 3.5              | II (1.3.1) (i), II (1.3) (i), CPCC (1.1), I ANNEX (1.2) (1.1.1), |
|                         | 4. ESTABLISHMENT OF PROCEDURES  | 4.1, 4.9, 4.10             | II (8) (a), II (8) (g), CPCC (14.2), CPCC (9.1)                  |
|                         | 5. FLOW OF MATERIAL             | 5.6                        | II ANNEX (11.2) (2) (4)  |
|                         | 6. INFORMATION REQUIREMENTS     | 6.11                       | II (8) (e), II (8) (f), II ANNEX (11.2) (2) (4)                  |
|                         | 7. DOCUMENTATION REQUIREMENTS   | 7.1, 7.4                   | CPCC (2.1), II (3.1) (a)   |
|                         | 8. STRUCTURE & RESPONSIBILITIES |                            |  |

| Standard reference | GTC Section                      | Related GTC Control Points         | GlobalG.A.P V5.2 Clauses   |
|--------------------|----------------------------------|------------------------------------|--|
|                    | 9. TRAINING                      | 9.1                                | II (2.2) (b), II (2.2) (c), CPCC (2.1)   |
|                    | 10. SUPPLY CHAIN COORDINATION    | 10.1, 10.2, 10.3, 10.4, 10.5, 10.6 | CPCC (13.4), II (9) (d), II (9) (a), II (9) (b), CPCC (17.1), II (9) (c), CPCC (9.1) |
|                    | 11. MONITORING                   |                                    |  |
|                    | 12. INTERNAL AND EXTERNAL AUDITS | 12.1, 12.2, 12.3                   | II (5) (a), II (5) (d), II (6) (f), II (7) (g)                                       |
|                    | TOTAL REFERENCE POINTS           | 22                                 | 27   |

### A.2.7 GFSI Benchmarking Requirements

The GFSI referenced document is a “benchmarking schema” for food safety which seeks to harmonise the different approaches by industry organisations like BRC, Global Gap, FSM and other certifications. The aim of the Global Food Safety Initiative is to improve food safety and business efficiency. The following table presents the cross reference between the GS1 GTC Checklist and the related key elements requirements of the GFSI Benchmarking Requirements document focusing on the following:

- AI: Farming of Animals for Meat/Milk/Eggs/Honey
- AII: Farming of Fish and Seafood
- BI: Farming of Plants (other than Grains and Pulses)
- BII: Farming of Grains and Pulses
- BIII: Pre-Process Handling of Plant Products
- CO: Animal Primary Conversion
- CI: Processing of Perishable Animal Products
- CII: Processing of Perishable Plant Products
- CIII: Processing of Perishable Animal and Plant Products (Mixed Products)
- CIV: Processing of Ambient Stable Animal and Plant Products (Mixed Products)
- K: Production of (Bio) Chemicals and Bio-Cultures used as Food Ingredients or Processing Aids in Food Production
- I: Production of Food Packaging

| Standard reference             | GTC Section            | Related GTC Control Points | GFSI Benchmarking Requirements  |
|--------------------------------|------------------------|----------------------------|---|
| GFSI Benchmarking Requirements | 1.CHOICE OF OBJECTIVES | 1.1, 1.3, 1.4              | AI (FSM) (4.1), AI (FSM) (14.1.1), AII (FSM) (4.1), AII (FSM) (4.1.1), CO (FSM) (4.1), CO (FSM) (14.1.1), CIII (FSM) (3), CIII (FSM) (10.1), CIII (FSM) (14.1.1), CIV (FSM) (3), CIV (FSM) (10.1), CIV (FSM) (14.1.1), K (FSM) (3), K (FSM) (10.1), K (FSM) (14.1.1), AI (FSM) (1), AII (HACCP) (1.1), AII (HACCP) (1.4), CO (HACCP) (1.1), CO (HACCP) (1.4), CI (FSM) (2), I (FSM) (3), I (FSM) (10.1), I (FSM) (14.1.1) |

| Standard reference | GTC Section                     | Related GTC Control Points           | GFSI Benchmarking Requirements  |
|--------------------|---------------------------------|--------------------------------------|---|
|                    | 2. PRODUCT DEFINITIONS          | 2.1, 2.3                             | AI (GAP) (17), AII (FSM) (14.1.1), CO (FSM) (14.1.1), BI (FSM) (14.1.1), BII (FSM) (14.1.1), BIII (FSM) (14.1.1), CII (FSM) (14.1.1), CI (FSM) (18.2)   |
|                    | 3. SUPPLY CHAIN PLACEMENT       |                                      |   |
|                    | 4. ESTABLISHMENT OF PROCEDURES  | 4.1, 4.2, 4.4, 4.8, 4.9, 4.10        | AI (FSM) (11), AII (FSM) (11), CO (FSM) (11), CI (FSM) (4), CI (FSM) (13.1.2), BI (FSM) (14.1.1), BI (FSM) (13.1.1), BII (FSM) (14.1.1), BII (FSM) (13.1.1), BIII (FSM) (14.1.1), BIII (FSM) (13.1.1), CII (FSM) (11), CII (FSM) (14.1.1), CI (FSM) (14.1.1), AI (FSM) (9.1), AI (FSM) (14.2), AI (FSM) (22), AI (FSM) (22.3), AI (FSM) (13.2.1), AII (FSM) (1), AII (FSM) (14.1.1), AII (FSM) (14.2), AII (FSM) (22), AII (FSM) (22.3), CO (FSM) (1), CO (FSM) (14.1.1), CO (FSM) (14.2), CO (FSM) (22), CO (FSM) (22.3), CI (FSM) (4), CI (FSM) (14.1.1), CI (FSM) (22), BI (FSM) (7.1), BII (FSM) (7.1), BIII (FSM) (7.1), CII (FSM) (7.1), CIII (FSM) (14.2), CIV (FSM) (14.2), K (FSM) (7.1), I (FSM) (14.2) |
|                    | 5. FLOW OF MATERIAL             | 5.1, 5.2, 5.3, 5.5, 5.8, 5.12        | CI (FSM) (18.2), BI (FSM) (14.1.1), BII (FSM) (14.1.1), BIII (FSM) (14.1.1), CII (FSM) (14.1.1), AI (FSM) (14.1.1), AII (FSM) (14.1.1), AII (FSM) (14.1.1), CI (FSM) (14.1.1), CI (FSM) (18.2), CI (GMP) (9)  |
|                    | 6. INFORMATION REQUIREMENTS     | 6.1, 6.3, 6.4, 6.9, 6.10, 6.11, 6.12 | AI (FSM) (14.1.1), AI (GAP) (17), AII (FSM) (14.1.1), CO (FSM) (14.1.1), AI (FSM) (13.2.1), BI (FSM) (13.11), BII (FSM) (13.11), BIII (FSM) (13.11), CIII (FSM) (13.2.1), CIV (FSM) (13.2.1), K (FSM) (13.2.1), AI (GAP) (17), AI (FSM) (14.1.4), AII (FSM) (14.1.4), CO (FSM) (14.1.4), I (FSM) (13.2.1)   |
|                    | 7. DOCUMENTATION REQUIREMENTS   | 7.1, 7.2, 7.3, 7.4                   | AI (GAP) (17), AI (FSM) (1), AI (FSM) (9.1), AI (FSM) (9.2.1), AI (FSM) (4.1), AII (FSM) (1), AII (FSM) (9.2.1), AII (FSM) (4.1), AII (FSM) (14.2), CO (FSM) (1), CO (FSM) (9.2.1), CO (FSM) (4.1), CO (FSM) (14.2), CI (FSM) (1), CI (FSM) (9.2.1), CI (FSM) (4.1), BI (FSM) (14.2), BII (FSM) (14.2), BIII (FSM) (14.2), CII (FSM) (14.2), CIII (FSM) (14.2), CIV (FSM) (14.2), K (FSM) (14.2), I (FSM) (1), I (FSM) (9.2.1), I (FSM) (14.2)  |
|                    | 8. STRUCTURE & RESPONSIBILITIES | 8.2, 8.3                             | AI (FSM) (12), AII (FSM) (12), CO (FSM) (12), CI (FSM) (12), CO (FSM) (11), CO (GMP) (7), CI (FSM) (4),   |



| Standard reference | GTC Section                      | Related GTC Control Points         | GFSI Benchmarking Requirements  |
|--------------------|----------------------------------|------------------------------------|---|
|                    | 9. TRAINING                      | 9.1, 9.2                           | AII (FSM) (2), CO (FSM) (2), CI (GMP) (7), CIII (GMP) (7), CIV (GMP) (7), K (GMP) (7), CIII (FSM) (20), CIV (FSM) (20), K (FSM) (20), I (GMP) (7), I (FSM) (20)   |
|                    | 10. SUPPLY CHAIN COORDINATION    | 10.1, 10.2, 10.3, 10.4, 10.5, 10.6 | CO (FSM) (14.1.1), AI (FSM) (14.1.4), AII (FSM) (14.1.4), CO (FSM) (14.1.4), CIII (FSM) (24.1), CIV (FSM) (24.1), K (FSM) (24.1), AI (FSM) (11), AII (FSM) (11), CO (FSM) (11), BI (FSM) (7.2), BII (FSM) (7.2), BIII (FSM) (7.2), CII (FSM) (7.2), CIII (FSM) (7.2), CIV (FSM) (7.2), K (FSM) (7.2), AI (FSM) (1), AII (FSM) (1), CO (FSM) (1), CIII (HACCP) (1.1), CIV (HACCP) (1.1), K (HACCP) (1.1), AI (FSM) (22), AI (FSM) (22.3), AII (FSM) (22), AII (FSM) (22.3), CO (FSM) (22), CO (FSM) (22.3), CI (FSM) (22), BI (FSM) (22), BII (FSM) (22), BIII (FSM) (22), CII (FSM) (22), CIII (FSM) (22), CIV (FSM) (22), K (FSM) (22), CI (FSM) (9.1), I (FSM) (24.1), I (FSM) (7.2), I (HACCP) (1.1), I (FSM) (22) |
|                    | 11. MONITORING                   | 11.1, 11.2                         | AI (FSM) (9.1), AI (FSM) (14.2), AI (FSM) (3), AII (FSM) (9.1), AII (FSM) (14.2), AII (FSM) (3), CO (FSM) (9.1), CO (FSM) (14.2), CO (FSM) (3), CI (FSM) (3), CI (FSM) (14.2), BI (FSM) (14.2), BI (FSM) (9.1), BII (FSM) (14.2), BII (FSM) (9.1), BIII (FSM) (14.2), BIII (FSM) (9.1), CII (FSM) (14.2), CII (FSM) (9.1), CIII (FSM) (9.1), CIII (FSM) (14.2), CIII (GMP) (9), CIV (FSM) (9.1), CIV (FSM) (14.2), CIV (GMP) (9), K (FSM) (9.1), K (FSM) (14.2), I (FSM) (9.1), I (FSM) (14.2)  |
|                    | 12. INTERNAL AND EXTERNAL AUDITS | 12.1, 12.2, 12.3                   | AI (FSM) (14.2), AI (FSM) (20), AI (FSM) (3), AI (FSM) (24.1), AI (FSM) (25), AII (FSM) (14.2), AII (FSM) (20), AII (FSM) (24.1), AII (FSM) (25), CO (FSM) (14.2), CO (FSM) (20), CO (FSM) (24.1), CO (FSM) (25), CI (FSM) (20), CI (FSM) (24.1), CI (FSM) (25), BI (FSM) (20), BI (FSM) (24.1), BII (FSM) (20), BII (FSM) (24.1), BIII (FSM) (20), BIII (FSM) (24.1), CII (FSM) (20), CII (FSM) (24.1), CIII (FSM) (24.1), CIV (FSM) (24.1), K (FSM) (24.1), I (FSM) (24.1)  |
|                    | TOTAL REFERENCE POINTS           | 43                                 | 168   |

### A.2.8 ISO 10377-2013

ISO 10377 is a standard that seeks to provide practical guidance to strengthen safety for consumer products, in fostering their reach in two respects, the first, in the verification, assessment and management of product risks, and the second, to provide consumers with hazard warnings and instructions for safe use. The following table presents the cross reference between the GS1 GTC Checklist and the traceability requirements and clauses of ISO 10377-2013 Standard:

| Standard reference | GTC Section                      | Related GTC Control Points                    | ISO 10377 Clauses          |
|--------------------|----------------------------------|---|----------------------------|
| ISO 10377          | 1.CHOICE OF OBJECTIVES           | 1.1, 1.3, 1.4                                 | 4.1.1, 5.4, 4.1.3          |
|                    | 2. PRODUCT DEFINITIONS           | 2.1, 2.3                                      | 5.5.2                      |
|                    | 3. SUPPLY CHAIN PLACEMENT        |   |                            |
|                    | 4. ESTABLISHMENT OF PROCEDURES   | 4.1, 4.2, 4.4, 4.5, 4.6, 4.8, 4.9, 4.10       | 5.5.1, 5.5.2, 6.3.4.1, 8.6 |
|                    | 5. FLOW OF MATERIAL              | 5.1, 5.3, 5.5, 5.6, 5.10, 5.11, 5.12          | 5.5.2, 7.3.1, 5.5.1        |
|                    | 6. INFORMATION REQUIREMENTS      | 6.1, 6.2, 6.3, 6.4, 6.5, 6.7, 6.9, 6.11, 6.12 | 5.2.3, 5.5.1, 6.3.4.1      |
|                    | 7. DOCUMENTATION REQUIREMENTS    | 7.1, 7.3, 7.4                                 | 5.2.3, 5.5.1, 4.1.4        |
|                    | 8. STRUCTURE & RESPONSIBILITIES  | 8.2, 8.3                                      | 5.2.2                      |
|                    | 9. TRAINING                      | 9.1   | 5.2.1, 7.2.2.4, 7.5.2      |
|                    | 10. SUPPLY CHAIN COORDINATION    | 10.1, 10.2, 10.3, 10.4, 10.5, 10.6            | 6.3.4.1, 5.2.2             |
|                    | 11. MONITORING                   | 11.1, 11.2                                    | 5.3                        |
|                    | 12. INTERNAL AND EXTERNAL AUDITS | 12.1, 12.2, 12.3                              | 7.5.1                      |
|                    | TOTAL REFERENCE POINTS           | 46  | 16                         |

### A.2.9 ISO 10393 - 2013

ISO 10393 is an international standard that seeks to provide tools that extend consumer confidence assurance by eliminating unsafe products in a global market. The following table presents the cross reference between the GS1 GTC Checklist and the traceability requirements and clauses of ISO 10393-2013 Standard:

| Standard reference | GTC Section                    | Related GTC Control Points    | ISO 10393 Clauses         |
|--------------------|--------------------------------|-------------------------------|---------------------------|
| ISO 10393          | 1.CHOICE OF OBJECTIVES         | 1.1, 1.3, 1.4                 | 5.2, 5.3                  |
|                    | 2. PRODUCT DEFINITIONS         | 2.4                           | 6.4.1                     |
|                    | 3. SUPPLY CHAIN PLACEMENT      | 3.2, 3.6                      | 6.1                       |
|                    | 4. ESTABLISHMENT OF PROCEDURES | 4.1, 4.2, 4.4, 4.5, 4.9, 4.10 | 6.2, 7.1, 7.2, 7.3, 7.2.5 |

| Standard reference | GTC Section                      | Related GTC Control Points   | ISO 10393 Clauses    |
|--------------------|----------------------------------|------------------------------|----------------------|
|                    | 5. FLOW OF MATERIAL              |                              |                      |
|                    | 6. INFORMATION REQUIREMENTS      | 6.7, 6.12                    | 6.4.1, 7.2           |
|                    | 7. DOCUMENTATION REQUIREMENTS    | 7.1                          | 6.4                  |
|                    | 8. STRUCTURE & RESPONSIBILITIES  | 8.2                          | 7.1.4                |
|                    | 9. TRAINING                      | 9.1                          | 5.6                  |
|                    | 10. SUPPLY CHAIN COORDINATION    | 10.2, 10.3, 10.4, 10.5, 10.6 | 7.2, 7.1.3, 6.3, 5.2 |
|                    | 11. MONITORING                   | 11.1, 11.2                   | 8                    |
|                    | 12. INTERNAL AND EXTERNAL AUDITS |                              |                      |
|                    | TOTAL REFERENCE POINTS           | 24                           | 15                   |

### A.2.10 ISO 14001-2015

ISO 14001-2015, Environmental Management Systems - Requirements. This standard specifies requirements for a environmental management system to ensure socio-economic growth, without affecting the environment and the changing conditions presented by the environment. The following table presents the cross reference between the GS1 GTC Checklist and the traceability requirements and clauses of the ISO 14001-2015 Standard:

| Standard reference | GTC Section                      | Related GTC Control Points             | ISO 14001-2015 Clauses |
|--------------------|----------------------------------|--|------------------------|
| ISO 14001-2015     | 1. CHOICE OF OBJECTIVES          | 1.1, 1.2, 1.3                          | 4.2, 4.3               |
|                    | 2. PRODUCT DEFINITIONS           | 2.1, 2.2, 2.3, 2.4, 2.5                | 8.1                    |
|                    | 3. SUPPLY CHAIN PLACEMENT        | 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7      | 8.1                    |
|                    | 4. ESTABLISHMENT OF PROCEDURES   | 4.1, 4.2, 4.3, 4.4, 4.5, 4.6           | 8.1, 8                 |
|                    | 5. FLOW OF MATERIAL              | 5.5, 5.6, 5.11, 5.12                   | 8.1, 4.3, 8            |
|                    | 6. INFORMATION REQUIREMENTS      | 6.1, 6.2, 6.3, 6.4, 6.5, 6.6, 6.7, 6.8 | 7.5, 8.1               |
|                    | 7. DOCUMENTATION REQUIREMENTS    | 7.1, 7.2, 7.3, 7.4                     | 7.5, 5.3,              |
|                    | 8. STRUCTURE & RESPONSIBILITIES  | 8.2, 8.3                               | 7.1                    |
|                    | 9. TRAINING                      | 9.1, 9.2                               | 7.1                    |
|                    | 10. SUPPLY CHAIN COORDINATION    | 10.1, 10.2, 10.4, 10.6                 | 8.1, 8.2, 5.3, 6.1     |
|                    | 11. MONITORING                   | 11.1, 11.2                             | 9.1                    |
|                    | 12. INTERNAL AND EXTERNAL AUDITS | 12.1, 12.2, 12.3                       | 9.2                    |

| Standard reference | GTC Section            | Related GTC Control Points | ISO 14001-2015 Clauses |
|--------------------|------------------------|----------------------------|------------------------|
|                    | TOTAL REFERENCE POINTS | 47                         | 11                     |

### A.2.11 ISO 22095-2020

ISO 22095-2020, Chain of Custody. "The aim of this document is to provide unambiguous definitions of the different chain of custody models, and the corresponding requirements, which are independent of sectors, materials, products, and issues addressed". The following table presents the cross reference between the GS1 GTC Checklist and the traceability requirements and clauses of the ISO 22095-2020 Standard:

| Standard reference | GTC Section                      | Related GTC Control Points                                     | ISO 22095-2020 Clauses                                      |
|--------------------|----------------------------------|--|---|
| ISO 22095-2020     | 1. CHOICE OF OBJECTIVES          | 1.1, 1.4   | 6.2, 6.3, 6.4   |
|                    | 2. PRODUCT DEFINITIONS           | 2.1, 2.2, 2.4  | 5.2, 5.3.1.1, 5.3.1.2, 5.3.2.2, 5.4.1.2                     |
|                    | 3. SUPPLY CHAIN PLACEMENT        | 3.4, 3.5, 3.6, 3.7   | 5.3.2.2   |
|                    | 4. ESTABLISHMENT OF PROCEDURES   | 4.1, 4.2, 4.5a, 4.8, 4.9, 4.10                                 | 5.3.1.2, 5.3.1.3, 5.3.2.2, 5.4.1.2, 6.6.2, 6.6.1, 6.2, 6.12 |
|                    | 5. FLOW OF MATERIAL              | 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 5.8, 5.9, 5.10              | 5.3.2.2, 5.2, 6.7   |
|                    | 6. INFORMATION REQUIREMENTS      | 6.1, 6.2, 6.3, 6.4, 6.5, 6.7, 6.8, 6.9, 6.10, 6.11, 6.12, 6.13 | 5.4.1.2, 5.1, 5.3.1.1, 5.3.1.2, 5.3.1.3, 6.6.1, 6.7         |
|                    | 7. DOCUMENTATION REQUIREMENTS    | 7.2, 7.3, 7.4  | 6.3, 6.2, 5.3.1.1, 5.4.1.4,                                 |
|                    | 8. STRUCTURE & RESPONSIBILITIES  | 8.2, 8.3   | 6.2, 6.3  |
|                    | 9. TRAINING                      | 9.1  | 6.2, 6.3  |
|                    | 10. SUPPLY CHAIN COORDINATION    | 10.1   | 5.3.1.1, 5.3.1.2, 5.3.1.3                                   |
|                    | 11. MONITORING                   |  |   |
|                    | 12. INTERNAL AND EXTERNAL AUDITS | 12.1, 12.2, 12.3   | 6.5   |
|                    | TOTAL REFERENCE POINTS           | 47   | 16  |

### A.2.12 IFS Logistics 2.2

IFS Logistics Standard covers application for all types of transport: truck, train, boat, plane or any other type of transport at controlled temperature or at room temperature. The scope of IFS Logistics is food and non-food products. IFS Logistics includes all Logistics activities such as, loading, transport, unloading, storage, handling and subsequent distribution. The following table presents the cross reference between the GS1 GTC Checklist and the traceability requirements and clauses of IFS Logistics 2.2 Standard:

| Standard reference | GTC Section                      | Related GTC Control Points | IFS Logistics 2.2 Clauses        |
|--------------------|----------------------------------|----------------------------|----------------------------------|
| IFS Logistics 2.2  | 1.CHOICE OF OBJECTIVES           | 1.1, 1.2                   | 5.1, 5.7.3,11, 4, 1.3            |
|                    | 2. PRODUCT DEFINITIONS           |                            |                                  |
|                    | 3. SUPPLY CHAIN PLACEMENT        |                            |                                  |
|                    | 4. ESTABLISHMENT OF PROCEDURES   |                            |                                  |
|                    | 5. FLOW OF MATERIAL              |                            |                                  |
|                    | 6. INFORMATION REQUIREMENTS      |                            |                                  |
|                    | 7. DOCUMENTATION REQUIREMENTS    |                            |                                  |
|                    | 8. STRUCTURE & RESPONSIBILITIES  |                            |                                  |
|                    | 9. TRAINING                      | 9.1                        | 2.2                              |
|                    | 10. SUPPLY CHAIN COORDINATION    |                            |                                  |
|                    | 11. MONITORING                   | 11.1, 11.2                 | 5.4, 4.1.4, 5.5                  |
|                    | 12. INTERNAL AND EXTERNAL AUDITS | 12.1, 12.2, 12.3           | 5.6, 5.1, 5.1.1, 5.7, 5.8.2, 5.8 |
|                    | TOTAL REFERENCE POINTS           | 8                          | 14                               |

### A.2.13 IFS Global Market Logistics

IFS Global Market Logistics seeks to evaluate logistical services in relation to products safety and quality. This is based on a progressive and voluntary assessment for a small or less developed businesses in order for the business to access the local market and create mutual acceptance along the supply chain. The following table presents the cross reference between the GS1 GTC Checklist and the traceability requirements and clauses of IFS Global Market Logistics Standard:

| Standard reference          | GTC Section                     | Related GTC Control Points | IFS Global Market Logistics Clauses |
|-----------------------------|---------------------------------|----------------------------|-------------------------------------|
| IFS Global Market Logistics | 1.CHOICE OF OBJECTIVES          | 1.2                        | 4                                   |
|                             | 2. PRODUCT DEFINITIONS          |                            |                                     |
|                             | 3. SUPPLY CHAIN PLACEMENT       |                            |                                     |
|                             | 4. ESTABLISHMENT OF PROCEDURES  |                            |                                     |
|                             | 5. FLOW OF MATERIAL             |                            |                                     |
|                             | 6. INFORMATION REQUIREMENTS     |                            |                                     |
|                             | 7. DOCUMENTATION REQUIREMENTS   |                            |                                     |
|                             | 8. STRUCTURE & RESPONSIBILITIES |                            |                                     |
|                             | 9. TRAINING                     |                            |                                     |

| Standard reference | GTC Section                      | Related GTC Control Points | IFS Global Market Logistics Clauses |
|--------------------|----------------------------------|----------------------------|-------------------------------------|
|                    | 10. SUPPLY CHAIN COORDINATION    |                            |                                     |
|                    | 11. MONITORING                   |                            |                                     |
|                    | 12. INTERNAL AND EXTERNAL AUDITS | 12.1, 12.3                 | 5.1, 5.4, 5.7.2                     |
|                    | TOTAL REFERENCE POINTS           | 3                          | 4                                   |

### A.2.14 IFS HPC

IFS HPC standard describes audit protocols for products and processes of suppliers manufacturing household and personal care products. The following table presents the cross reference between the GS1 GTC Checklist and the traceability requirements and clauses of IFS HPC Standard:

| Standard reference | GTC Section                      | Related GTC Control Points | IFS HPC Clauses     |
|--------------------|----------------------------------|----------------------------|---------------------|
| IFS HPC            | 1.CHOICE OF OBJECTIVES           | 1.1, 1.3                   | 6.1, 6.7.3, 3.3     |
|                    | 2. PRODUCT DEFINITIONS           |                            |                     |
|                    | 3. SUPPLY CHAIN PLACEMENT        |                            |                     |
|                    | 4. ESTABLISHMENT OF PROCEDURES   |                            |                     |
|                    | 5. FLOW OF MATERIAL              |                            |                     |
|                    | 6. INFORMATION REQUIREMENTS      |                            |                     |
|                    | 7. DOCUMENTATION REQUIREMENTS    |                            |                     |
|                    | 8. STRUCTURE & RESPONSIBILITIES  |                            |                     |
|                    | 9. TRAINING                      | 9.1                        | 3.3                 |
|                    | 10. SUPPLY CHAIN COORDINATION    |                            |                     |
|                    | 11. MONITORING                   | 11.1, 11.2                 | 3.3, 4.14, 6.4, 6.6 |
|                    | 12. INTERNAL AND EXTERNAL AUDITS | 12.1, 12.3                 | 6.6, 6.8            |
|                    | TOTAL REFERENCE POINTS           | 7                          | 7                   |

### A.2.15 HL7 Implementation Guide for Clinical Document Architecture Release 2: Consolidates CDA Templates for Clinical Notes

HL7 Implementation Guide for Clinical Notes provides material and templates to support Clinical Notes documentation. The following table presents the cross reference between the GS1 GTC Checklist and the traceability requirements and clauses of HL7 Implementation Guide for Clinical Notes:

| Standard reference                             | GTC Section                      | Related GTC Control Points | HL7 R2 Implementation Guide for Clinical Notes Clauses |
|--|----------------------------------|----------------------------|--|
| HL7 R2 Implementation Guide for Clinical Notes | 1. CHOICE OF OBJECTIVES          |                            |  |
|  | 2. PRODUCT DEFINITIONS           | 2.1, 2.2                   | 3.85   |
|  | 3. SUPPLY CHAIN PLACEMENT        |                            |  |
|  | 4. ESTABLISHMENT OF PROCEDURES   |                            |  |
|  | 5. FLOW OF MATERIAL              | 5.5, 5.6, 5.10             | 3.85   |
|  | 6. INFORMATION REQUIREMENTS      | 6.3, 6.7, 6.8, 6.9, 6.10   | 3.85   |
|  | 7. DOCUMENTATION REQUIREMENTS    |                            |  |
|  | 8. STRUCTURE & RESPONSIBILITIES  |                            |  |
|  | 9. TRAINING                      |                            |  |
|  | 10. SUPPLY CHAIN COORDINATION    |                            |  |
|  | 11. MONITORING                   |                            |  |
|  | 12. INTERNAL AND EXTERNAL AUDITS |                            |  |
|  | TOTAL REFERENCE POINTS           | 10                         | 1  |

**A.2.16 HL7 CDA R2 Implementation Guide: C-CDA supplemental templates for Unique Device Identifier (UDI) for Implantable Medical Devices, Release 1**

HL7 Implementation Guide for UDI provides material to implement support for Unique Device Identifiers (UDIs) for implantable medical devices. The following table presents the cross reference between the GS1 GTC Checklist and the traceability requirements and clauses of HL7 Implementation Guide for UDI:

| Standard reference                  | GTC Section                     | Related GTC Control Points | HL7 R2 Implementation Guide for UDI Clauses |
|-------------------------------------|---------------------------------|----------------------------|---|
| HL7 R2 Implementation Guide for UDI | 1. CHOICE OF OBJECTIVES         |                            |   |
|                                     | 2. PRODUCT DEFINITIONS          | 2.1, 2.2                   | 2.2.5                                       |
|                                     | 3. SUPPLY CHAIN PLACEMENT       |                            |   |
|                                     | 4. ESTABLISHMENT OF PROCEDURES  |                            |   |
|                                     | 5. FLOW OF MATERIAL             | 5.6, 5.10                  | 2.2.5, 2.2.12                               |
|                                     | 6. INFORMATION REQUIREMENTS     | 6.7, 6.8, 6.9, 6.10        | 2.2.5, 2.2.12                               |
|                                     | 7. DOCUMENTATION REQUIREMENTS   |                            |   |
|                                     | 8. STRUCTURE & RESPONSIBILITIES |                            |   |

| Standard reference | GTC Section                      | Related GTC Control Points | HL7 R2 Implementation Guide for UDI Clauses |
|--------------------|----------------------------------|----------------------------|---|
|                    | 9. TRAINING                      |                            |   |
|                    | 10. SUPPLY CHAIN COORDINATION    |                            |   |
|                    | 11. MONITORING                   |                            |   |
|                    | 12. INTERNAL AND EXTERNAL AUDITS |                            |   |
|                    | TOTAL REFERENCE POINTS           | 8                          | 2   |

### A.2.17 US DSCSA (Drug Quality and Security Act)

The Drug Quality and Security Act “outlines steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States”. The following table presents the cross reference between the GTC Checklist and the traceability requirements and clauses of DSCSA:

| Standard reference | GTC Section                      | Related GTC Control Points | DSCSA Clauses   |
|--------------------|----------------------------------|----------------------------|---|
| DSCSA              | 1. CHOICE OF OBJECTIVES          |                            |   |
|                    | 2. PRODUCT DEFINITIONS           | 2.1, 2.4                   | 614 (D)(2), 617(d)(2), 620(2)(A)(i), 621(2)(A)(iii), 621(2)(A)(iv)  |
|                    | 3. SUPPLY CHAIN PLACEMENT        | 3.1, 3.6                   | 590(11)(b)(1)(A)(i), 605(a)(2)(A)   |
|                    | 4. ESTABLISHMENT OF PROCEDURES   | 4.1, 4.8, 4.9, 4.10        | 590/591(2)(A)(i), 590/591(2)(A)(ii), 616(d)(1)(A)(iii), 619/620(1)(A)(iii), 591(4)(C)(V), 591(4)(c)(ii)                                 |
|                    | 5. FLOW OF MATERIAL              | 5.1, 5.5, 5.6, 5.9, 5.10   | 607/608(9)(A)(ii), 608/609(2)(A)(B), 589(10)(A)(i)  |
|                    | 6. INFORMATION REQUIREMENTS      | 6.3, 6.7, 6.11             | 616(d)(1)(A)(ii), 616(d)(1)(A)(iii), 617(d)(1)(D), 620(e)(1)(C), 620(e)(1)(A)(ii), 620(e)(1)(A)(iii), 608(b)(1)(A)(i), 608(b)(1)(A)(ii) |
|                    | 7. DOCUMENTATION REQUIREMENTS    | 7.1, 7.3                   | 605(a)(2)(A), 615(4)(A)(iii), 616(B)(v), 618(4)(A)(iv), 619(B)(v), 621(4)(A)(iii), 622(B)(v)  |
|                    | 8. STRUCTURE & RESPONSIBILITIES  |                            |   |
|                    | 9. TRAINING                      |                            |   |
|                    | 10. SUPPLY CHAIN COORDINATION    | 10.1, 10.2, 10.5, 10.6     | 589(10)(A)(ii)(v), 614(C), 614(D), 617(d)(1)(D), 620(e)(1)(C), 588(4)   |
|                    | 11. MONITORING                   |                            |   |
|                    | 12. INTERNAL AND EXTERNAL AUDITS |                            |   |
|                    | TOTAL REFERENCE POINTS           | 22                         | 30  |

### A.2.18 Falsified Medicine Directive 2011/62/EU and Regulation 2016/161

The Falsified Medicine Directive “introduces harmonised European measures to fight medicine falsifications and ensure that medicines are safe and that the trade in medicines is rigorously controlled”. The regulation provides details the characteristics of the safety features. The following table presents the cross reference between the GTC Checklist and the traceability requirements and clauses of the Falsified Medicine Directive and Regulation:

| Standard reference  | GTC Section                      | Related GTC Control Points | Falsified Medicine Directive and Regulation Clauses    |
|---|----------------------------------|----------------------------|--|
| Falsified Medicine Directive 2011/62/EU and Regulation 2016/161 | 1.CHOICE OF OBJECTIVES           |                            |  |
|   | 2. PRODUCT DEFINITIONS           | 2.1, 2.2, 2.4              | Directive: (11) Article 54 – Identify individual packs |
|   | 3. SUPPLY CHAIN PLACEMENT        |                            |  |
|   | 4. ESTABLISHMENT OF PROCEDURES   | 4.2                        | Regulation: (II) Article 4                             |
|   | 5. FLOW OF MATERIAL              | 5.10                       | Regulation: (II) Article 4                             |
|   | 6. INFORMATION REQUIREMENTS      |                            |  |
|   | 7. DOCUMENTATION REQUIREMENTS    | 7.3                        | Regulation: Article 15                                 |
|   | 8. STRUCTURE & RESPONSIBILITIES  |                            |  |
|   | 9. TRAINING                      |                            |  |
|   | 10. SUPPLY CHAIN COORDINATION    | 10.2                       | Regulation: Article 36                                 |
|   | 11. MONITORING                   |                            |  |
|   | 12. INTERNAL AND EXTERNAL AUDITS |                            |  |
|   | TOTAL REFERENCE POINTS           | 7                          | 4  |

## B Cross Reference Summary

The following table is a summary of all cross references Standards and Best Practices in relation to the Control Points:

| Control Points   | 22005 | 9001 | 22000 | BRC | IFS Food | Global GAP | GFSI | 10377 | 10393 | 14001 | ISO 22095 | IFS Logistics | IFS GML | IFS HPC | HL7 Clinical Notes | HL7 UDI | DSCSA | Falsified Medicine Directive & Regulation |
|------------------|-------|------|-------|-----|----------|------------|------|-------|-------|-------|-----------|---------------|---------|---------|--------------------|---------|-------|---|
| 1.1              | X     | X    | X     |     |          | X          | X    | X     | X     | X     | X         | X             |         | X       |                    |         |       |   |
| 1.2              |       | X    | X     |     | X        | X          |      |       |       | X     |           | X             | X       |         |                    |         |       |   |
| 1.3              | X     | X    | X     | X   | X        |            | X    | X     | X     | X     |           |               |         | X       |                    |         |       |   |
| 1.4              | X     | X    | X     | X   | X        |            | X    | X     | X     |       | X         |               |         |         |                    |         |       |   |
| 2.1              | X     | X    |       | X   | X        | X          | X    |       | X     | X     | X         |               |         |         | X                  | X       | X     | X   |
| 2.2              |       | X    |       |     |          | X          |      |       |       | X     | X         |               |         |         | X                  | X       |       | X   |
| 2.3              |       | X    | X     | X   | X        |            | X    |       | X     | X     |           |               |         |         |                    |         |       |   |
| 2.4              |       | X    |       |     |          |            |      | X     |       | X     | X         |               |         |         |                    |         | X     | X   |
| 2.5              |       | X    |       |     |          |            |      |       |       | X     |           |               |         |         |                    |         |       |   |
| 3.1 (US Bio Act) |       | X    | X     | X   | X        | X          |      |       |       | X     |           |               |         |         |                    |         | X     |   |
| 3.2              | X     | X    |       |     |          |            |      | X     |       | X     |           |               |         |         |                    |         |       |   |
| 3.3              |       | X    |       |     | X        |            |      |       |       | X     |           |               |         |         |                    |         |       |   |
| 3.4              |       | X    | X     | X   |          | X          |      |       |       | X     | X         |               |         |         |                    |         |       |   |
| 3.5              |       |      |       |     |          | X          |      |       |       | X     | X         |               |         |         |                    |         |       |   |
| 3.6              |       | X    | X     | X   |          |            |      | X     |       | X     | X         |               |         |         |                    |         | X     |   |
| 3.7              |       | X    |       |     |          |            |      |       |       | X     | X         |               |         |         |                    |         |       |   |
| 4.1              |       | X    |       |     | X        | X          | X    | X     | X     | X     | X         |               |         |         |                    |         | X     |   |
| 4.2              | X     | X    |       |     |          |            | X    | X     | X     | X     | X         |               |         |         |                    |         |       | X   |
| 4.3              |       | X    |       |     |          |            |      |       |       | X     |           |               |         |         |                    |         |       |   |
| 4.4              |       | X    | X     | X   |          |            | X    | X     | X     | X     |           |               |         |         |                    |         |       |   |
| 4.5              |       | X    | X     |     |          |            |      | X     | X     | X     |           |               |         |         |                    |         |       |   |
| 4.5a             |       |      |       |     |          |            |      |       |       |       | X         |               |         |         |                    |         |       |   |
| 4.6              |       | X    |       |     |          |            |      |       | X     | X     |           |               |         |         |                    |         |       |   |
| 4.7              |       |      |       |     |          |            |      |       |       |       |           |               |         |         |                    |         |       |   |
| 4.8              |       | X    |       |     | X        |            | X    |       | X     |       | X         |               |         |         |                    |         | X     |   |
| 4.9              |       | X    | X     |     | X        | X          | X    | X     | X     |       | X         |               |         |         |                    |         | X     |   |



| Control Points | 22005 | 9001 | 22000 | BRC | IFS Food | Global GAP | GFSI | 10377 | 10393 | 14001 | ISO 22095 | IFS Logistics | IFS GML | IFS HPC | HL7 Clinical Notes | HL7 UDI | DSCSA | Falsified Medicine Directive & Regulation |
|----------------|-------|------|-------|-----|----------|------------|------|-------|-------|-------|-----------|---------------|---------|---------|--------------------|---------|-------|---|
| 4.10           |       | X    | X     |     | X        | X          | X    | X     | X     |       | X         |               |         |         |                    |         | X     |   |
| 4.11           |       |      |       |     | X        |            |      |       |       |       |           |               |         |         |                    |         |       |   |
| 5.1            |       |      |       | X   | X        |            | X    |       | X     |       | X         |               |         |         |                    |         | X     |   |
| 5.2            |       |      |       |     |          |            | X    |       |       |       | X         |               |         |         |                    |         |       |   |
| 5.3            |       |      |       | X   | X        |            | X    |       | X     |       | X         |               |         |         |                    |         |       |   |
| 5.4            |       |      |       |     |          |            |      |       |       |       | X         |               |         |         |                    |         |       |   |
| 5.5            | X     | X    |       |     |          |            | X    |       | X     | X     | X         |               |         |         | X                  | X       | X     |   |
| 5.6            |       | X    | X     | X   | X        | X          |      |       | X     | X     | X         |               |         |         | X                  |         | X     |   |
| 5.7            |       | X    |       |     |          |            |      |       |       |       | X         |               |         |         |                    |         |       |   |
| 5.8            | X     |      |       |     |          |            | X    |       |       |       | X         |               |         |         |                    |         |       |   |
| 5.9            | X     |      |       |     |          |            |      |       |       |       | X         |               |         |         |                    |         | X     |   |
| 5.10           |       | X    |       |     | X        |            |      |       | X     |       | X         |               |         |         | X                  | X       | X     | X   |
| 5.11           | X     | X    | X     | X   | X        |            |      |       | X     | X     |           |               |         |         |                    |         |       |   |
| 5.12           |       |      | X     |     |          |            | X    |       | X     | X     |           |               |         |         |                    |         |       |   |
| 6.1            |       | X    |       | X   |          |            | X    |       | X     | X     | X         |               |         |         |                    |         |       |   |
| 6.2            |       | X    |       |     |          |            |      |       | X     | X     | X         |               |         |         |                    |         |       |   |
| 6.3            |       | X    | X     | X   | X        |            | X    |       | X     | X     | X         |               |         |         | X                  |         | X     |   |
| 6.4            |       | X    | X     | X   |          |            | X    |       | X     | X     | X         |               |         |         |                    |         |       |   |
| 6.5            |       | X    |       | X   |          |            |      |       | X     | X     | X         |               |         |         |                    |         |       |   |
| 6.6            |       | X    |       |     |          |            |      |       |       | X     | X         |               |         |         |                    |         |       |   |
| 6.7            |       | X    | X     | X   | X        |            |      | X     | X     | X     | X         |               |         |         | X                  | X       | X     |   |
| 6.8            |       |      |       |     |          |            |      |       |       | X     | X         |               |         |         | X                  | X       |       |   |
| 6.9            | X     |      |       |     | X        |            | X    |       | X     |       | X         |               |         |         | X                  | X       |       |   |
| 6.10           |       |      |       |     |          |            | X    |       |       |       | X         |               |         |         | X                  | X       |       |   |
| 6.11           |       | X    |       |     | X        | X          | X    |       | X     |       | X         |               |         |         |                    |         | X     |   |
| 6.12           |       | X    |       | X   |          |            | X    | X     | X     |       | X         |               |         |         |                    |         |       |   |
| 6.13           |       |      |       |     |          |            |      |       |       |       | X         |               |         |         |                    |         |       |   |
| 7.1            |       |      |       |     | X        | X          | X    | X     | X     | X     |           |               |         |         |                    |         | X     |   |
| 7.2            |       | X    | X     | X   | X        |            | X    |       |       | X     | X         |               |         |         |                    |         |       |   |
| 7.3            | X     | X    |       |     | X        |            | X    |       | X     | X     | X         |               |         |         |                    |         | X     | X   |



| Control Points | 22005 | 9001 | 22000 | BRC | IFS Food | Global GAP | GFSI | 10377 | 10393 | 14001 | ISO 22095 | IFS Logistics | IFS GML | IFS HPC | HL7 Clinical Notes | HL7 UDI | DSCSA | Falsified Medicine Directive & Regulation |
|----------------|-------|------|-------|-----|----------|------------|------|-------|-------|-------|-----------|---------------|---------|---------|--------------------|---------|-------|---|
| 7.4            |       | X    | X     | X   | X        | X          | X    |       | X     | X     | X         |               |         |         |                    |         |       |   |
| 7.5            |       | X    | X     |     | X        |            |      |       |       |       |           |               |         |         |                    |         |       |   |
| 8.1            | X     |      |       | X   | X        |            |      |       |       |       |           |               |         |         |                    |         |       |   |
| 8.2            | X     |      |       |     | X        |            | X    | X     | X     | X     | X         |               |         |         |                    |         |       |   |
| 8.3            | X     |      | X     | X   | X        |            | X    |       | X     | X     | X         |               |         |         |                    |         |       |   |
| 9.1            | X     | X    | X     | X   | X        | X          | X    | X     | X     | X     | X         | X             |         | X       |                    |         |       |   |
| 9.2            |       | X    |       |     |          |            | X    |       |       | X     |           |               |         |         |                    |         |       |   |
| 10.1           | X     | X    | X     | X   |          | X          | X    |       | X     | X     | X         |               |         |         |                    |         | X     |   |
| 10.2           | X     |      | X     | X   | X        | X          | X    | X     | X     | X     |           |               |         |         |                    |         | X     | X   |
| 10.3           | X     | X    |       |     | X        | X          | X    | X     | X     |       |           |               |         |         |                    |         |       |   |
| 10.4           |       |      |       |     | X        | X          | X    | X     | X     | X     |           |               |         |         |                    |         |       |   |
| 10.5           |       | X    | X     |     | X        | X          | X    | X     | X     |       |           |               |         |         |                    |         | X     |   |
| 10.6           |       | X    |       |     |          | X          | X    | X     | X     | X     |           |               |         |         |                    |         | X     |   |
| 11.1           | X     | X    | X     |     | X        |            | X    | X     | X     | X     |           | X             |         | X       |                    |         |       |   |
| 11.2           |       | X    | X     |     | X        |            | X    | X     | X     | X     |           | X             |         | X       |                    |         |       |   |
| 12.1           | X     | X    | X     | X   | X        | X          | X    |       | X     | X     | X         | X             | X       | X       |                    |         |       |   |
| 12.2           |       | X    | X     | X   | X        | X          | X    |       | X     | X     | X         | X             |         |         |                    |         |       |   |
| 12.3           |       | X    | X     | X   | X        | X          | X    |       | X     | X     | X         | X             | X       | X       |                    |         |       |   |