USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM

PROCUREMENT AND SUPPLY MANAGEMENT

GS1 STANDARDS IMPLEMENTATION

Technical Review of the Ability of ARTMIS to Support GS1 Standards

February 9, 2017

USAID FROM THE AMERICAN PEOPLE

PEPFAR U.S. President's Emergency Plan for AIDS Relief

USAID FROM THE AMERICAN PEOPLE CDC

U.S. President's Malaria Initiative

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CONTENTS

ACRONYMS 1

INTRODUCTION 2

EXECUTIVE SUMMARY OF RECOMMENDATIONS 3

USAID Requirements 5

Constrictions 5

Findings 5

Mitigations 6

GLOBAL TRADE ITEM NUMBER 7

Overview 7

High-level Approach to Systems Integration 7

ARTMIS Design 8

Description of Current Approach 8

Recommended Adjustments/Mitigating Strategies 8

Task List 9

GLOBAL LOCATION NUMBER 10

Overview 10

High-level Approach to Systems Integration 11

ARTMIS Design 11

Description of Current Approach 11

Recommended Adjustments/Mitigating Strategies 11

GS1 US DataHub Location: Capturing and Sharing GLN Information 13

Task List 15

ATTRIBUTES 16

Overview 16

High-level Approach to Systems Integration 17

ARTMIS Design 17

Description of Current Approach 17

Recommended Adjustments/Mitigating Strategies 17

Task List 20

BATCH AND LOT INFORMATION 21

Overview 21

High-level Approach to Systems Integration 21

ARTMIS Design 21

Description of Current Approach 21
Recommended Adjustments/Mitigating Strategies 21
Task List 21
PALLET AND CASE INFORMATION 22
Overview 22
High-level Approach to Systems Integration 22
ARTMIS Design 23
Description of Current Approach 23
Recommended Adjustments/Mitigating Strategies 23
Task List 23
GS1 STANDARDS AND LOGISTICS MANAGEMENT 24
Overview 24
Key GS1 Standards Involved 24
Operational/Business Process Implementation View 26
Transition to GS1 Standards 26
LEVERAGING GS1 STANDARDS FOR REPORTING AND ANALYTICS 27
Overview 27
High Level Approach to Systems Integration 27
ARTMIS Design 27
Recommended Adjustments/Mitigating Strategies 27
LEVERAGING GS1 STANDARDS FOR USAID SOURCING BUSINESS PROCESSES 29
Overview 29
Best Practices: Data-Driven Organizations 29
Legacy Business Processes 29
Recommended Adjustments/Mitigating Strategies 29
THE FUTURE OF SERIALIZATION AND TRACK AND TRACE DUE TO REGULATORY CHANGES 30
The Global Regulatory Landscape 30
Implications for ARTMIS and USAID 30
Description of Current Approach 30
Recommended Adjustments/Mitigating Strategies 30
Task List 31
ANNEX 1: GDSN ATTRIBUTES FOR MEDICAL DEVICES 32

ACRONYMS

ARTMIS	Automated Requisition Tracking Management Information System
CBV	Core Business Vocabulary
EDI	electronic data interchange
GDSN	Global Data Synchronization Network
GLN	Global Location Number
GPC	Global Product Code
GTIN	Global Trade Item Number
HDA	Healthcare Distribution Alliance
K+N	Kuehne + Nagel
LMIS	logistics management information system
MDM	Master Data Management
RFID	radio frequency identification
SKU	stock-keeping unit
SOPs	standard operating procedures
SSCC	serial shipping container code
3PL	third-party logistics
UNSPSC	United Nations Standard Products and Services Code
UOM	unit of measure

INTRODUCTION

The GS1 Standards Implementation Project developed strategic recommendations for implementing and supporting GS1 Standards across USAID's global health supply chain. Primary objectives included ensuring that ARTMIS is designed properly to capture product information according to GS1 Standards, developing a strategy for implementing GS1 Standards with the USAID supplier base, and informing country-level logistics management information system (LMIS) tools on the USAID/GHSC-PSM GS1 implementation to help ensure data can continue down the chain to truly create end-to-end visibility.

Five reports were produced for this project:

- Report 1, *Technical Review of the Ability of ARTMIS to Support GS1 Standards*
- Report 2, *Assessment of the USAID Supplier Base and the Ability of ARTMIS to Support GS1-compliant and Noncompliant Suppliers*
- Report 3, *Implementation Strategies for Engaging Suppliers and Capturing GS1 Data in ARTMIS*
- Report 4, *Guidance for USAID's In-country LMIS Projects*
- Report 5, *Summary of Key Findings and Additional Recommendations*

This document is *Report 1, Technical Review of the Ability of ARTMIS to Support GS1 Standards*. The review of ARTMIS supporting this report considered GS1 identifiers, data attributes, data capture mechanisms, data sharing, reporting, serialization, and track and trace. This report:

- Identifies any major design issues in ARTMIS
- Identifies any major process gaps in leveraging ARTMIS design, particularly around Source and Deliver/Return functions
- Develops mitigating strategies
- Provides a roadmap for the future of serialization and track and trace due to regulatory changes
- Provides detailed analysis and enhancements to ARTMIS as a result of anticipated regulatory changes

EXECUTIVE SUMMARY OF RECOMMENDATIONS

USAID has made a strategic decision to 1) adopt and implement GS1 Standards throughout its current business processes and systems and 2) help recipient countries adopt and implement GS1 Standards in their business practices and supporting systems.

RC Partners was engaged to determine if GHSC-PSM's main system, Automated Requisition Tracking Management Information System (ARTMIS) and recipient countries' LMIS, are GS1 "compliant." Since there is no official definition of criteria with which to measure a GS1 Standards compliant system, RC Partners conducted a high-level review of ARTMIS and LMIS design to determine if GS1 Standards were sufficiently implemented to be reasonably able to use the base-level GS1 Standards for:

- Contracting
- Order-to-cash processing
- Logistics
    - Forward logistics (receiving, storage, retrieval, packing, unpacking, shipping)
    - Reverse logistics (returns, recalls, withdrawals)
- Master data management (trade item, party entity, and party locations)
- Track and trace

Many individual standards in the GS1 system may be valuable to use. To support these business practices using GS1 Standards, a system should minimally be able to transact business with suppliers and customers using the following subset of the GS1 Standards:

Business practice	Basic GS1 standards for support	GS1 standard practices	Additional GS1 standards for consideration
Contracting	Global Trade Item Number (GTIN), Global Location Number (GLN),)trade item and party attributes	GTIN hierarchy, GLN hierarchy, Master Data Management (MDM) practices, Labeling Guidelines, Serialization Guideline	GS1 order-to-cash messaging format requirements
Order-to-cash processing	GTIN, GLN, trade item and party attributes	GTIN hierarchy, GLN hierarchy, MDM practices	GS1 electronic data interchange (EDI) or extensible markup language order-to-cash messages
Logistics	GTIN, GLN, serial shipping container code (SSCC) trade item and party attributes, barcode, logistic labeling	Logistic package labeling guidelines — GS1 and Healthcare Distribution Alliance (HDA)	Core Business Vocabulary (CBV) "Biz Step" use
Master data management	GTIN, GLN, trade item and party attributes	Global Data Synchronization Network (GDSN) use guidelines	MDM archival guideline (non-GS1)
Track and trace	GTIN, GLN, GS1 attributes (serial number, expiration date, etc.). Barcode technical standard (128 and data matrix).	Order-to-cash messaging use for limited track and trace. Electronic Product Code (EPC), Electronic Product Code Information Service, CBV, Tag Data Standard, GS1 US Guideline for Rx Traceability (includes serialization, package level identification).	HDA labeling guideline (based on GS1 Standards)

USAID REQUIREMENTS

1. GS1 Standards will be the means of transacting business within and between USAID and all external entities, e.g., suppliers, vendors, warehouses, recipient countries.
2. USAID will work with suppliers to provide standardized labels on logistics units (including barcode and human readable) and standardized product barcodes (DataMatrix).

CONSTRICTIONS

1. The software systems and applications supporting GHSC-PSM operations and analysis are pre-existing, off-the-shelf applications. To enable future upgrades and to minimize cost and work, customized enhancements to the system must remain at a minimum.
2. The system needs to accommodate other identifiers in the transition to GS1 Standards.

FINDINGS

1. **GTIN:** ARTMIS carries a specific field to hold the GTIN. However, we could not find a screen, report, or electronic transaction that displayed the GTIN as the identifier for trade items.
2. **Other identifiers:** GHSC-PSM will (most notably with medical devices) receive trade iems identified with non-GS1 identifiers and/or marked with non-GS1 barcodes. GHSC-PSM should create an attribute in the ARTMIS system to accommodate these other identifiers for tracking purposes and also for supplier scorecarding efforts.
3. **GLN:** ARTMIS does not have a way to hold and transact business with a GLN.
4. **Trade item and party attributes:** ARTMIS includes many product data elements that can be mapped to GDSN attributes. Although those attributes seem to be defined in a way that will be compatible with GS1 attributes, harmonization with a GDSN-certified data pool (once selected) is needed to fully align ARTMIS with supply chain and GDSN principles. Many ARTMIS attributes have been defined to overly accommodate attribute values and lengths (i.e., many are defined as 400-character fields). A strong trade item (and product) master data management strategy is in place that can leverage GDSN trade item attribute synchronization as the basis of the GHSC-PSM product catalog.

   > *Note:* GDSN reflects **current** attribute value synchronization. There are business reasons why **historical** trade item master data are also needed, e.g., recalls, expired product returns, regulatory issues. We did not observe a trade item master data archiving process based on historical retrieval of trade item data requirements. This may be a future planned activity.

5. **SSCC:** In our discussions with the logistics team, we were shown pallet labels that did not seem to be standardized and did not carry SSCCs as their identifiers. ARTMIS does not carry a logistics identifier that could be used for SSCC.
6. **Track and trace:** ARTMIS can track inventories of trade items and can reflect receiving, storage, and shipping of inventories by product or trade Item. However, it does not seem to be able to track or trace trade items at the instance (serialized) level. In its current configuration, ARTMIS does not seem to be able to manage individual, serialized package levels (item, case or tote, pallet).

NOTE: The ARTMIS system, feeder systems in place at Kuehne + Nagel (K+N), and K+N practices in place for USAID are not configured to receive trade items using standardized logistics labels with barcodes (SSCC or GTIN+serial number pairs). Logistics items that, for whatever reason, become separated from their original pallets are not marked or accounted for to enable an unbroken trail that could be traced using GS1 Standards-based guidelines.

MITIGATIONS

We recommend the following steps:

1. Prominantly display GTINs on all screens and reports and electronically shared transactions so that GHSC-PSM, K+N, manufacturers and suppliers, and recipient countries refer to them (when available) in their daily activities.
2. Ensure that in the Product Master database, supporting systems, and transaction messages, GTIN fields are a fixed-length, 14-digit **text** field (not numeric), right-justified with leading zeros. This ensures that any leading zeros are not inadvertently stripped off, a step essential for data quality.
3. Identify USAID/GHSC-PSM internal and external parties and locations using GLNs. USAID/GHSC-PSM's hierarchy of locations needs to be established.
4. Prominantly display GLNs on all screens, reports, and electronically shared transactions so that USAID, GHSC-PSM, K+N, manufacturers and suppliers, and recipient countries refer to them (when available) in their daily activities.
5. Conduct further work to map GDSN-defined attributes to ARTMIS attributes. Some GDSN attributes are named through collaboration between many industries. The name itself may not be enough to recognize it as a needed attribute. RC Partners or GS1 can help with this mapping.
6. Launch a project to create a USAID Logistics Label Guideline. The guideline should be based on GS1 Standards and borrow from the existing GS1 Logistics Label Guideline. This effort will tie the physical logistics units with the information captured and produced on those units and will form an important cornerstone for future track and trace efforts.
7. Complete work to accomplish track and trace at the level that USAID desires and is possible, given the business practices within recipient countries.
8. Have RC Partners outline and demonstrate the possibilities for track and trace throughout the USAID system (including recipient countries). This model should then be parsed into phases where GHSC-PSM, suppliers, logistics vendors, and recipient countries could gain incremental value from building on the system's capabilities. This could also result in request for information and request for proposal support for external track and trace systems.
9. Have GHSC-PSM establish clear scorecards for manufacturers, suppliers, third-party logistic (3PL) providers, and recipient countries based on USAID/GHSC-PSM requirements and recommendations. These scorecards can be used as a basis for communications on USAID expectations, contracting, and future exceptions for handling noncompliant products or business practices.

GLOBAL TRADE ITEM NUMBER

OVERVIEW

The GTIN is the globally unique GS1 identification number used to identify trade items, i.e., products that may be priced, ordered, or invoiced. GTINs are used to uniquely identify a product at each packaging level, e.g., a bottle of 100 aspirin tablets, a case of 200 bottles of aspirin tablets.

GTINs are assigned by the product's manufacturer, or "brand owner." In assigning, or allocating, a GTIN, the manufacturer defines a prescribed set of data about the product to which that GTIN relates. These product description attributes define core data that is consistent across all instances of the product, e.g., size, color, brand information. (Attributes are discussed further below.) Once the GTIN is allocated and the attributes are defined, the GTIN and its associated attributes are then saved in a database (like a GDSN-certified data pool) and shared among supply chain partners.

Supply chain partners use GTINs to identify products and provide a link to information about a product.

- **Identify products:** Manufacturers mark their products with barcodes that encode the product's GTIN, and trading partners scan the barcodes to identify physical products. Trading partners also use GTINs to identify and reference products in their supply chain systems, transactions, and communications.

- **Link to information about products:** Trading partners and their systems use GTINs as a link to information about a product in their systems, e.g., core data (attributes) for that GTIN in the Product Master database, inventory levels, transactions.

HIGH-LEVEL APPROACH TO SYSTEMS INTEGRATION

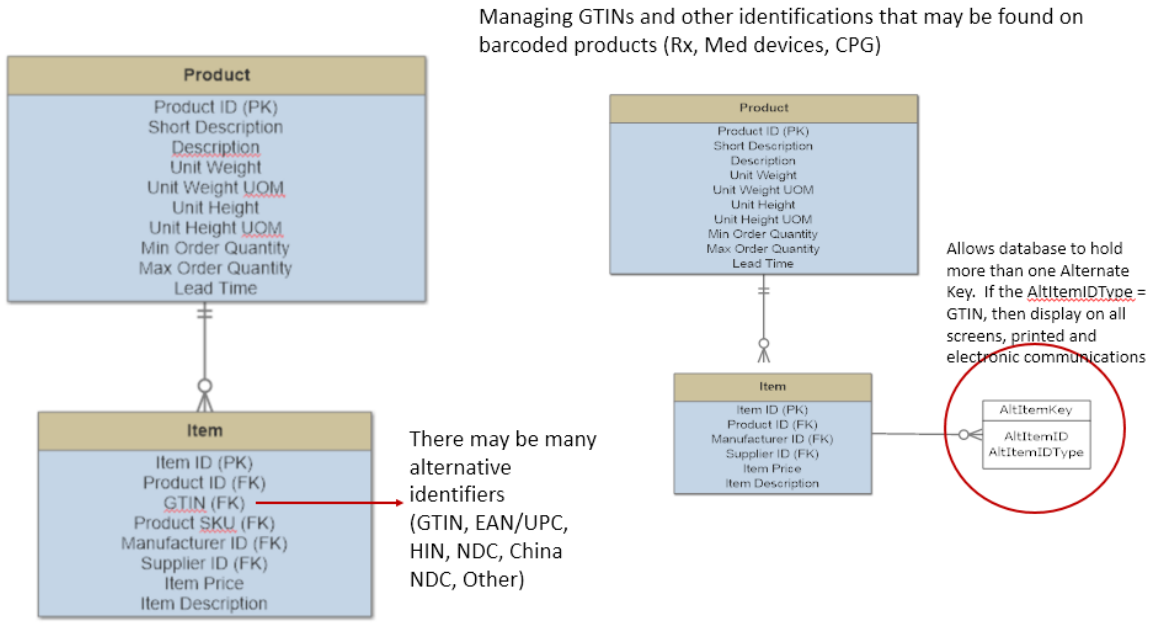
The key is for GTINs to be stored in the Product Master database, used in business processes, and used by supporting systems. In the Product Master database, supporting systems, and transaction messages, GTIN fields should be a fixed-length, 14-digit **text** field (not numeric,) right-justified with leading zeros. This ensures that any leading zeros are not inadvertently stripped off, a step essential for data quality.

ARTMIS DESIGN

Description of Current Approach

The ARTMIS Product Master includes a hard-coded GTIN field to be populated with the GTIN value. Also, the Product Master includes a stock-keeping unit (SKU) field, and an item key field, which serves as the primary key for the item table. All three item identifiers are pushed out to various systems.

In the transition to GS1 Standards, the Product Master will include products that have GTINs and products that do not. Even after the transition, some products will still not have GTINs and will require an "exceptions handling" approach in the database design. Therefore, suppliers are expected to use various other types of product identifiers that need to be accommodated in the Product Master.



Recommended Adjustments/Mitigating Strategies

Product Master

The recommended approach is to create an Alternate Item Key table. This table should contain a name/value pair, in which one field is for identifier type, e.g., GTIN, HIN, and the other field is for the identifier value (i.e., the actual number). There should be a 0-to-many relationship between the Item table and the Alternate Item Key table to accept multiple values, and it should include type option Other to accommodate any unexpected value. This table should be used for the GTIN, the SKU, and any other product identifiers. The benefit of this approach is that it standardizes queries and accommodates any unexpected/unknown product identification types/values. Based on this approach, the current GTIN field and SKU field can be omitted, since both GTIN and SKU will then be accommodated in the Alternate Item Key table.

Note: The GTIN metadata standards require that GTINs be stored in a fixed-length, 14-digit **text** field (not numeric), right-justified with leading zeros. This should be applied for GTINs in the Alternate Item Key table.

The item key field in the database can be maintained as the primary key, intended to ensure one unique identifier for each product in the database. Once GTINs are assigned to products, the GTIN will be displayed on all screens, reports, and printed and electronic transactions. However, it is important to maintain the item key in the database to ensure performance, continuity, and historical connection to records about a product before its GTIN was assigned.

Application Systems

Once a trade item has a GTIN assigned, the GTIN should be used to identify the trade item in all systems and electronic communications about the trade item. All supplier- and customer-facing communications should have in them only the GTIN. At that time, the item key shoud be used only internally for possible performance reasons, and the SKU might be kept for exception-handling reasons. All related Job Aids will need to be updated to reflect that, if available, GTINs will be displayed or printed in place of, or in addition to, other product identifiers.

Note: Although many warehouse systems use SKUs, the encoded identifier on the product packaging will be a GTIN. Therefore, if the warehouse system uses an identifier other than GTIN, i.e., the SKU, there will need to be a cross-walk or map between the scanned GTIN and the warehouse system SKU. Generally, one identifier is better than two (especially when one is a global standard), and USAID's movement toward GS1 Standards provides the opportunity to align product/case/pallet identification across all systems for best results. Newer warehouse systems are being built off GTINs, and although K+N may still be using SKUs, it is recommended that this approach be implemented, as cross-walk tables require maintenance and are an opportunity for data quality issues to arise.

TASK LIST

- Adjust Product Master as described above.
- Define a conversion process to modify queries throughout application systems as described above to reflect the new design and ensure the ability to flow the data through those processes so that the GTIN is reflected in output and on screens, e.g., order-to-pay process, reporting and analytics, warehouse.
    - *Note:* Supplier scorecards will likely provide insight on how to prioritize this process. Scorecards will be discussed in Scope of Work 3.
- All related Job Aids will need to be updated to reflect that, if available, GTINs will be displayed or printed in place of the item key, SKU product key, or other identifiers.

GLOBAL LOCATION NUMBER

OVERVIEW

The Global Location Number is the globally unique GS1 identification number for locations and parties. The GLN can be used to identify a functional entity (like an accounting department or hospital pharmacy), a physical entity (like a warehouse or delivery point or even a particular room in a building), or a legal entity (like a supplier parent corporation or subsidiary).

Types of parties and locations GLNs are used to identify[1]

Each trading partner is responsible for allocating GLNs to its own locations/entities. When a user assigns a GLN, the user defines a prescribed set of core data about the location/entity to which that GLN relates, e.g., name, address, location type, e.g., ship to, bill to, deliver to. Once the GLN is allocated and the attributes are defined, the GLN and its associated attributes are then saved in a database (like GS1 US DataHub Location) and shared among supply chain partners.

Supply chain partners use GLNs to reference their own locations/entities and their trading partners' locations/entities in supply chain transactions and communications. Trading partners and ther systems also use GLNs as a link to information about a location/entity, e.g., core data for that GLN in the party/location master, purchasing history for that trading partner, deliveries received at a warehouse. (Note: GLNs can also be encoded in barcodes, or radio frequency identification (RFID) tags, and posted at various locations and functional entities throughout a facility for accurate, electronic identification.)

HIGH-LEVEL APPROACH TO SYSTEMS INTEGRATION

The key is for GLNs to be stored in the party/location master database(s) with their corresponding data set, and used by supporting systems. In the party/location master database, supporting systems and transaction messages, GLN fields should be 13 digits and formatted as a **text** field (not numeric) so that any leading zeros are not inadvertently stripped off.

ARTMIS DESIGN

Description of Current Approach

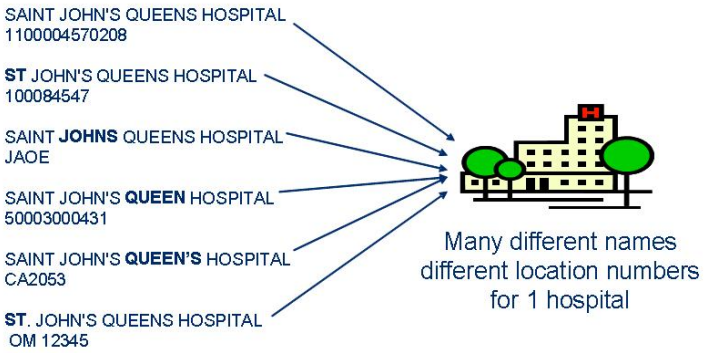
ARTMIS includes separate tables to maintain party and location information about different entity types, e.g., suppliers, carriers. Those tables include various key fields, e.g., order header key, enterprise key, organization key, contact key, customer key, supplier key. These fields are formatted as numeric. The tables also include other types of party identifiers, e.g., DUNS, federal tax ID, as well as fields for the associated party and location data, e.g., address, phone.

The ARTMIS Product Master also includes the following fields for manufacturer and supplier information, which are entered manually into the table:

- Manufacturer name
- Manufacturer location
- Supplier name
- Supplier location

Without standards for party and location information in systems and transactions, the risk is high of duplicate entries and data quality issues. For example, a company may be entered as "Company X," "Company X, Inc.," "Company X Inc." Also, issues may arise in the accuracy and correct level of address information being entered.

Examples of party and location inconsistencies that GLN helps to avoid[1]



Recommended Adjustments/Mitigating Strategies

The recommended approach is to use GLNs for identifying USAID/GHSC-PSM parties and locations, as well as trading partner parties and locations, and to store GLNs and the

[1] GS1 US Healthcare Supplier GLN Tool Kit. GS1 US. 2015.

standardized GLN data set in the ARTMIS Party tables, e.g., suppliers, carriers, and use them across application systems.

Existing Party/Location Tables for USAID Trading Partners

As with the Alternate Item Key table, the recommended approach is to create an Alternate Party Key table to be associated with each ARTMIS party/location table. This table should contain a name/value pair, in which one field is for identifier type, e.g., GLN, DUNS, fed tax ID, and the other field is for the identifier value, i.e., the actual number. There should be a 0-to-many relationship between this ARTMIS Party/Location tables and the new Alternate Party Key table to accept multiple values, and it should include type option *Other* to accommodate any unexpected value.

Then, the Alternate Party Key table should be used for GLN, DUNS, federal tax ID, and any other party/location identifiers, and the party/location identifier fields in the current table design, e.g., GLN, DUNS, federal tax ID, can be omitted. The benefit of this approach is that it standardizes queries and accommodates any unexpected/unknown party/location identification types/values. (*Note:* The GLN metadata standards require that GLN fields must be 13 digits long and formatted as a **text** field (not numeric). This should be applied for GLNs in the Alternate Item Key values.

Also, the fields in party master databases should include the core data set associated with GLNs, e.g., name, address, location type (e.g., ship to, bill to, deliver to). This data set and accompanying standards can be obtained from GS1 US DataHub. GLN attributes can be added or mapped to the existing structure as needed, noting that GLN metadata rules must be followed in the resulting fields regardless of approach. Finally, a series of crosswalks or maps will need to be developed to feed trading partner GLN attributes from either GS1 US DataHub Location or GLN import spreadsheets into the existing table structure.

New Party/Location Table for GHSC-PSM

It was unclear if the current design has a table for USAID/GHSC-PSM parties and locations. If not, the recommended approach is to create such a table to be populated with GLNs and associated GLN data for USAID/GHSC-PSM parties and locations. If a table for USAID/GHSC-PSM parties and locations currently exists, the recommended approach is to create a GLN field (13 digits long and formatted as a **text** field (not numeric) per the standards) and create crosswalk maps to feed GLN attributes from GS1 US DataHub Location.

The fields in the GHSC-PSM party/location master should include the core data set associated with GLNs, e.g., name, address, location type (e.g., ship to, bill to, deliver to). GLN attributes can be added or mapped to the existing structure as needed, noting that metadata rules must be followed in the resulting fields regardless of approach.

Note: A GLN strategy for USAID/GHSC-PSM locations and parties will need to be defined and implemented to assign GLNs to all pertinent USAID/GHSC-PSM parties and locations.

Product Master

The manufacturer fields in the Product Master should be changed to implement GLNs. The recommendation is to make the following adjustments in the manufacturer fields in the Product Master:

- Manufacturer Name field: change field name to Manufacturer GLN, which is a GDSN attribute. (Manufacturer name associated with that GLN should be stored in the standardized field in the Manufacturer table.)
- Manufacturer Location field: delete this field. (Location information should be stored in the corresponding standardized field in the manufacturer table for each GLN.)

  Note: We were unable to determine definitively if there is a Manufacturer table (i.e., appears in the text in one place but is missing from the diagram in another). If ARTMIS does not have a Manufacturer table, then something equivalent will need to be created to accommodate the data flow described above.)

For the supplier fields in the Product Master, some of the system documentation specified a "one to many" relationship between supplier and item (i.e., one supplier for many items). A supplier can be a wholesaler. Not only can many wholesalers sell the same product, but the possibility of manufacturer direct-drop shipping products that are normally purchased through a wholesaler creates a situation where many parties sell many products and many products are sold by many suppliers. We expected to see, at a high level, a "many to many" relationship resolved by an intersecting entity (i.e., many suppliers for each item, and many items for each supplier). We assume this is a documentation error in our recommendation to make the following adjustments in the supplier fields in the Product Master:

Generally, supplier information should be stored in and retrieved from the Supplier table, not repeated in the Product Master as it is today. Therefore, the recommendation is to make the following adjustments to the Product Master:

- Supplier Name field: delete (unless there is a specific need, in which case it should be changed to GLN for the appropriate location type)
- Supplier Location field: delete

Application Systems

Once a party/location has a GLN assigned, the GLN should be used to identify the party/location in all systems and electronic communications. At that time, all supplier- and customer-facing communications should only have the GLN in them. Other party/location identifiers should only be passed through and visible to applications and systems if specifically needed. Also, all related Job Aids will need to be updated to reflect that. if available, GLNs will be displayed or printed in place of or in addition to other party/location identifiers.

GS1 US DATAHUB LOCATION: CAPTURING AND SHARING GLN INFORMATION

GS1 US provides a tool called DataHub Location that enables users to:

- Create, store, and manage their own GLNs and associated location information
- Search, view, and download other companies' GLNs and location information

- Connect to the GS1 US DataHub using an API

Any company can use GS1 US DataHub Location for a fee. USAID/GHSC-PSM can use DataHub Location to support USAID/GHSC-PSM with GLN implementation with both U.S. and non-U.S. trading partners.

Specifically, USAID/GHSC-PSM and its GS1-compliant trading partners can use DataHub Location as follows:

PARTY	WHOSE GLNs	CAN USE DATAHUB LOCATION TO:
USAID/GHSC-PSM	Its own GLNs	• Create, store, manage, and download USAID/GHSC-PSM GLNs and associated location information. • Share USAID/GHSC-PSM GLNs and location information with trading partners in one of two ways: ○ **Trading partners who subscribe to DataHub:** access USAID/PSM GLNs and information from directly from DataHub ○ **Trading partners who do not subscribe to DataHub:** USAID can download a spreadsheet of USAID/GHSC-PSM's own GLNs and associated location information and share it directly with trading partners
USAID/PSM	Trading partner GLNs	• **Trading partners who subscribe to DataHub:** USAID/GHSC-PSM can search, view, and download itsGLNs and associated location information directly from DataHub • **Trading partners who do not subscribe to DataHub:** USAID/GHSC-PSM can use the DataHub Location download spreadsheet as the template for its own spreadsheet to receive its GLNs and associated location information
Partners	Their own GLNs	• **Trading partners who subscribe to DataHub:** ○ *If you are a GS1 U.S. member*: automatically generate/create GLNs from within DataHub ○ *If you are not a GS1 U.S. member*: enter externally assigned GLNs and associated location information into DataHub manually • **Trading partners who do not subscribe to DataHub:** USAID/GHSC-PSM can use the DataHub Location download spreadsheet as the template for its own spreadsheet for trading partners to submit their GLNs and associated location information
Partners	USAID/PSM GLNs	• **Trading partners who subscribe to DataHub:** search, view, and download USAID/GHSC-PSM GLNs and associated location information directly from DataHub • **Trading partners who do not subscribe to DataHub:** USAID/GHSC-PSM can download a spreadsheet of USAID/GHSC-PSM's own GLNs and associated location information and share it directly with trading partners

Also, for non-GS1-compliant trading partners, USAID/GHSC-PSM trading partners can still leverage the DataHub Location spreadsheet to facilitate communication and receipt of location information.

TASK LIST

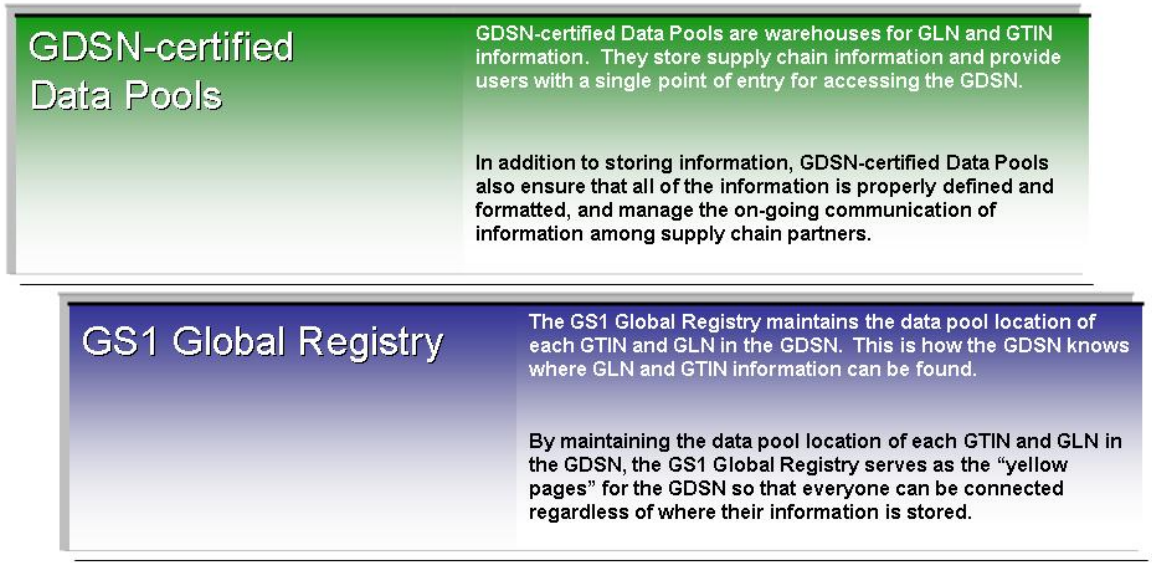
- Adjust each ARTMIS Party/Location table for GLN as described above.
- Adjust the ARTMIS Product Master manufacturer and supplier fields as described above.
- Develop and implement a GLN strategy for USAID/GHSC-PSM locations and parties.
- Create or adjust a Party/Location table for USAID/GHSC-PSM GLNs as described above.
- Define a conversion process to modify queries throughout application systems to reflect this design and ensure the ability to flow the data through those processes so GLNs are reflected in output and on screens, e.g., order-to-pay process, reporting and analytics, warehouse.
- Update all related Job Aids to reflect that if available, GLN will be displayed or printed in place of, or in addition to, the Enterprise Key or Organization Keys. All search screens need to be able to search by GLN value in place of internally created account number values for buyers and suppliers.

ATTRIBUTES

OVERVIEW

As described above, when manufacturer assign ("allocate") a GTIN, they define a prescribed set of data about the trade items to which that GTIN relates. These trade item description *attributes* define core data that is consistent across all instances of the trade item, e.g., size, color, brand information. The GS1 System includes data standards for trade item attributes. These standards include attribute name, definition, metadata, etc.

GS1 standardized attributes can be shared among trading partners through the GS1 GDSN. The basic structure of the GDSN is a network of GDSN-certified data pools connected by the GS1 Global Registry.



Basic Structure of the GDSN[2]

There are two types of participants in the GDSN: data sources and data recipients:

- Data sources are manufacturers and brand owners who define the trade item attributes associated with their GTINs, and "publish" them to their trading partners through the GDSN.
- Data recipients are trading partners who "subscribe" to receive data from GDSN data sources, e.g., retailers, wholesalers, distributors. In the GDSN, USAID/GHSC-PSM would be a data recipient.

[2] GS1 US Healthcare Supplier GDSN Tool Kit. GS1 US. 2015.

As of November 7, 2016, the GDSN currently has **2,836 attributes**. This does **not** mean that manufacturers define and recipients receive 2,836 attributes for every GTIN. Rather, this is the complete universe of standardized attributes available. Some attributes only apply to certain types of trade items/industries. For example, Annex I provides the current list of attributes for medical devices (as obtained from GS1 US Attribute Explorer, an online tool for GDSN attribute standards and trading partner requirements).

The set of GDSN attributes that trading partners exchange varies, depending on industry, product type, trading partner business process needs, etc. Outside of the GDSN, the data recipients communicate the attributes they want from their suppliers (often through a "GDSN Implementation Requirements Guide" posted on either their website or their data pool, or in the U.S. on GS1 US Attribute Explorer). Within the GDSN, data sources "publish" **one** set of attributes for each GTIN that encompasses **all** of their trading partner requirements. Then, data recipients (or their data pool) can extract only the attributes they want.

HIGH-LEVEL APPROACH TO SYSTEMS INTEGRATION

The key is to identify the data needed to support USAID business processes, and then to use GDSN attributes for that data wherever possible. This will maximize the benefits to be ultimately achieved from GS1 Standards and the GDSN, and will also provide standards-based definitions and metadata for the vehicle(s) used to receive data from non-GDSN users, e.g., spreadsheet, portal.

ARTMIS DESIGN

Description of Current Approach

The definition of data attributes required for USAID business processes continues to be developed by the GHSC-PSM team and the Data Integrity Team. The current list is approximately 63 attributes based on business processes. To find a vehicle to support the use of generic commodities (not specific Items and brand names) in the aid recipient store front, attributes are currently being classified as either "Product" attributes, i.e., product type or classification level, or "Item" attributes, i.e., GTIN level).

Recommended Adjustments/Mitigating Strategies

The recommended approach is to identify the data elements needed to support GHSC-PSM business processes, and to use GDSN data attributes for those data elements wherever possible to minimize the list of non-GDSN attributes in the Product Master.

With regard to the commodities for the recipient store front, our current thinking is to not classify the attributes (i.e., product versus item), but rather to classify the Items in the Product Master by adding a field to specify each item's store front product category/name.

Attribute Requirements

The recommended approach is to further examine current list of attributes based on GHSC-PSM business processes based on the type of commodities purchased by USAID/GHSC-PSM, e.g., medical devices, pharmaceuticals. To support this effort, identify all commodity types purchased by GHSC-PSM and then obtain the list of all GDSN attributes for those commodity types from GS1 US Attribute Explorer. This provides the universe of GDSN attributes available for USAID/GHSC-PSM commodity types. (*Note:* This was demonstrated to the Data Integrity

team during a conference call November 7, 2016. The list of GDSN attributes for medical devices was previously gathered for that call, and is provided in Appendix A). Our review of commodity types indicates that the trade items purchased by USAID/GHSC-PSM generally fall into three GDSN product categories: pharmaceuticals, medical devices, "other" (information technology, office equipment, etc.). For additional insight, the "other" commodity type could be broken down further on review of the product categories on the GS1 US Attribute Explorer page.

Comparing the current list of attributes based on USAID business processes against the list of GDSN attributes for commodity types purchased by USAID may offer additional insights as to varying data requirements, and/or additional GDSN attributes that would be helpful for USAID/GHSC-PSM operations.

"Commodity Category/Name" for the Recipient StoreFront

GHSC-PSM review of existing product classification codes revealed that none of those classification systems could adequately support the needs of the aid recipient store front (i.e., generic commodities without specific Item and brand names). Moreover, the need for these types of classifications or categories is not limited to USAID, but extends to other global aid agencies to support their own work as well as coordination and collaboration among aid agencies.

To respond to this challenge, GHSC-PSM has defined a naming convention for USAID commodity categories/names to be used in the store front, and the list of commodity categories/names is being developed. The recommended approach is to continue to build out that commodity category/name set, and then go to a global standards organization like GS1 to bring together global aid agencies to work together to make that commodity category/name set a standard for "Healthcare Commodity Classification Code." This enables USAID to provide leadership to help the community respond to this need to improve coordination, collaboration and reporting.

Note: Since the initial submission of this report, GHSC-PSM has decided to leverage United Nations Standard Products and Services Code (UNSPSC) for pharmaceutical products and GS1 Global Product Code (GPC) for medical devices and all other commodities. It is recommended that USAID share this approach with their donor organization partners and recipient countries to help promote alignment across the global health supply chain.

Classifying Attributes as Product or Item

As noted above, GHSC-PSM attributes are currently being classified as either "Product" attributes (i.e., product type or classification level) or "Item" attributes (i.e., GTIN level) to support Product and Item tables. However, due to different relationships between the GDSN attributes, it is unclear at this time if there would be enough Product-level attributes to justify the effort. It would be helpful for us to go through a data normalization exercise with GHSC-PSM to gain the insight we would need to definitively recommend whether to continue on as designed (Product and Item tables).

Our current thinking is to *not classify the attributes* as product versus Item, but rather to *classify the Items* in the Product Master by adding a field to specify each item's store front commodity category/name.

Product Master

The Product Master continues to be developed to define the list of attributes and associate those attributes with GDSN attributes. There are two recommendations in this area:

1. To support the aid recipient store front, add a field to the Product Master for *Commodity Type*. This field should be populated with UNSPSC or GPC codes per GHSC-PSM requirements, e.g., UNSPSC for pharmaceuticals, GPC for medical devices. This will provide the connection to the commodities offered on the aid recipient storefront for sourcing activities.
2. Once all of the attributes needed to support USAID business processes are defined, use GDSN data attributes for as many of those data elements as possible. Once identified, GDSN attributes can be added or mapped to the existing structure as desired, noting that GDSN metadata rules must be followed in the resulting fields regardless of approach.

Identifying which GDSN attribute(s) correspond to USAID data elements will require research. Naming conventions and database structure vary between companies and organizations, and there is often no one-to-one relationship of attribute name between systems. This reality also applies to the GDSN. Often, identifying the GDSN attribute that can be used to provide the needed information is not a simple look-up of the same attribute name. For example, the naming convention defined for the GHSC-PSM aid recipient store front commodity type is based on:

- Generic/standard name
- Strength/specifications
- Form/type
- Pack size

For pharmaceuticals, the first two elements, *Generic/Standard Name* and *Strength/Specifications*, are actually found in the GDSN **nonFoodIngredient Module**, which consists of a group of attributes that are repeated for multiple nonfood ingredients. For example, a product like "acetaminophen with codeine" would look like this:

nonFoodIngredient Module:

Attribute	Ingredient 1	Ingredient 2
NonFoodIngredientName	acetaminophen	codeine
Generic	Y	N
Strength — value and unit of measure (UOM)	250 mg	50 mg

As this example illustrates, identification of GDSN attribute(s) that correspond to USAID data elements is not always intuitively obvious, and will likely require support and assistance from your data pool.

TASK LIST

- Examine the current list of USAID attributes further based on USAID business processes **and** the type of products purchased by USAID, e.g., medical devices, pharmaceuticals.
- Communicate and share information about GHSC-PSM's decision to use UNSPSC for pharmaceutical products and GS1 GPC for medical devices and all other commodities with other donor organizations and recipient countries to help promote alignment across the global health supply chain.
- Add a field to the Product Master for *Commodity Type* to accommodate the UNSPSC or GPC diesgnoation for the aid recipient store front.
- Perform a data normalization exercise to gain the insight about whether to continue on as designed with Product and Item tables (i.e., classifying attributes as product or item), or to combine them and simply use the store front commodity categories/names in the Item master.
- Use GDSN data attributes for as many of USAID data elements as possible.
- Develop crosswalks or maps between GDSN attributes and Product Master attributes as needed.

BATCH AND LOT INFORMATION

OVERVIEW

Batch/lot numbers are assigned by manufacturers. The batch or lot number associates an item with information the manufacturer considers relevant for traceability of the trade item. A batch/lot number may be a production lot number, a shift number, a machine number, a time, or an internal production code. (*Note:* The terms *batch* and *lot* as defined here are interchangeable.) The content and format of batch/lot numbers typically vary from one company to another, depending on company practice and the precision desired. For example, a batch/lot can represent all product produced in a day at one facility, or the product produced in one hour from an individual packing line, or it could represent a unique recipe run.

Pursuant to GS1 Standards, a batch/lot number is an alphanumeric string whose length is variable between one and 20 characters. Batch/lot numbers can be encoded in GS1 barcodes using Application Identifier (AI) 10. (*Note:* GDSN also includes an attribute to indicate if a batch/lot number is included on the product label (Y/N).)

HIGH-LEVEL APPROACH TO SYSTEMS INTEGRATION

Manufacturers mark batch/lot numbers on products (in plain text, in barcodes or both) and/or use them in transactions. Databases, applications and messages that need to contain a batch/lot number should be designed to accommodate any batch/lot number consisting of 1–20 alphanumeric characters. "Zero" characters in batch/lot numbers are treated as any other alphanumeric character such that batch/lot numbers 7, 07, and 007 are all different batch/lot numbers according to the standard. Consequently, databases and applications should treat the batch/lot number as a **text field** so that leading zeros are not inadvertently stripped off.

ARTMIS DESIGN

Description of Current Approach

Batch/lot is stored in tables related to receiving processes, including the Shipments table (batch/lot field) and the Goods Received Note Line Item table (Manufacturer_product_lot).

Recommended Adjustments/Mitigating Strategies

USAID will capture batch/lot numbers through barcodes on products and/or transactions. The recommended approach is to verify that all transactions, tables, and applications in which batch/lot appears conform to the corresponding GS1 metadata standards. Specifically, batch/lot fields must be capable of holding 1–20 alphanumeric characters, and formatted as a **text** field (not numeric) so that any leading zeros are not inadvertently stripped off.

TASK LIST

- Examine batch/lot fields throughout all transactions, tables, and applications to ensure they conform to GS1 batch/lot metadata standards as described above.

PALLET AND CASE INFORMATION

OVERVIEW

In the GS1 System, logistics units are identified with the serial shipping container code. However, because cases can also be an orderable unit, cases can be identified in the GS1 System using GTIN **or** using SSCC, depending on how the case is being used:

- **Use GTIN** if the case is orderable and if your customer is expecting to identify the contents from the case barcode or EPC/RFID tag
- **Use SSCC** if the case is to be treated as a logistics unit

Pallets are always identified using the SSCC.

Homogeneous case	GTIN or SSCC
Mixed/partial case	SSCC
Pallet	SSCC

The GTIN was introduced in the first chapter. The SSCC is the globally unique GS1 Identification Number used to identify individual logistics units, such as cases, cartons, pallets, or air cargo containers of trade items as they travel through shipping and receiving. A logistic unit can be any combination of units configured for transport or storage such as case, pallet or truck where the configured unit needs to be managed in the supply chain. The SSCC is assigned for the lifetime of the transport item and is a mandatory element on the GS1 Logistic Label. SSCCs serve as "license plates" from the carton level to the trailer load level to facilitate simple tracking of goods and reliable look up of complex load detail.

The SSCC enables a logistics unit to be tracked individually, which brings benefits for order and delivery tracking and automated goods receiving. Because the SSCC provides a unique number for the delivery, it can be used as a lookup number to provide not only detailed information regarding the contents of the load, but also as part of an Advance Ship Notice (ASN) process.

HIGH-LEVEL APPROACH TO SYSTEMS INTEGRATION

Brand owners marks GTINs or SSCCs on cases and pallets with barcodes, and use them in transactions and supply chain communications, e.g., purchase order, advance ship notice. When encoded in GS1 barcodes, SSCCs are represented using AI (00).

Databases, applications and messages should be designed to accommodate the following:

- **GTIN:** GTIN fields should be fixed, 14-digit text fields (not numeric) right justified with leading zeros.
- **SSCC:** SSCC fields should be 18 digits long and represented as a text field (not numeric), so that leading zeros are not inadvertently dropped.

ARTMIS DESIGN

Description of Current Approach

Pallet and case information should be captured from barcodes and transactions as part of logistics processes. Due to transitions in USAID logistics management, SOPs, and additional details around logistics processes and systems were not yet available.

Recommended Adjustments/Mitigating Strategies

The recommended approach is to verify that all transactions, tables, and applications in which pallet and case information appear conform to the corresponding GS1 metadata standards described above.

TASK LIST

- Examine GTIN and SSCC fields throughout all transactions, tables, and applications to ensure that they conform to GS1 metadata standards as described above.

GS1 STANDARDS AND LOGISTICS MANAGEMENT

OVERVIEW

The movement of USAID health commodities across the global supply chain is a complex endeavor involving numerous parties, such as logistic services providers, transport service providers, carriers, freight forwarders, warehouse service providers, customs brokers, etc. If these parties use different business processes and different formats for data interchange, e.g., nonstandard identifiers and EDI transactions, daily freight forwarding and logistics operations can become overly complex and burdened by lack of visibility and unnecessary costs.

The application of GS1 Standards to transportation and logistics management at different stages of the supply chain can offer real benefits to complex transportation and logistics matters like freight forwarding, customs clearance, warehouse, split shipments, repackaging, etc. GS1 Standards for transportation and logistics are in place across many important transportation and logistics functions today. Many ocean, air, and land carriers already use GS1 Standards, as do many 3PL providers. Moreover, many in-country traceability or authentication regulations across the globe allow the use of GS1 Standards to help streamline the movement and acceptance of products.

KEY GS1 STANDARDS INVOLVED

Much of the previous discussion addressed GHSC-PSM implementation of GS1 Standards to support *order-to-cash* business processes. At a high level, that effort involves implementing GS1 party and location identifiers (GLNs) and product identifiers (GTINs), and using them in systems, applications and transactions, e.g., purchase order, invoice. Implementation of GS1 Standards for *transportation and logistics* is the same high level process: implementing the applicable GS1 identifiers and using them in systems, applications, business processes, and transactions. The context and locations change, but the fundamental process is the same.

GS1 identifiers commonly used across transportation and logistics processes are presented in the table below. GHSC-PSM will likely begin with GTINs, SSCCs, and GLNs, and then continue its evaluation of whether any of the additional GS1 identification standards (shown in the table below) would provide value.

	GS1 Standard(s)	Application
Party and location identifiers	GLN	Inventory location; ship-from location; ship-to location; pick-up location; drop-off location, etc.
Asset identifiers	GRAI and/or GIAI	Assets used in transport and logistics, e.g., trucks, ships, airplanes, trailers, containers, crates
Logistics unit identifiers	SSCC	Goods packaged together for transport and storage, e.g., cases, pallets, totes
Shipment identifiers	GSIN	National and international shipments

OPERATIONAL/BUSINESS PROCESS IMPLEMENTATION VIEW

In our discussions with GHSC-PSM, USAID and K+N team members, it was noted that the expectations were that product was expected to be shipped by suppliers to GHSC-PSM main warehouses managed by K+N at the pallet level, and stored and shipped also at the pallet level. In a few instances, pallets will be broken down to sases, stored as intact cases, and then either re-palletized and shipped out or possibly shipped out as cases. No provision is required to pick at the item level.

Due to transitions in USAID logistics management, standard operating procedures (SOPs) and additional details around logistics processes and systems were not yet available. The recommended approach is fully evaluate the opportunity to use GS1 Standards in transportation and logistics processes to:

- Facilitate the movement of goods across different regions of the world
- Enhance operational efficiency and eliminate unnecessary cost
- Promote visibility and transparency as goods flow through the supply chain

To support that effort, two resources (submitted with this report) are recommended as background material:

- GS1 US Standards in Action – Healthcare: the first half of this document describes the GS1 Standards, while the second half of the document (starting on page 23) presents each supply chain role with explanation of their use of the standards in business processes. The material in this second half provides a helpful top-level view of the use of GS1 Standards within each supply chain role and across the entire supply chain to connect information. (*Note:* A video presenting this material is on the GS1 U.S. website as well.)
- GS1 Logistics Label Guideline: providing a good overview of the information on and processing of GS1 Standards-based logistics labels throughout the supply chain, with explanation of actions taken by each supply chain role.

TRANSITION TO GS1 STANDARDS

USAID has made the strategic decision to use GS1 Standards to do business with its suppliers and served countries. For logistics package levels, this means that there will be a transition from unmarked or nonstandard marked packaging at the pallet and case levels, to GS1 identifiers, barcodes and labels at the pallet and case levels.

During the transition, pallets will always transition from no or non-standard identifier to the SSCC. At the case level, cases that function as true logistics units will also transition from no or non-standard identifier to SSCC. Cases that are "orderable units" will transition to GTINs

Suppliers need to identify, label, and mark (barcode) pallets and cases using the SSCC (or GTINs for orderable unit cases), and the same identifiers that are encoded into the physical packaging levels need to be stored and expressed in all printed and electronic messages. Also, USAID/PSM parties and locations supporting or involved with logistics processes will need to be identified with GLNs.

With that, advance ship notices, bills of lading, packing slips, return authorizations, etc. will transition from identifying products and logistics units using internally generated identifiers to GS1 identifiers (most notably, GTIN and SSCC), and transition from identifying business entities and locations, e.g., bill-to, ship-to, deliver-to, using internally generated identifiers or identifiers to GS1 GLN.

LEVERAGING GS1 STANDARDS FOR REPORTING AND ANALYTICS

OVERVIEW

The move toward GS1 Standards will align USAID with standardization initiatives in healthcare around the world — enabling USAID to better leverage outside data and analytics based on GS1 Standards that might be provided by manufacturers, wholesalers, hospitals, and even retail establishments. The globally accepted uniqueness of GS1 trade item, logistics, and track and trace capabilities can leverage statistical information, best practices and big data mining efforts performed globally and made available from leading organizations and universities. Equipment and systems used will better integrate with industry and governmental systems around the world.

Standardized identifiers, categories, and quality barcodes in particular will provide more accurate data across the USAID architecture — better enabling USAID to compare performance metrics of equipment, supplies, medications and devices with outside agencies and analysts.

HIGH-LEVEL APPROACH TO SYSTEMS INTEGRATION

By standardizing on GS1 identifiers, attributes and messages, USAID systems should find it easier to integrate with off-the-shelf applications based on GS1 identification and messaging standards. Currently, GS1 identifiers and some data attributes are held as alternate attributes and are not prominently experienced through reports generated by the ARTMIS system. As suppliers and recipient countries are educated on GS1 Standards and begin to comply with PSM requirements for GS1 product marking and information, USAID/GHSC-PSM will experience better use of and benefits from GS1 Standards.

ARTMIS DESIGN

The current ARTMIS design accommodates GS1 identifiers as "alternates" to internally created identifiers. This is a common design for systems that need to operate in an imperfect world where there is not 100 percent compliance with a single standard, and where misinterpretations/misapplications of GS1 Standards occur, e.g., removing leading zeroes from GTIN and GLN; inserting dashes or underlines in the identifiers; incorrectly calculating check digits.

Concerning the operational database physical design, GITN is easily accommodated for in the current design and should be easiest to accommodate in all printed or electronic communications with USAID/PSM Suppliers and Recipient Countries. GLNs may be more difficult to implement, as so many tables hold "Entity or Location" data. However, once adjustments are made, it should be possible to express GS1 identifiers and attributes in all communications printed and electronic.

RECOMMENDED ADJUSTMENTS/MITIGATING STRATEGIES

After the recommendations regarding GTIN, GLN, and attributes have been implemented in the database, a query strategy needs to be developed to expose and use GS1 keys. A common

method of showing GS1 keys and attributes via queries would be helpful in rippling the changes throughout the system. It has been expressed in some of our meetings that the GS1 identifier or attribute could be displayed or printed, along with the existing identifier or attribute. While that tactic is feasible, it also means that the two identifiers or attributes may cause some confusion among casual users of the system, and it may be more difficult to make the mental changeover within the user community. Also, there is the issue of space on printed forms and screen real estate.

LEVERAGING GS1 STANDARDS FOR USAID SOURCING BUSINESS PROCESSES

OVERVIEW

Without standards, trading partners and systems, e.g., purchasing, inventory management, logistics, and reporting, all use their own identifiers and data formats. This approach breaks the connection between those systems, creating a high-maintenance, error-prone environment that adds complexity, inaccuracy, and cost. Using standards maintains their connection, enabling systems to be used collectively to enhance the quality and amount of data available to support operational processes. These capabilities and the associated benefits are why standards are such an integral part of data-driven industries, such as grocery, retail, and consumer packaged goods, why the effort to adopt standards and implement them across USAID's supply chain presents such a tremendous opportunity.

BEST PRACTICES: DATA-DRIVEN ORGANIZATIONS

Numerous industries have long understood the "make or break" connection between supply chain and performance and the essential role that supply chain operations play in their success or failure. They are information-driven industries that manage not only the physical flow of products but also the flow of information about those products. They optimize supply chain information across their business processes and systems to fuel operational efficiencies and process improvements. They also manage the flow of detailed spend, use, and outcome data on the reverse side to gain visibility and guide strategic decision-making to reduce costs, enhance quality, and elevate performance.

LEGACY BUSINESS PROCESSES

To become an information-driven organization, USAID needs to better leverage information technologies to transform its operations and improve performance. In the past, lack of standards has been a major roadblock to IT optimization, and USAID legacy business processes were developed/created to function in that environment. The opportunity presented through implementing GS1 Standards is not simply to add GTINs and GLNs to the mix. Rather, the opportunity is to enhance the quality and amount of data available to support operational processes.

RECOMMENDED ADJUSTMENTS/MITIGATING STRATEGIES

Implementation of GS1 Standards across USAID's supply chain and systems supports *automated connections* between and among systems to push/pull/view more data, automate business process, and support analytics and reporting. This can and should be transformational for business processes.

Therefore, the recommended approach is to review business processes in light of the new technical capabilities to leverage standardized data in the product and party masters, and across GHSC-PSM systems. Look for opportunities to optimize supply chain information across business processes and systems to fuel operational efficiencies and process improvements.

THE FUTURE OF SERIALIZATION AND TRACK AND TRACE DUE TO REGULATORY CHANGES

THE GLOBAL REGULATORY LANDSCAPE

Note: The GS1 Workshop held November 9, 2016, provided a detailed overview of numerous countries and their progress and efforts in serialization and track and trace efforts. To avoid repeating that information here, we defer to that PowerPoint deck. We will continue here with our discussion of the impact of that regulatory environment on USAID and its goals to GS1 Standards adoption.

IMPLICATIONS FOR ARTMIS AND USAID

As more countries adopt serialization and track and trace requirements, suppliers have sought out GS1 Standards as a way to standardize across countries. In the pharmaceutical industry, suppliers have adopted serialization through barcoding at the item, case, and pallet levels. The pharmaceutical industry has implemented identification of medicines for some time now and is further along in implementing tracking strategies and solutions. The medical device industry has also started to adopt serialization strategies and traditional means to track at the pallet and case levels using traditional transactions such as advance ship notices (ASNs).

ASNs enable companies to track shipments between adjacent trading partners (usually referred to as "one-up-one-down"). Within GS1, a suite of standards has been developed to enable tracking and tracing of products through the supply chain at many packaging levels (pallet, case, or each) and at many levels of granularity (GTIN, GTIN + lot#, GTIN + serial number).

DESCRIPTION OF CURRENT APPROACH

Currently, the ARTMIS system, along with K+N, can track outer containers on a one-up/one-down basis by using advance ship notices. Inbound shipments, warehousing, and outbound shipments are managed and reported from K+N systems and can be tracked and accounted for in quantity of product on hand (*x* pallets of item *y*, *x* cases of item "*y*").

RECOMMENDED ADJUSTMENTS/MITIGATING STRATEGIES

To accomplish true track and trace at any level (pallet, case, or each), several changes are needed:

- Suppliers need to mark their product using either the GTIN + serial number pair or serial shipping container codes (SSCCs).
- Suppliers need to provide tracking data at the appropriate level of packaging, K+N will (at a minimum) need to check-in and check-out shipments, providing the serialized hierarchy as product is shipped (could also provide put-away, reserving, and picking events).

- Recipient countries will need to scan the outer labels and provide "receiving" events. More granular events, such as unpacking, put-away, picking, dispensing, and administration, could also be captured by reading the serialized barcode and reporting events and disposition (status) of the product.

TASK LIST

Traceability is part of the "use" phase of the standards adoption life cycle (i.e., awareness, adoption, implementation, use). This is a longer-term effort that will build on the foundation being laid across USAID/GHSC-PSM systems and trading partners. The following topics should be analyzed further to support the journey to track and trace as implementation progresses:

- Refine strategy for tracking and tracing of products.
    - Focus on tracking (where is it now?) **and** tracing (where has it been?)
    - Decide on level of tracing (pallet, case, each)
    - Determine granularity of tracing (GTIN, GTIN + lot number, GTIN + serial number)
    - Decide on extensibility of tracing:
        - Supplier shipment through recipient county receipt
        - Trace back to manufacturer?
        - Include tracking within recipient country?
- Develop roadmap and plan to acquire/build track and trace capability

ANNEX 1: GDSN ATTRIBUTES FOR MEDICAL DEVICES

**As of November 7, 2016*

Cardinality	Number of attributes
GDSN mandatory	6
Mandatory (if class invoked)	0
Mandatory (if module invoked)	13
Optional	368
TOTAL	387

Attribute	Data type/tormat
areBatteriesIncluded	Boolean
areBatteriesRequired	Boolean
avpList	GS1 AVP List
areBatteriesBuiltIn	NonBinary Logic
batteryTechnologyTypeCode	Code [BatteryTechnologyTypeCode]
batteryTypeCode	Code [BatteryTypeCode]
batteryWeight	Measurement (Number and UOM)
quantityOfBatteriesBuiltIn	Integer (NonNegative)
quantityOfBatteriesRequired	Integer (NonNegative)
additionalCertificationOrganisationIdentfier	Text
certificationAgency	Text (1–200 characters)
certificationOrganisationIdentifier	Identifier (GLN)
certificationStandard	Text (1–200 characters)
avpList	GS1 AVP list
certificationValue	Text (1–200 characters)
certificationIssuanceDateTime	DateTime (CCYYMMDDTHH:MM:SS)
certificationAssessmentDateTime	DateTime (CCYYMMDDTHH:MM:SS)
certificationEffectiveEndDateTime	DateTime (CCYYMMDDTHH:MM:SS)
certificationEffectiveStartDateTime	DateTime (CCYYMMDDTHH:MM:SS)
certificationIdentification	Text (1–35 characters)
avpList	GS1 AVP List
controlOfHazardousSubstancesRegulationsAgency	Text (1–200 characters)
controlOfHazardousSubstancesRegulationsRegulationName	Text (1–200 characters)
avpList	GS1 AVP list

dangerousSubstanceGasDensity	Measurement (number and UOM)
dangerousSubstanceHeatOfCombustion	Measurement (number and UOM)
dangerousSubstanceName	Text (1–70 characters)
dangerousSubstancePhaseOfMatterCode	Code [PhaseOfMatterCode]
dangerousSubstancesWaterSolubilityCode	Code DangerousSubstancesWaterSolubi...]
flammableSubstanceMaximumPercent	Decimal
flammableSubstanceMinimumPercent	Decimal
isDangerousSubstance	NonBinary Logic
isDangerousSubstanceAMixture	NonBinary Logic
avpList	GS1 AVP list
riskPhraseCode	Code [ExternalCodeValueInformation]
dangerousSubstanceWasteCode	Code [ExternalCodeValueInformation]
safetyPhraseCode	Code [ExternalCodeValueInformation]
waterHazardCode	Code [ExternalCodeValueInformation]
avpList	GS1 AVP list
agreedMaximumBuyingQuantity	Integer (NonNegative)
agreedMinimumBuyingQuantity	Integer (NonNegative)
canTradeItemBeBackOrdered	NonBinary Logic
consumerFirstAvailabilityDateTime	DateTime (CCYYMMDDTHH:MM:SS)
firstDeliveryDateTime	DateTime (CCYYMMDDTHH:MM:SS)
firstShipDateTime	DateTime (CCYYMMDDTHH:MM:SS)
endAvailabilityDateTime	DateTime (CCYYMMDDTHH:MM:SS)
endDateTimeOfExclusivity	DateTime (CCYYMMDDTHH:MM:SS)
endMaximumBuyingQuantityDateTime	DateTime (CCYYMMDDTHH:MM:SS)
endMinimumBuyingQuantityDateTime	DateTime (CCYYMMDDTHH:MM:SS)
firstOrderDateTime	DateTime (CCYYMMDDTHH:MM:SS)
goodsPickupLeadTime	Measurement (number and UOM)
isOneTimeBuy	NonBinary Logic
isProductCustomizable	Boolean
isTradeItemReorderable	Boolean
isTradeItemShippedInMultipleContainers	Boolean
isTradeItemSizeBasedPricing	Boolean
lastOrderDateTime	DateTime (CCYYMMDDTHH:MM:SS)
lastShipDateTime	DateTime (CCYYMMDDTHH:MM:SS)
orderingUnitOfMeasure	Text (1–35 characters)
orderQuantityMaximum	Integer
orderQuantityMinimum	Integer
orderQuantityMultiple	Integer

orderSizingFactor	Measurement (number and UOM)
shippingQuantityMinimum	Integer (NonNegative)
startAvailabilityDateTime	DateTime (CCYYMMDDTHH:MM:SS)
startDateMaximumBuyingQuantity	DateTime (CCYYMMDDTHH:MM:SS)
startDateMinimumBuyingQuantity	DateTime (CCYYMMDDTHH:MM:SS)
avpList	GS1 AVP list
distributionMethodCode	Code [DistributionMethodCode]
isDistributionMethodPrimary	NonBinary Logic
orderingLeadTime	Measurement (number and UOM)
firstReturnableDatetime	DateTime (CCYYMMDDTHH:MM:SS)
isNonSoldTradeItemReturnable	Boolean
lastReturnableDateTime	DateTime (CCYYMMDDTHH:MM:SS)
orderableReturnableConditionsCode	Code [OrderableReturnableConditionsC...]
returnGoodsPolicyCode	Code [RightofReturnForNonSoldTradeIt...]
dutyFeeTaxAgencyCode	Code [ResponsibleAgencyCode]
dutyFeeTaxTypeCode	Text (1–80 characters)
dutyFeeTaxAgencyName	Text (1–200 characters)
dutyFeeTaxCountryCode	Code [CountryCode (ISO 3166-1)]
dutyFeeTaxEffectiveEndDateTime	DateTime (CCYYMMDDTHH:MM:SS)
dutyFeeTaxEffectiveStartDateTime	DateTime (CCYYMMDDTHH:MM:SS)
isTradeItemACombinationItem	NonBinary Logic
dutyFeeTaxClassificationCode	Text
dutyFeeTaxTypeDescription	Description (1–70 characters)
avpList	GS1 AVP list
dutyFeeTaxAmount	Amount
dutyFeeTaxCategoryCode	Code [TaxCategoryCode]
dutyFeeTaxBasis	Measurement (number and UOM)
dutyFeeTaxCountrySubdivisionCode	Code [CountrySubdivisionCode (ISO 31...]
dutyFeeTaxExemptPartyRoleCode	Code [PartyRoleCode]
dutyFeeTaxRate	Decimal
dutyFeeTaxReductionCriteriaDescription	Description (1–200 characters)
avpList	GS1 AVP list
isTradeItemImplantable	NonBinary Logic
mRICompatibilityCode	Code [MRICompatibilityCode]
avpList	GS1 AVP list
manufacturerDeclaredReusabilityTypeCode	Code [HealthcareTradeItemReusability...]
maximumCyclesReusable	Integer (NonNegative)
maximumReusableDays	Integer (NonNegative)

reuseInstructions	Description (1–1000 characters)
initialManufacturerSterilisationCode	Code [SterilizationTypeCode]
initialSterilisationPriorToUseCode	Code [SterilizationTypeCode]
isTradeItemRequiredToRemainSterile	NonBinary Logic
manufacturerSpecifiedAcceptableResterilisationCode	Code [SterilizationTypeCode]
doPackagingMaterialsContainLatex	NonBinary Logic
numberOfPackagesForSetPiecesGTIN	Integer (NonNegative)
averageDistanceTravelledToPointOfPackagingCode	Code [AverageDistanceToPointOfPackag...]
doesPackagingHaveWheels	NonBinary Logic
isPackagingExemptFromRefuseObligation	NonBinary Logic
isPackagingSuitableForAirShipment	NonBinary Logic
isRadioFrequencyIDOnPackaging	Boolean
packagingFeatureCode	Code [PackagingFeatureCode]
packagingFunctionCode	Code [PackagingFunctionCode]
packagingLevel	Integer (NonNegative)
packagingOwnerIdentification	Identifier (GLN)
packagingOwnerName	Text (1–200 characters)
packagingRecyclingProcessTypeCode	Code [PackagingRecyclingProcessTypeC...]
packagingRecyclingSchemeCode	Code [PackagingRecyclingSchemeCode]
packagingRefundObligationName	Text (1–200 characters)
packagingRefuseObligationName	Text (1–200 characters)
packagingShapeCode	Code [PackagingShapeCode]
packagingSustainabilityFeatureCode	Code [SustainabilityFeatureCode]
packagingTermsAndConditionsCode	Code PackagingTermsAndConditionsCod...]
packagingTypeCode	Code [PackageTypeCode]
packagingWeight	Measurement (number and UOM)
platformTermsAndConditionsCode	Code [PlatformTermsAndConditionsCode]
platformTypeCode	Code [PlatformTypeCode]
shippingContainerQuantityDescription	Description (1–200 characters)
usableProductVolume	Measurement (number and UOM)
avpList	GS1 AVP list
depositValueEffectiveDateTime	DateTime (CCYYMMDDTHH:MM:SS)
depositValueEndDateTime	DateTime (CCYYMMDDTHH:MM:SS)
returnablePackageDepositAmount	Amount
returnablePackageDepositIdentification	Identifier (GTIN)
returnablePackageDespositRegion	
packagingDepth	Measurement (number and UOM)
packagingHeight	Measurement (number and UOM)

packagingWidth	Measurement (number and UOM)
alternativeReturnableAssetIdentification	
grai	Identifier (GRAI)
isReturnableAssetEmpty	NonBinary Logic
returnableAssetCapacityContent	Measurement (number and UOM)
returnableAssetsContainedQuantity	Decimal
returnableAssetOwnerId	Identifier (GLN)
returnableAssetOwnerName	Text (1–200 characters)
returnableAssetPackageDeposit	
packagingMaterialTypeCode	Code [PackagingMaterialTypeCode]
isPackagingMaterialRecoverable	NonBinary Logic
isPrimaryMaterial	NonBinary Logic
packagingMaterialAppliedProcessCode	Code [PackagingMaterialAppliedProces...]
packagingCompositeMaterialDescription	Description (1–70 characters)
packagingMaterialCoatingTypeDescription	Description (1–70 characters)
packagingMaterialCompositionQuantity	Measurement (number and UOM)
packagingMaterialLaunchDateTime	DateTime (CCYYMMDDTHH:MM:SS)
packagingMaterialPerformanceCode	Code [PackagingMaterialPerformanceCo...]
packagingMaterialThickness	Measurement (number and UOM)
packagingMaterialTypeCode	Code [PackagingMaterialTypeCode]
packagingMaterialCompositionQuantity	Measurement (number and UOM)
packagingMaterialThickness	Measurement (number and UOM)
consumerPackageDisclaimer	Description (1–1,000 characters)
hasBatchNumber	Boolean
isNetContentDeclarationIndicated	Boolean
isPackagingMarkedReturnable	Boolean
isPriceOnPack	Boolean
isTradeItemMarkedAsRecyclable	Boolean
offerOnPack	Text (1–70 characters)
packagingMarkedLabelAccreditationCode	Code [PackagingMarkedLabelAccreditat...]
packagingMarkedLanguageCode	Code [LanguageCode (ISO 639)]
packagingMarkedRecyclableScheme	Text (1–70 characters)
serialNumberLocationCode	Code [SerialNumberLocationCode]
warningCopyDescription	Description (1–1,000 characters)
avpList	GS1 AVP list
tradeItemDateOnPackagingFormatName	Text (1–70 characters)
tradeItemDateOnPackagingFormatTypeCode	Code [DateOnPackagingFormatTypeCode]
tradeItemDateOnPackagingTypeCode	Code [TradeItemDateOnPackageTypeCode]

tradeItemDateOnPackagingLocation	Text (1–70 characters)
avpList	GS1 AVP list
importClassificationCountrySubdivisionRegionOfOrigin	Code [CountrySubdivisionCode (ISO 31...]
importClassificationTypeCode	Code [ImportClassificationTypeCode]
importClassificationValue	Text (1–70 characters)
statisticalReportingMeasurement	Measurement (number and UOM)
canFileStream	NonBinary Logic
fileAspectRatio	Text (1–70 characters)
fileBackgroundColourDescription	Description (1–70 characters)
fileColourCalibration	Description (1–70 characters)
fileColourSchemeCode	Code [FileColourSchemeCode]
fileCompressionType	Description (1–70 characters)
fileContrast	Text (1–70 characters)
filePixelHeight	Integer (NonNegative)
filePixelWidth	Integer (NonNegative)
filePlaybackRate	Integer (NonNegative)
filePrintHeight	Measurement (number and UOM)
filePrintWidth	Measurement (number and UOM)
fileResolutionDescription	Description (1–70 characters)
fileRunTime	Time (hh:mm:ss)
fileSize	Measurement (number and UOM)
isFileBackgroundTransparent	NonBinary Logic
avpList	GS1 AVP list
areHumanModelsInFile	NonBinary Logic
fileAuthorName	Text (1–70 characters)
fileCameraPerspective	Description (1–70 characters)
fileDepictedSceneDescription	Description (1–1,000 characters)
fileDepictedSeason	Description (1–70 characters)
fileItemPositionCode	Code [ItemPositionCode]
fileLayerQuantity	Integer (NonNegative)
fileLifestyleDescription	Description (1–70 characters)
fileStoryDescription	Description (1–1,000 characters)
fileTalentDescription	Description (1–1,000 characters)
itemDepictionTypeCode	Code [ItemDepictionCode]
itemsInFileDescription	Description (1–70 characters)
numberOfItemsInDigitalAsset	Integer (NonNegative)
areFeesRequiredForUse	NonBinary Logic
canFilesBeEdited	NonBinary Logic

fileCampaignDescription	Description (1–1,000 characters)
fileCopyrightDescription	Description (1–1,000 characters)
fileDisclaimerInformation	Description (1–1,000 characters)
fileFeeDescription	Description (1–1,000 characters)
fileRecommendedUsageDescription	Description (1–1,000 characters)
fileRightsDescription	Description (1–1,000 characters)
intendedPublicationCountryCode	Code [CountryCode (ISO 3166-1)]
intendedPublicationMediaTypeDescription	Description (1–1,000 characters)
isFileForInternalUseOnly	NonBinary Logic
isTalentReleaseOnFile	NonBinary Logic
regulatoryAct	Text (1–80 characters)
regulatoryAgency	Text (1–80 characters)
regulationTypeCode	Code [TradeItemRegulationTypeCode]
avpList	GS1 AVP list
permitEndDateTime	DateTime (CCYYMMDDTHH:MM:SS)
permitStartDateTime	DateTime (CCYYMMDDTHH:MM:SS)
regulatoryPermitIdentification	Text (1–200 characters)
avpList	GS1 AVP list
accidentalReleaseMeasuresDescription	Description (1–1,000 characters)
additionalSDSInformation	Description (1–1,000 characters)
conditionsToAvoid	Description (1–1,000 characters)
ecologicalInformationDescription	Description (1–1,000 characters)
firstAidProceduresDescription	Description (1–1,000 characters)
hazardousMaterialsHandlingProcedures	Description (1–1,000 characters)
isRegulatedForTransportation	NonBinary Logic
noteToPhysician	Description (1–1,000 characters)
sDSSheetNumber	Text (1–200 characters)
sDSStandardCode	Code [SDSStandardCode]
sDSStandardVersion	Text (1–35 characters)
storageRequirementsDescription	Description (1–1,000 characters)
toxicologicalInformationDescription	Description (1–1,000 characters)
volatileOrganicCompound	Measurement (number and UOM)
volatileOrganicCompoundBasis	Measurement (number and UOM)
volatileOrganicCompoundPercent	Decimal
avpList	GS1 AVP List
chemicalIngredientOrganisation	Text (1–200 characters)
chemicalIngredientScheme	Text (1–200 characters)
chemicalIngredientConcentration	Measurement (number and UOM)

chemicalIngredientConcentrationBasis	Measurement (number and UOM)
chemicalIngredientIdentification	Text (1–35 characters)
chemicalIngredientName	Text (1–200 characters)
rEACHChemicalRegistrationNumber	Text (1–35 characters)
avpList	GS1 AVP list
lethalConcentration50	Measurement (number and UOM)
lethalConcentration50Basis	Measurement (number and UOM)
lethalDose50	Measurement (number and UOM)
lethalDose50Basis	Measurement (number and UOM)
routeOfExposureCode	Code [RouteOfExposureCode]
testSpeciesCode	Code [TestSpeciesCode]
testSpeciesDescription	Description (1–200 characters)
avpList	GS1 AVP List
extinguishingMediaDescription	Description (1–1,000 characters)
fireFighterProtectiveEquipmentDescription	Description (1–1,000 characters)
flammablePropertiesDescription	Description (1–1,000 characters)
gHSSignalwordsCode	Code [GHSSignalwordsCode]
gHSSymbolDescriptionCode	Code [GHSSymbolDescriptionCode]
hazardStatementsCode	Text (1–35 characters)
hazardStatementsDescription	Description (1–1,000 characters)
precautionaryStatementsCode	Text (1–35 characters)
precautionaryStatementsDescription	Description (1–1,000 characters)
hazardousWasteAgency	Text (1–200 characters)
hazardousWasteCode	Text (1–35 characters)
hazardousWasteDescription	Description (1–1,000 characters)
isAcutelyHazardousWaste	NonBinary Logic
isUniversalWaste	NonBinary Logic
nonHazardousWasteDescription	Description (1–1,000 characters)
autoIgnitionTemperature	Measurement (number and UOM)
boilingPoint	Measurement (number and UOM)
freezingMeltingPoint	Measurement (number and UOM)
lowerExplosiveLimit	Decimal
physicalFormDescription	Description (1–1,000 characters)
physicalStateCode	Code [PhaseOfMatterCode]
upperExplosiveLimit	Decimal
waterSolubilityTypeCode	Code [WaterSolubilityTypeCode]
avpList	GS1 AVP List
flashPointTemperature	Measurement (Number and UOM)

flashPointTestMethodCode	Code [FlashPointTestMethodCode]
avpList	GS1 AVP List
exactPH	Decimal
maximumPH	Decimal
minimumPH	Decimal
specificGravity	Decimal
specificGravityReferenceMaterialCode	Code [SpecificGravityReferenceMateri...]
avpList	GS1 AVP List
protectiveEquipmentAdditionalDescription	Description (1–1,000 characters)
ProtectiveEquipmentBodyAreaCode	Code [ProtectiveEquipmentBodyAreaCod...]
protectiveEquipment	Description (1–1,000 characters)
protectiveEquipmentStatusCode	Code [RecommendedStatusCode]
isSubstanceOfVeryHighConcern	NonBinary Logic
isTradeItemREACHRelevant	NonBinary Logic
rEACHChemicalProductUseDescriptorCode	Text (1–35 characters)
rEACHEnvironmentReleaseUseCategoryCode	Text (1–35 characters)
rEACHProcessUseDescriptorCode	Text (1–35 characters)
rEACHSectorUseDescriptorCode	Text (1–35 characters)
storageCompatibilityAgency	Text (1–200 characters)
storageCompatibilityCode	Text (1–35 characters)
storageCompatibilityDescription	Description (1–1,000 characters)
additionalTradeItemDescription	Description (1–500 characters)
descriptionShort	Description (1–35 characters)
functionalName	Description (1–35 characters)
invoiceName	Description (1–35 characters)
labelDescription	Description (1–500 characters)
productRange	Text (1–35 characters)
regulatedProductName	Description (1–500 characters)
tradeItemDescription	Description (1–200 characters)
tradeItemFormDescription	Text (1–35 characters)
tradeItemGroupIdentificationCodeReference	Code [Code (externally managed)]
variantDescription	Description (1–35 characters)
avpList	GS1 AVP list
brandName	Text (1–70 characters)
languageSpecificBrandName	Description (1–70 characters)
languageSpecificSubbrandName	Description (1–70 characters)
subBrand	Text (1–70 characters)
tradeItemVariantTypeCode	Code [TradeItemVariantTypeCode]

tradeItemVariantValue	Text (1–70 characters)
avpList	GS1 AVP list
areHazardousComponentsRemovable	NonBinary Logic
componentsLabeledForDisassemblyRecyclingPercent	Decimal
isTradeItemConsumerUpgradeableOrMaintainable	NonBinary Logic
isTradeItemDesignedForEasyDisassembly	NonBinary Logic
isTradeItemUniversalWaste	NonBinary Logic
doesTradeItemHaveRefuseObligations	NonBinary Logic
doesManufacturerHaveTakeBackProgram	NonBinary Logic
manufacturerTakeBackProgramFee	Amount
wasteAmount	Measurement (number and UOM)
wasteDirectiveApplianceType	Text (1–35 characters)
wasteDirectiveName	Text (1–200 characters)
wasteDirectiveRegistrationNumber	Text (1–35 characters)
clampPressure	Code value
handlingInstructionsCodeReference	Code
handlingInstructionsDescription	Description (1–1000 characters)
avpList	GS1 AVP list
stackingFactor	Integer (NonNegative)
stackingFactorTypeCode	Code [StackingFactorTypeCode]
stackingWeightMaximum	Measurement (number and UOM)
doesTradeItemHaveAutoReaderTracker	NonBinary Logic
minimumTradeItemLifespanFromTimeOfArrival	Integer (NonNegative)
minimumTradeItemLifespanFromTimeOfProduction	Integer (NonNegative)
openedTradeItemLifespan	Integer (NonNegative)
supplierSpecifiedMinimumConsumerStorageDays	Integer (NonNegative)
avpList	GS1 AVP list
depth	Measurement (number and UOM)
diameter	Measurement (number and UOM)
height	Measurement (number and UOM)
inBoxCubeDimension	Measurement (number and UOM)
individualUnitMaximumSize	Measurement (number and UOM)
individualUnitMinimumSize	Measurement (number and UOM)
netContent	Measurement (number and UOM)
tradeItemCompositionDepth	Measurement (number and UOM)
tradeItemCompositionWidth	Measurement (number and UOM)
width	Measurement (number and UOM)
avpList	GS1 AVP list

pegHoleNumber	Integer (NonNegative)
pegHoleTypeCode	Code [PegHoleTypeCode]
pegHorizontal	Measurement (number and UOM)
pegVertical	Measurement (number and UOM)
nestingDirectionCode	Code [NestingDirectionCode]
nestingIncrement	Measurement (number and UOM)
nestingTypeCode	Code [NestingTypeCode]
orientationPreferenceSequence	Integer (NonNegative)
orientationTypeCode	Code [OrientationtypeCode]
drainedWeight	Measurement (number and UOM)
grossWeight	Measurement (number and UOM)
netWeight	Measurement (number and UOM)
marinePollutantTechnicalName	Text (1–200 characters)
reportableQuantityTechnicalName	Text (1–200 characters)
transportationModeRegulatoryAgency	Text (1–200 characters)
isProhibitedForTransportation	NonBinary Logic
prohibitedForTransportationReason	Description (1–1,000 characters)
shippingRegulationException	Description (1–1,000 characters)
specialRequirementsDescription	Description (1–1,000 characters)
specialPermitOrExemptionIdentification	Identifier
transportationMaximumQuantity	Measurement (number and UOM)
transportationModeCode	Code [HazardousMaterialsTransportati...]