PDG Blueprint Chapter 1

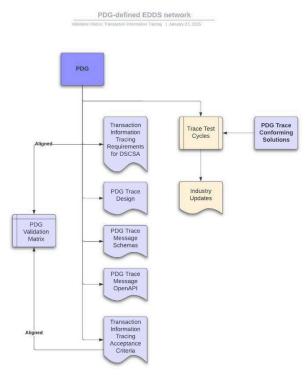Trace Requirements and Acceptance Criteria

Figure 1 - Alignment between PDG Requirements, Acceptance Criteria and Tracing Requirements

Contents

Categories

1. Authentication/Authorization
2. TI Request
3. TI Response
4. TI Request & Response

PDG Blueprint Chapter 1

Trace Requirements and Acceptance Criteria

REQ01 - Direction of Tracing

Systems and processes for Tracing must enable the Initiating Entity to trace the product forward (i.e., transactions subsequent to the first Responding ATP), trace the product backward (i.e., transactions prior to the first Responding ATP), or identify the last ATP known to have owned the product. [57]

Category

TI Request & Response

Source Document

PDG Blueprint Chapter 1 - Tracing Requirements

Source ID

Requirement-Trac-001

Notes

[57]   It is important to read the requirements in this section together as a whole, for example, Requirement-Trac-001 should be read with the understanding that Requirement-Trac-002, -003 and -004 apply and these are all intended to be interdependent. Similarly, Requirement-Trac-001 must be read in conjunction with Requirements-Trac-013 and -014 which make clear no individual ATP is responsible for producing the full information contemplated under Requirement-Trac-001.

Acceptance Criteria

1. Acceptance Criterion:
   Define the specific conditions that must be met for the requirement to be successfully fulfilled.

   a. A series of TI Request / Response transactions that results in a trace forward chronologically of a package.
   b. A series of TI Request / Response transactions that results in a trace backward chronologically of a package.

2. Prerequisites:
   Specify any conditions that need to be met before the interaction can proceed.

   a. Direct Trading Partners have exchanged Trace connectivity information (Trace endpoints and Trace Contact Information).

3. Testable Condition:
   Describe how the acceptance criterion can be tested objectively.
   Specify the steps, procedures, or tools used for testing.

   a. **Executing an upstream trace:**
      The following steps are taken with each of these "response type requested" variations in the TI Request:
      - "Transaction Information",
      - "All Known Owners",
      i. A Requester sends the TI Request to the endpoint of a customer Trading Partner (Responder).
      ii. Responder sends a TI Response to the endpoint specified by the Requester's callbackAddress.

      iii. Using the tiRequestConnectivityInformation for parties in the TI Response, the Requester sends a TI Request to the endpoint of the next upstream Trading Partner (next Responder).

      iv. The process is repeated until TI Responses do not include any further upstream Trading Partner information.

  b. Executing a downstream trace:
The following steps are taken with each of these "response type requested" variations in the TI Request:

- "Transaction Information",
- "All Known Owners",
- "Last Known Owner"

  c.

      i. A Requester sends a TI Request to the endpoint of a supplier Trading Partner (Responder).

      ii. Responder sends a TI Response to the endpoint specified by the Requester's callbackAddress.

      iii. Using the tiRequestConnectivityInformation for parties in the TI Response, the Requester sends a TI Request to the endpoint of the next downstream Trading Partner (next Responder).

      iv. The process is repeated until TI Responses do not include any further downstream Trading Partner information.

4. **Pass/Fail Criteria:**
   Clearly define what constitutes a "pass" or "fail" for the acceptance criterion.
   Include any thresholds, tolerances, or standards that must be met.

   a. Pass Criteria:

       i. **Requester:** be able to issue successful TI Requests and can piece them together.

         1. Inability to issue subsequent TI Requests based on information received in a previous TI Response where additional parties are indicated in the ownershipFromInformation or ownershipToInformation.

         2. Previous TI Response did not include a useable trace endpoint (tiRequestConnectivityInformation)

       ii. **Responder:** be able to provide a TI Response to TI Requests

       iii. **Requester and Responding systems** can handle exceptions.

   b. Fail Criteria:

       i. Failure Of Pass Criteria

5. **Expected Successful Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is met.
   For each variation of "response type requested" in the TI Request:
   - "Transaction Information",
   - "All Known Owners",
   - "Last Known Owner"

   a. **Executing an upstream trace:**
      i. A Requester can gather TI information (or Trading Partner information) leading to the manufacturer or repackager of the product.
   b. **Executing a downstream trace:**
      i. A Requester can gather TI information (or Trading Partner information) leading to the full set of downstream owners.

6. **Expected Failure Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is unmet.

   a. A Requester is unable to continue the series of TI Requests based on the information provided by Responders.

REQ02 - Who May Initiate Tracing for What Purpose - ATPs

Systems and processes for Tracing-Suspect and Tracing-Illegitimate [58] must enable only (i) an ATP involved in the investigation of the suspect or illegitimate product at issue or (ii) a Regulator to act as an Initiating Entity. [59]

Category

Authentication/Authorization

Source Document

PDG Blueprint Chapter 1 - Tracing Requirements

Source ID

Requirement-Trac-002

Notes

[58]   It is important to note that these use cases may only by utilized when the product has been declared suspect or illegitimate, which triggers obligations under the DSCSA, such as investigation and quarantine requirements.

[59] It is anticipated that the discussion and development of technical specifications will evaluate the role of credentialing to support this requirement.

Acceptance Criteria

Maturity Level 1

1. Acceptance Criterion:
   Define the specific conditions that must be met for the requirement to be successfully fulfilled.

   a. Assume the entity is involved in the investigation if they provided investigationReasonAttestation and investigationCircumstances.

   b. Entities that send TI Requests with investigationReasonAttestation = "Suspect Product Investigation" or "Illegitimate Product Investigation" must be proven to be an ATP, ATP-Equivalent, or DSCSA Authority to receive a TI Response with TI, All Known or Last Known information.

2. Testable Condition:
   Describe how the acceptance criterion can be tested objectively.
   Specify the steps, procedures, or tools used for testing.

   a. **Executing a successful TI Request/Response pair:**

      i. A Requester sends a TI Request where investigationReasonAttestation = "Suspect Product Investigation" or "Illegitimate Product Investigation" for an item that the Responder has TI record(s) and the Responder can Authenticate and Authorize the Requester.

      ii. A Requester sends a TI Request where investigationReasonAttestation = "Suspect Product Investigation" or "Illegitimate Product Investigation" for an item that the Responder has TI record(s) and the Responder cannot Authenticate and Authorize the Requester.

3. Prerequisites:
   Specify any conditions that need to be met before the interaction can proceed.

   a. TI Request passes data format and mandatory element checks as per TI Request schema.
   b. investigationReasonAttestation is "Suspect Product Investigation" or "Illegitimate Product Investigation."
   c.

4. Pass/Fail Criteria:
   Clearly define what constitutes a "pass" or "fail" for the acceptance criterion.
   Include any thresholds, tolerances, or standards that must be met.

   a. **Manual Authentication & Authorization:** Responder and Requester use internal procedures to verify the ATP, ATP equivalent, or Regulator status of the other party.
   b. Responder is or is not able to Authenticate and Authorize the Requester that sent a TI Request where with investigationReasonAttestation = "Suspect Product Investigation" or "Illegitimate Product Investigation".

5. Expected Successful Outcome:
   Clearly state the expected result or behavior when the system interaction requirement is met.

   a. Responding system can verify the status of the Requester.
      i. The Responder uses internal processes to determine action.
   b. Only Requests and Responses from a verified ATP, ATP-Equivalent or DSCSA Authority are Responded to with TI, All Known Owners, or Last Known Owner.

6. Expected Failure Outcome:
   Clearly state the expected result or behavior when the system interaction requirement is met.

   a. TI Responding system cannot verify the status of the Requester.
      i. The Responder uses internal processes to determine action.
   b. TI Requesting system is unable to verify the status of the Responder.
      i. The Requester uses internal processes to determine the validity of the TI Response and their action.

Maturity Levels 2 and 3

1. Acceptance Criterion:
   Define the specific conditions that must be met for the requirement to be considered successfully fulfilled.

   c. Assume the entity is involved in the investigation if they provided investigationReasonAttestation and investigationCircumstances.
   d. Entities that send TI Requests with investigationReasonAttestation = "Suspect Product Investigation" or "Illegitimate Product Investigation" must be proven to be an ATP, ATP-Equivalent, or DSCSA Authority to receive a TI Response with TI, All Known or Last Known information.

2. Testable Condition:
   Describe how the acceptance criterion can be tested objectively.
   Specify the steps, procedures, or tools that will be used for testing.

   1. **Executing a successful TI Request/Response pair:**

      i. A Requester sends a TI Request where investigationReasonAttestation = "Suspect Product Investigation" or "Illegitimate Product Investigation" and a credential for an item that the Responder has TI record(s) and the Responder can verify the Credential and Credential Presentation.

      ii. A Requester sends a TI Request where investigationReasonAttestation = "Suspect Product Investigation" or "Illegitimate Product Investigation" for an item that the Responder has TI record(s) and the Responder cannot verify the Credential or Credential Presentation.

3. Prerequisites:
   Specify any conditions that need to be met before the interaction can proceed.

   a. TI Request passes data format and mandatory element checks as per TI Request schema.
   b. investigationReasonAttestation is "Suspect Product Investigation" or "Illegitimate Product Investigation"
   c. Requester and Responder include an ATP, ATP-Equivalent or DSCSA Authority Credential in the TI Request or TI Response

4. Pass/Fail Criteria:
   Clearly define what constitutes a "pass" or "fail" for the acceptance criterion.
   Include any thresholds, tolerances, or standards that must be met.

   a. The Credential fails to Verify and/or the Credential Presentation fails to Verify.
   b. The Trading Partner or solution is unable to authenticate the identity of the Requester or verify the ATP, ATP-Equivalent or DSCSA Authority status.

5. Expected Successful Outcome:
   Clearly state the expected result or behavior when the system interaction requirement is met.

   1. **Automated Authentication & Authorization:** Responder and Requester verify the Credentials and Credential Presentations to verify the ATP, ATP equivalent, or Regulator status of the other party.
   2. Only Requests and Responses from a verified ATP, ATP-Equivalent or DSCSA Authority are accepted.

6. Expected Failure Outcome:
   Clearly state the expected result or behavior when the system interaction requirement is met.

   a. TI Request includes the wrong Credential / investigationReasonAttestation combination (ex: ATP credential and "Recall Product Investigation":
      i. Return Exception "xx2, Request Parameter error".
   b. Provided Credential fails verification:
      i. Return Exception "xx1, Credential verification failed."

7. Consideration:
   a. No Credential:
      i. Assume the party that didn't include a credential is operating at Maturity Level 1 (no credential capability)
      ii. Request or Response is processed as Maturity Level 1 capability.

REQ03 - Who May Initiate Tracing for What Purpose - Regulators

Systems and processes for Tracing-Recall must enable only a Regulator to act as an Initiating Entity. [60]

Category

Authentication/Authorization

Source Document

PDG Blueprint Chapter 1 - Tracing Requirements

Source ID

Requirement-Trac-003

Notes

[60]   It is anticipated that the discussion and development of technical specifications will evaluate the role of credentialing to support this requirement. For clarity, most recalls are expected to be initiated by the manufacturer or repackager as a voluntary recall, and the manufacturer or repackager may be key to starting the tracing process; this requirement simply recognizes that the DSCSA give FDA (and other regulators) the authority to request tracing once a recall has occurred.

Acceptance Criteria

1. Acceptance Criterion:
   Define the specific conditions that must be met for the requirement to be successfully fulfilled.
   For TI Requests where investigationReason = "Recalled Product Investigation", the Requesting Party must be a DSCSA Authority.
2. Prerequisites:
   Specify any conditions that need to be met before the interaction can proceed.

   a. TI Request passes data format and mandatory element checks as per TI Request schema.
   b. TI Request includes Investigation reason Attestation of "Recalled Product Investigation"
   c. DSCSA Authority Credential is provided, or assessment that the request is from a DSCSA Authority.
3. Testable Condition:
   Describe how the acceptance criterion can be tested objectively.
   Specify the steps, procedures, or tools used for testing.

   a. Credential Provided:
      1. The credential must be a DSCSA Authority credential.
      2. The DSCSA Authority credential must pass verification.
   b. No Credential Provided: The responding Trading Partner or service must use internal processes to determine that the Requester is a DSCSA Authority.
4. **Pass/Fail Criteria:**
   Clearly define what constitutes a "pass" or "fail" for the acceptance criterion.
   Include any thresholds, tolerances, or standards that must be met.

    a. Pass Criteria:

        1. Credential Provided:

            a. The credential is a DSCSA Authority credential.

            b. The DSCSA Authority credential is verified.

        2. No Credential Provided:

            a. The responding Trading Partner or service determines that the Requester is a DSCSA Authority.

    b. Fail Criteria: Failure Of Pass Criteria

5. Expected Successful Outcome:

Clearly state the expected result or behavior when the system interaction requirement is met.

- A TI Request from a DSCSA-Authority would result in a TI Response conformant with the TI Response schema (or response outside the electronic network).
- A TI Request from an entity not a DSCSA-Authority would result in a TI Response conformant with the TI Response schema with a Response Message Code xx2, Request Parameter error.

6. Expected Failure Outcome:

Clearly state the expected result or behavior when the system interaction requirement is unmet.

Maturity Level 1:

The assessment determines that the Requester is not a DSCSA Authority

    1. Requester may respond with "xx4 Request addressed via your supplied Contact information."

    2. May need a general "not authorized" response message

Maturity Level 2 or 3:

    a. TI Request includes the wrong Credential/investigationReasonAttestation combination (ex: ATP credential and "Recall Product Investigation"):

    b. Response may include Exception "xx2, Request Parameter error".

    c. Requester may respond with "xx4 Request addressed via your supplied Contact information"

    d. May need a general "not authorized" response message.

REQ04 - Who May Initiate Tracing for What Purpose - Other Uses

Any use of systems and processes for tracing for use cases other than those in Requirements-Trac-002 and -003 is a matter of commercial business practice that shall be left to and would require agreement by, the relevant ATPs. [61]

Category

TI Request & Response

Source Document

PDG Blueprint Chapter 1 - Tracing Requirements

Source ID

Requirement-Trac-004

Notes

[61] As a matter of commercial business practice, this activity is outside the scope of PDG's activities.

Acceptance Criteria – N/A

REQ05 - Level/Granularity of Tracing - Suspect and Illegitimate Product Investigations

Systems and processes for Tracing-Suspect and Tracing-Illegitimate must enable tracing of product by individual sGTIN.

Category

TI Request & Response

Source Document

PDG Blueprint Chapter 1 - Tracing Requirements

Source ID

Requirement-Trac-005

Acceptance Criteria

1. Acceptance Criterion:
   Define the specific conditions that must be met for the requirement to be successfully fulfilled.

   a. TI Requests with investigationReasonAttestation of "Suspect Product Investigation" or "Illegitimate Product Investigation", should be processed if they include Product ID of a valid GTIN and serialNumberOrLotNumber with a valid Serial Number for the GTIN.

2. Prerequisites:
   Specify any conditions that need to be met before the interaction can proceed.

   a. Must satisfy Req02 (ATP, ATP-Equivalent, DSCSA Authority)
   b. TI Request passes data format and mandatory element checks as per TI Request schema.
   c. TI Request includes:
      i. Investigation reason Attestation of "Suspect Product Investigation" or "Illegitimate Product Investigation" and
      ii. Product Identifier of type "GTIN" or "NDC"
      iii. Serial Number.

3. Testable Condition:
   Describe how the acceptance criterion can be tested objectively.
   Specify the steps, procedures, or tools used for testing.

   a. investigationResonAttestation = "Suspect Product Investigation" or "Illegitimate Product Investigation"
   b. A TI Request includes a request including a valid GTIN or NDC and a valid serialNumber for the GTIN or NDC.
   c. The Responder's system holds TI records for the GTIN or NDC and Serial Number pair.

4. **Pass/Fail Criteria:**
   Clearly define what constitutes a "pass" or "fail" for the acceptance criterion.
   Include any thresholds, tolerances, or standards that must be met.

    a. Pass Criteria:

        i. TI Requester sends a TI Request with the type of information requested in the responseTypeRequested.

    b. Fail Criteria:

        i. No TI Response is sent

5. **Expected Successful Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is met.
   This will result in a TI Response conformant with the TI Response schema (or response outside of the electronic network).

    a. Response may include appropriate TI

    b. Response may include "All Known" or "Last Known Owner"

    c. Response may include exception code "xx2 No TI found for the Request"

6. **Expected Failure Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is unmet.
   Responder may reply with:

    a. "xx2 Request parameter error"

    b. "xx5 Request FTIN, NDC, Lot Number or Serial Number not formatted correctly"

REQ06 - Level/Granularity of Tracing - Recalled Product Investigations

Systems and processes for Tracing-Recall may enable tracing of product by individual sGTIN or by IGTIN (lot number and GTIN). [62]

Category

TI Request & Response

Source Document

PDG Blueprint Chapter 1 - Tracing Requirements

Source ID

Requirement-Trac-006

Notes

In developing technical specifications PDG will specifically consider whether there are technical advantages to simultaneously tracing all sGTINs in a lot versus a single tracing process for the lot.

Note: Chapter 5 restricts lot level traces to FDA.

Acceptance Criteria

1. Acceptance Criterion:
   Define the specific conditions that must be met for the requirement to be successfully fulfilled.
   TI Request for Recalled Product Investigation investigationReasonAttestation includes requests for GTIN (or NDC) and Serial Number pairs or GTIN (or NDC) and Lot Number pairs.

2. Prerequisites:
   Specify any conditions that need to be met before the interaction can proceed.

   a. Must satisfy Req02 (DSCSA Authority only)
   b. TI Request passes data format and mandatory element checks as per TI Request schema.
   c. TI Request includes:
      i. Investigation reason Attestation of "Recalled Product Investigation"

3. Testable Condition:
   Describe how the acceptance criterion can be tested objectively.
   Specify the steps, procedures, or tools used for testing.

   i. TI Request:
      1. investigationReasonAttestation = "Recalled Product Investigation"
      2. productID = a GTIN or NDC
      3. serialNumberOrLotNumber = a Serial Number or Lot Number
   ii. TI Response:
      1. A TI Response is sent for TI that meets the request parameters

where the Responder holds matching TI records.

2. An appropriate error message is provided in the TI Response where the Responder does not hold matching TI records.

4. **Pass/Fail Criteria:**
   Clearly define what constitutes a "pass" or "fail" for the acceptance criterion.
   Include any thresholds, tolerances, or standards that must be met.

   a. Pass Criteria:
      i. TI Request contains the values defined in Testable Condition
      ii. TI Response contains matching TI or "xx2", "No Records Found"
   b. Fail Criteria:
      i. Failure Of Pass Criteria

5. **Expected Successful Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is met.
   Will result in a TI Response conformant with the TI Response schema (or response outside of the electronic network).

6. **Expected Failure Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is unmet.

   a. A Non DSCSA Authority has sent a TI Request with Investigation Reason Attestation of "Recall Investigation"
   b. Will result in a TI Response conformant with the TI Response schema with code "xx2, Request parameter error".
   c. May result in "TI Request Error" message at the TI Request line level.

REQ07 - Initiating a Trace - Suspect Product Investigations

To initiate the Tracing-Suspect process, the Initiating Entity shall provide the following:

1. The ~~four~~ elements of the product identifier (GTIN/NDC, serial number, ~~expiration date, and lot number~~). [63]
2. The reason "Suspect Product Investigation."
3. An attestation by the Initiating Entity that the process is being initiated to support a suspect product investigation.
4. If the tracing is being initiated by a Regulator, an attestation that the tracing is being initiated at the request of a Regulator.
5. As optional information, a description of the suspect product investigation. [64]

Category

TI Request

Source Document

PDG Blueprint Chapter 1 - Tracing Requirements

Source ID

Requirement-Trac-007

Notes

[62]   Pursuant to widely recognized international standards, the GTIN is encoded in the product identifier. Recognizing the FDA's reliance on NDC, continued discussion of technical specifications will address the interchangeability of, or methods for crosswalk to, the NDC.

[63]   Subject to confirmation that this will not impede interoperability or automation. Additionally, it is anticipated that the discussion and development of technical specifications will consider how a point-of-contact or other information can be incorporated.

Acceptance Criteria

1. Acceptance Criterion:
   Define the specific conditions that must be met for the requirement to be successfully fulfilled.
   TI Request with investigationReasonAttestation of "Suspect Product Investigation" must include tiRequsts for GTIN/NDC and Serial Number.
2. Prerequisites:
   Specify any conditions that need to be met before the interaction can proceed.

   a. Must satisfy Req02 (ATP, ATP-Equivalent or DSCSA Authority)
   b. TI Request passes data format and mandatory element checks as per TI Request schema.
   c. TI Request includes:
      i. Investigation reason Attestation of "Suspect Investigation
3. Testable Condition:
   Describe how the acceptance criterion can be tested objectively.
   Specify the steps, procedures, or tools used for testing.

   a. productID contains a GTIN or NDC

        b. serialNumberOrLotNumber contains a Serial Number or a Lot Number

4. **Pass/Fail Criteria:**
   Clearly define what constitutes a "pass" or "fail" for the acceptance criterion.
   Include any thresholds, tolerances, or standards that must be met.

   a. Pass Criteria:
      i. TI Request contains the values defined in Testable Condition
      ii. TI Response contains matching TI or "xx2", "No Records Found"
   b. Fail Criteria:
      iii. TI Request productID is missing, null or does not contain a GTIN or NDC or serialNumberOrLotNumber is missing, null or does not contain a Serial Number.

5. **Expected Successful Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is met.
   Will result in a TI Response conformant with the TI Response schema (or response outside of the electronic network).

6. **Expected Failure Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is unmet.
   TI Request does not include one of the required request attributes (GTIN/NDC, Serial Number, Investigation Reason = "Suspect Product Investigation", Investigation Circumstances (made mandatory in Chapter 5).

   a. Will result in a TI Response conformant with the TI Response schema with code "xx2, Request parameter error".
   b. May result in "TI Request Error" message at the TI Request line level.

REQ08 - Initiating a Trace - Illegitimate Product Investigations

To initiate the Tracing-Illegitimate process, the Initiating Entity shall provide the following:

1. The four elements of the product identifier (GTIN/NDC, serial number, expiration date, and lot number).
2. The reason "Illegitimate Product Investigation."
3. The incident number associated with the Form 3911 filed for the illegitimate product.   --- (pull forward Chapter 5 language).
4. An attestation by the Initiating Entity that the process is being initiated to support an illegitimate product investigation.
5. If the tracing is being initiated by a Regulator, an attestation that the tracing is being initiated at the request of a Regulator.
6. As optional information, a description of the illegitimate product investigation. [65]

Category

TI Request

Notes

[64]   Subject to confirmation that this will not impede interoperability or automation. Additionally, it is anticipated that the discussion and development of technical specifications will consider how a point-of-contact or other information can be incorporated.

Acceptance Criteria

1. Acceptance Criterion:
   Define the specific conditions that must be met for the requirement to be successfully fulfilled.
   TI Request with investigationReasonAttestation of "Illegitimate Product Investigation" must include tiRequsts for GTIN/NDC and Serial Number.

2. Prerequisites:
   Specify any conditions that need to be met before the interaction can proceed.

   a. Must satisfy Req02 (ATP, ATP-Equivalent or DSCSA Authority)
   b. TI Request passes data format and mandatory element checks as per TI Request schema.
   c. TI Request includes:
      i. Investigation reason Attestation of "Illegitimate Product Investigation", and
      ii. Product Identifier of type "GTIN" or "NDC", and
      iii. Serial Number, and
      iv. investigationCircumstances
   d.

3. Testable Condition:
   Describe how the acceptance criterion can be tested objectively.
   Specify the steps, procedures, or tools used for testing.

   a. productID contains a GTIN or NDC
   b. serialNumberOrLotNumber contains a Serial Number

4. **Pass/Fail Criteria:**

    c. Pass Criteria:

        i. TI Request contains the values defined in Testable Condition

        ii. TI Response contains matching TI or "xx2", "No Records Found"

    d. Fail Criteria:

        iii. TI Request productID is missing, null or does not contain a GTIN or NDC or serialNumberOrLotNumber is missing, null or does not contain a Serial Number.

5. **Expected Successful Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is met.
   Will result in a TI Response conformant with the TI Response schema (or response outside of the electronic network).

6. **Expected Failure Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is unmet.

    a. TI Request does not include one of the required request attributes (GTIN/NDC, Serial Number, Investigation Reason = "Suspect Product Investigation", Investigation Circumstances (made mandatory in Chapter 5).

    b. Will result in a TI Response conformant with the TI Response schema with code "xx2, Request parameter error".

    c. May result in "TI Request Error" message at the TI Request line level.

REQ09 - Initiating a Trace - Recalled Product Investigations

To initiate the Tracing-Recall process, the Initiating Entity shall provide the following:

1. The GTIN, ~~expiration date~~, lot number, and if applicable, the serial number(s).
2. The reason "Recall."
3. An attestation by the Initiating Entity that the process is being initiated on account of a recall.
4. A statement that the tracing is being initiated by a Regulator.
5. As optional information, a description of the recall. [66]

Category

TI Request

Source Document

PDG Blueprint Chapter 1 - Tracing Requirements

Source ID

Requirement-Trac-009

Notes

[65]   Subject to confirmation that this will not impede interoperability or automation. Additionally, it is anticipated that the discussion and development of technical specifications will consider how a point-of-contact or other information can be incorporated.

Acceptance Criteria

1. Acceptance Criterion:
   Define the specific conditions that must be met for the requirement to be successfully fulfilled.
   TI Request with investigationReasonAttestation of "Recalled Product Investigation" must only be made by a DSCSA Authority and include tiRequests for GTIN/NDC and Serial Number or tiRequests for GTIN/NDC and Lot Number.

2. Prerequisites:
   Specify any conditions that need to be met before the interaction can proceed.

   a. Must satisfy Req02 (DSCSA Authority only)
   b. TI Request passes data format and mandatory element checks as per TI Request schema.
   c. TI Request includes:
      i. Investigation reason Attestation of "Recalled Product Investigation", and
      ii. Product Identifier of type "GTIN" or "NDC", and
      iii. Serial Number or Lot Number, and
      iv. investigationCircumstances

3. Testable Condition:
   Describe how the acceptance criterion can be tested objectively.
   Specify the steps, procedures, or tools used for testing.

   a. productID contains a GTIN or NDC

      b. serialNumberOrLotNumber contains a Serial Number or a Lot Number

4. **Pass/Fail Criteria:**
   Clearly define what constitutes a "pass" or "fail" for the acceptance criterion.
   Include any thresholds, tolerances, or standards that must be met.

      e. Pass Criteria:

         iv. TI Request contains the values defined in Testable Condition

         v. TI Response contains matching TI or "xx2", "No Records Found"

      f. Fail Criteria:

         vi. TI Request productID is missing, null or does not contain a GTIN or NDC or serialNumberOrLotNumber is missing, null or does not contain a Serial Number or Lot Number.

5. **Expected Successful Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is met.
   Will result in a TI Response conformant with the TI Response schema (or response outside of the electronic network).

6. **Expected Failure Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is unmet.
   A Non-DSCSA Authority has sent a TI Request with Investigation Reason Attestation of "Recall Investigation"
   Will result in a TI Response conformant with the TI Response schema with code "xx2, Request parameter error".

REQ10 - Initiating a Trace - Regulator, DSCSA Section

If a Regulator is the Initiating Entity, the Regulator's request must clearly indicate whether it is a request for TI and TS under § 582(g)(1)(D) or a request under
§ 582(g)(1)(E)(i) to promptly facilitate gathering the information necessary to produce the TI for each transaction going back to the manufacturer, as applicable.

Note:

> (D) – Regulator only. Results in asking for "your" info (TI received and sent).
> (E) - Regulator or ATP. Results in asking for "your" info and help in contacting TP's.

> Our Design:
> - TI/TS + connectivity for all parties in TI
> - All Known (+ connectivity)
> - Last Known (+ connectivity)

> @ Chapter 1 drafting, a full trace was entertained.
> @ Chapter 5 drafting, we considered confidentiality of information and that Authorities would want control over the investigation and who knew about it (individual TI Requests if needed).

> **Team created a Change Request to address this issue.**

Category

TI Request & Response

Source Document

PDG Blueprint Chapter 1 - Tracing Requirements

Source ID

Requirement-Trac-010

Acceptance Criteria

1. Acceptance Criterion:
   Define the specific conditions that must be met for the requirement to be successfully fulfilled.

   A TI Request initiated from a DSCSA Authority must indicate if the request under § 582(g)(1)(D) or a request under § 582(g)(1)(E)(i).

2. Prerequisites:
   Specify any conditions that need to be met before the interaction can proceed.

   a. Must satisfy Req02 for DSCSA Authority
   b. TI Request passes data format and mandatory element checks as per TI Request schema.

3. Testable Condition:

Describe how the acceptance criterion can be tested objectively.
Specify the steps, procedures, or tools used for testing.

Ti Request investigationCircumstances contains "§ 582(g)(1)(D)" **or** "§ 582(g)(1)(E)(i)".

4. **Pass/Fail Criteria:**
   Clearly define what constitutes a "pass" or "fail" for the acceptance criterion.
   Include any thresholds, tolerances, or standards that must be met.

   a. Pass Criteria:
      Ti Request investigationCircumstances contains "§ 582(g)(1)(D)" **or** "§ 582(g)(1)(E)(i)".
   b. Fail Criteria:
      Failure Of Pass Criteria

5. **Expected Successful Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is met.
   This will result in a TI Response conformant with the TI Response schema (or response outside of the electronic network).

6. **Expected Failure Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is unmet.
   Could result in a TI Response conformant with the TI Response schema:
   a. Despite the exclusion, the ATP may decide to provide a Successful Outcome
   b. "xx2, Request parameter error",
   c. "xx4 Request addressed via your supplied Contact Information".

REQ11 - Output of Tracing - Output Types

Systems and processes for Tracing must enable the return of one of three outputs, as designated by the Initiating Entity: [67]

1.   Each TI associated with the sGTIN being traced, including both the TI generated by each selling ATP and the TI received and captured by each purchasing ATP.

2. A listing of each ATP that has owned the product associated with the sGTIN being traced.

3. Identification of the last ATP known to have owned the product associated with the sGTIN being traced.

Category

TI Response

Source Document

PDG Blueprint Chapter 1 - Tracing Requirements

Source ID

Requirement-Trac-011

Notes

[66]   Stated differently, the Initiating Entity should have the ability to designate which of the three types of output it is seeking. This does not reflect any presumption about how this output is gathered or who gathers the output; it simply defines the output of whatever process is ultimately agreed to. Here again it is important to note that this requirement must be read in conjunction with other requirements, particularly Requirements-Trac-013 and -014.

Acceptance Criteria

1. Acceptance Criterion:
   Define the specific conditions that must be met for the requirement to be successfully fulfilled.

   a.   .

2. Prerequisites:
   Specify any conditions that need to be met before the interaction can proceed.

   a.   Must satisfy Req02 (ATP, ATP-Equivalent or DSCSA Authority)

   b.   TI Request passes data format and mandatory element checks as per TI Request schema.

3. Testable Condition:
   Describe how the acceptance criterion can be tested objectively.
   Specify the steps, procedures, or tools used for testing.
   Allowable TI Request responseTypeRequested are:

   a.   "Transaction Information"

   b.   "All Known Owners"

   c.   "Last Known Owner"

4. **Pass/Fail Criteria:**
   Clearly define what constitutes a "pass" or "fail" for the acceptance criterion.
   Include any thresholds, tolerances, or standards that must be met.

       a. Pass Criteria:
            Allowable TI Request responseTypeRequested is provided.

       b. Fail Criteria:
            Failure Of Pass Criteria

5. **Expected Successful Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is met.

   Will result in a TI Response conformant with the TI Response schema (or response outside of the electronic network) with one of:
   - transactionInformationResponses,
   - ownershipInformationResponses, with either Last Know Owner or a list of All Known Owner information
   .

6. **Expected Failure Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is unmet.

   Will result in a TI Response conformant with the TI Response schema with code "xx2, Request parameter error".

REQ12 - Output of Tracing - Summary TI

With regard to the output in Requirement-Trac-011(1), the TI shall be limited to summary TI information [68] solely for the specific sGTIN(s) being traced. [69]

Category

TI Response

Source Document

PDG Blueprint Chapter 1 - Tracing Requirements

Source ID

Requirement-Trac-012

Notes

[67]   For example, if part of the TI is incorporated into an invoice, the response information shall be limited to only those pieces of information that are statutorily defined TI elements.

[68] For example, if the sGTIN being traced was part of a sale of 100 units, the TI shall be limited to that one individual sGTIN, not TI for all sGTINs in that sale.

Acceptance Criteria

1. Acceptance Criterion:
   Define the specific conditions that must be met for the requirement to be successfully fulfilled.

   a.   .

2. Prerequisites:
   Specify any conditions that need to be met before the interaction can proceed.

   a.   Must satisfy Req02 (ATP, ATP-Equivalent or DSCSA Authority)
   b.   TI Request passes data format and mandatory element checks as per TI Request schema.

3. Testable Condition:
   Describe how the acceptance criterion can be tested objectively.
   Specify the steps, procedures, or tools used for testing.
   No Testable Condition, the TI Response schema defines which data are returned based on the request parameters.

4. **Pass/Fail Criteria:**
   Clearly define what constitutes a "pass" or "fail" for the acceptance criterion.
   Include any thresholds, tolerances, or standards that must be met.
   No Pass/Fail Criteria, the TI Response schema defines which data are returned based on the request parameters.

5. **Expected Successful Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is met.
   Will result in a TI Response conformant with the TI Response schema (or response outside of the electronic network) including (respectively):

1. transactionInformationResponses for the specific GTIN (or NDC) / Serial Number pair.
2. ownershipInformationResponses, with either Last Know Owner or a list of All Known Owner information for the specific GTIN (or NDC) / Serial Number pair.

6. **Expected Failure Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is unmet.

   Will result in a TI Response conformant with the TI Response schema with code "xx2, Request parameter error".

REQ13 - Output of Tracing - Seller and Purchaser TI

With regard to the output in Requirement-Trac-011 and 012, the TI (or a subset of the TI elements) collected shall include both the TI provided by the seller in a given transaction and the TI received and maintained by the purchaser in that transaction, and both the selling ATP and purchasing ATP shall provide their respective information. [70]

Category

TI Response

Source Document

PDG Blueprint Chapter 1 - Tracing Requirements

Source ID

Requirement-Trac-013

Notes

[69]   For example, assume only one transaction has occurred—a sale from manufacturer to wholesale distributor. The manufacturer must provide the relevant information associated with the sale of the product, and the wholesale distributor must provide the corresponding information associated with the purchase of the product. Neither the manufacturer nor the wholesale distributor shall be individually responsible for the information associated with both sides of the transaction.

Acceptance Criteria

1. Acceptance Criterion:
   Define the specific conditions that must be met for the requirement to be successfully fulfilled.
   If TI records exist in the Responders system provided by the Seller and provided to the subsequent Buyer they must be provided in the TI Response.

2. Prerequisites:
   Specify any conditions that need to be met before the interaction can proceed.

   a. Must satisfy Req02 (ATP, ATP-Equivalent or DSCSA Authority)
   b. TI Request passes data format and mandatory element checks as per TI Request schema.
   c. TI Request responseTypeRequested:
      i. "Transaction Information"

3. Testable Condition:
   Describe how the acceptance criterion can be tested objectively.
   Specify the steps, procedures, or tools used for testing.
   Responder has TI Records for the GTIN/NDC – Serial Number/Lot Number parameters.

4. **Pass/Fail Criteria:**
   Clearly define what constitutes a "pass" or "fail" for the acceptance criterion.

Include any thresholds, tolerances, or standards that must be met.

    a. Pass Criteria:

        The responder finds TI records that match the Request that were provided by the Responder's Supplier and provided to the Responder's Customer.

    b. Fail Criteria:

        i. Failure Of Pass Criteria

5. **Expected Successful Outcome:**

Clearly state the expected result or behavior when the system interaction requirement is met.

Will result in TI Response conformant with the TI Response schema (or response outside of the electronic network) including (respectively):

- transactionInformationResponses,
- for the specific GTIN (or NDC) / Serial Number pair for both inbound TI (provided by supplier) and outbound TI (provided to customer).

6. **Expected Failure Outcome:**

Clearly state the expected result or behavior when the system interaction requirement is unmet.

If multiple TI are available (Supplier-provided and provided-to-Customer), return TI (or requested ownership info for a sub-set of TI found, or no response.

REQ14 - Output of Tracing - ATP Responsibility Limitation

Systems and processes for Tracing shall not require an ATP to speak to or bear responsibility for the content of any TI other than the TI that ATP received at the time of purchase and the TI it provided at the time of sale. [71]

Category

TI Response

Source Document

PDG Blueprint Chapter 1 - Tracing Requirements

Source ID

Requirement-Trac-014

Notes

[70] Even if an ATP facilitates the gathering of additional information from other ATPs, it should not be responsible for that other ATP's TI.

Examples:

- The Responder does not include TI gathered as a result of their own trace.
- A Wholesaler that passed through TI for a Dropship (Manufacturer to Dispenser).

Acceptance Criteria

1. Acceptance Criterion:
   Define the specific conditions that must be met for the requirement to be successfully fulfilled.

   a. .

2. Prerequisites:
   Specify any conditions that need to be met before the interaction can proceed.

   a. Must satisfy Req02 (ATP, ATP-Equivalent or DSCSA Authority)
   b. Responder has already conducted a trace on the same parameters, or a wholesaler has passed the Manufacturer's Drop-Ship TI to the Dispenser.
   c. TI Request passes data format and mandatory element checks as per TI Request schema.

3. Testable Condition:
   Describe how the acceptance criterion can be tested objectively.
   Specify the steps, procedures, or tools used for testing.
   Responder provides TI Response based on the request parameters and the TI the Responder received from their supplier and sent to their customer.

4. **Pass/Fail Criteria:**
   Clearly define what constitutes a "pass" or "fail" for the acceptance criterion.

Include any thresholds, tolerances, or standards that must be met.

   a. Pass Criteria:

      i. Responder's TI Response is based on TI they received from their supplier and TI they sent to their customer in the original transactions.

   b. Fail Criteria:

      i. Responder provides TI based on TI gathered in the Responder's Trace process.

5. **Expected Successful Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is met.
   Will result in TI Response conformant with the TI Response schema (or response outside of the electronic network) including (respectively): transactionInformationResponses, for the specific GTIN (or NDC) / Serial Number pair for both inbound TI (<u>as</u> provided by supplier) and outbound TI (provided to customer)

6. **Expected Failure Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is unmet.

   a. Responder fails to provide a TI Response.

   b. Responder provides TI for transactions that they did not participate in as an owner of the product.

REQ15 - Output of Tracing - Confidentiality

A request for Tracing and the outputs of systems and processes for Tracing shall be treated as confidential by all ATPs, and

    (i)   shall only be used for purposes of supporting a suspect or illegitimate product investigation or recall, as relevant, and;

    (ii)   shall only be made available to individuals within the ATP who have a specific need for the information. *… Note, the WG created a change request to add to the definition of investigationReasonAttestation, to attest that the information received will only be used for investigation and Conformance Audit purposes.*

Category

TI Request & Response

Source Document

PDG Blueprint Chapter 1 - Tracing Requirements

Source ID

Requirement-Trac-015

Acceptance Criteria

1. Acceptance Criterion:
   Define the specific conditions that must be met for the requirement to be successfully fulfilled.

   a.   investigationReasonAttestation is a required attribute and is part of the schema verification process.

2. Prerequisites:
   Specify any conditions that need to be met before the interaction can proceed.

   a.   Must satisfy Req02 (ATP, ATP-Equivalent or DSCSA Authority)

   b.   TI Request passes data format and mandatory element checks as per TI Request schema.

3. Testable Condition:
   Describe how the acceptance criterion can be tested objectively.
   Specify the steps, procedures, or tools used for testing.
   Check that investigationReasonAttestation has a value consistent with the enumeration list for the attribute in the TI Request schema.

4. **Pass/Fail Criteria:**
   Clearly define what constitutes a "pass" or "fail" for the acceptance criterion.
   Include any thresholds, tolerances, or standards that must be met.

   a.   Pass Criteria:

         i.   investigationReasonAttestation holds a valid value.

   b.   Fail Criteria:

         i.   Failure Of Pass Criteria

5. **Expected Successful Outcome:**
Clearly state the expected result or behavior when the system interaction requirement is met.
TI Request is processed.

6. **Expected Failure Outcome:**
Clearly state the expected result or behavior when the system interaction requirement is unmet.

    a. A Schema error is returned, or

    b. TI Request is not processed.

REQ16 - Speed of Tracing

The systems and processes for Tracing shall be configurable to enable Responding ATPs the optionality to respond in a rapid automated manner or to manually review the request and respond within one business day. [71]

Category

TI Response

Source Document

PDG Blueprint Chapter 1 - Tracing Requirements

Source ID

Requirement-Trac-016

Notes

[71]   As discussion of the technical specifications to meet this requirement advances, it is recommended that stakeholders consider whether it is feasible to respond more rapidly in certain use cases (e.g., a recall or an output of the list of owners) versus other use cases (e.g., an illegitimate product). It is anticipated that this requirement will evolve as stakeholders continue to evaluate options and solutions and as FDA guidance provides directional input.

Acceptance Criteria

1. Acceptance Criterion:
   Define the specific conditions that must be met for the requirement to be successfully fulfilled.
   TI Responses are given within 1 business day.

2. Prerequisites:
   Specify any conditions that need to be met before the interaction can proceed.

   a. Must satisfy Req02 (ATP, ATP-Equivalent or DSCSA Authority)
   b. TI Request passes data format and mandatory element checks as per TI Request schema.

3. Testable Condition:
   Describe how the acceptance criterion can be tested objectively.
   Specify the steps, procedures, or tools used for testing.
   Time to Respond to a TI Request is greater than 1 business day.

4. **Pass/Fail Criteria:**
   Clearly define what constitutes a "pass" or "fail" for the acceptance criterion.
   Include any thresholds, tolerances, or standards that must be met.

   a. Pass Criteria:
      i. TI Response is provided or contact is made with the Requester within 1 business day.
   b. Fail Criteria:
      i. Failure Of Pass Criteria

5. **Expected Successful Outcome:**
    Clearly state the expected result or behavior when the system interaction requirement is met.
    Will result in a TI Response conformant with the TI Response schema (or response outside of the electronic network) within 1 business day.

6. **Expected Failure Outcome:**
    Clearly state the expected result or behavior when the system interaction requirement is unmet.
    No response is given, or response or contact is made outside of 1 business day.

REQ17 - Audit / Testing

Systems and processes for Tracing-Suspect, Tracing-Illegitimate, and Tracing-Recall must allow tracing for audit or testing purposes. When performed for testing or audit purposes, the systems and process must clearly identify for all Responding ATPs that the tracing process is being performed for the purpose of audit or testing.

Category

TI Request & Response

Source Document

PDG Blueprint Chapter 1 - Tracing Requirements

Source ID

Requirement-Trac-017

Acceptance Criteria

1. Acceptance Criterion:
   Define the specific conditions that must be met for the requirement to be successfully fulfilled.

   a. A Response is provided for TI Requests where investigationReasonAttestation is "Compliance Audit".

2. Prerequisites:
   Specify any conditions that need to be met before the interaction can proceed.

   a. Must satisfy Req02 (ATP, ATP-Equivalent or DSCSA Authority)
   b. TI Request passes data format and mandatory element checks as per TI Request schema.
   c. investigationReasonAttestation contains "Compliance Audit".

3. Testable Condition:
   Describe how the acceptance criterion can be tested objectively.
   Specify the steps, procedures, or tools used for testing.

      i. investigationReasonAttestation = "Compliance Audit"

4. **Pass/Fail Criteria:**
   Clearly define what constitutes a "pass" or "fail" for the acceptance criterion.
   Include any thresholds, tolerances, or standards that must be met.

   a. Pass Criteria:
      i. A TI Response is provided.
   b. Fail Criteria:
      i. Failure Of Pass Criteria

5. **Expected Successful Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is met.

   a. Will result in TI Response conformant with the TI Response schema (or

response outside of the electronic network).

    b. May result in a message of "xx3 Compliance audit Request received."

.

6. **Expected Failure Outcome:**
   Clearly state the expected result or behavior when the system interaction requirement is unmet.

   a. No response is given, or contact made.