



Stewardship and Compliance Incident Management

Key Third Parties



Feb 2024



Stewardship, Compliance, and Quality



Contributing to sustainable agriculture by ensuring product responsibility and product safety data integrity across the product life cycle to build trust with customers, stakeholders and society.

/// We develop stewardship strategies and programs to support innovation and **responsible use of Crop Science products**

/// We collaborate with functions to ensure effective implementation and monitoring of **stewardship procedures and programs**

/// We ensure data supporting regulatory submissions **meets compliance standards**

/// We foster a **robust stewardship and quality** culture across the organization to promote product responsibility and quality standards

/// We **engage externally** to promote industry standards and initiatives to support innovation and responsible management of products

Global

/// **Stewardship, Compliance, and Quality**

NA
/// **SCQ**

LATAM
/// **SCQ**

EMEA
/// **SCQ**

APAC
/// **SCQ**





Stewardship and Compliance Incident Management includes activities under Bayer control and contracted parties in all functions

In Scope:

- regulatory compliance requirements
 - internal procedures and
 - stewardship requirements



Seeds and Traits

Biotech traits, conventional seed, treated seed



Crop Protection

Synthetic chemistry



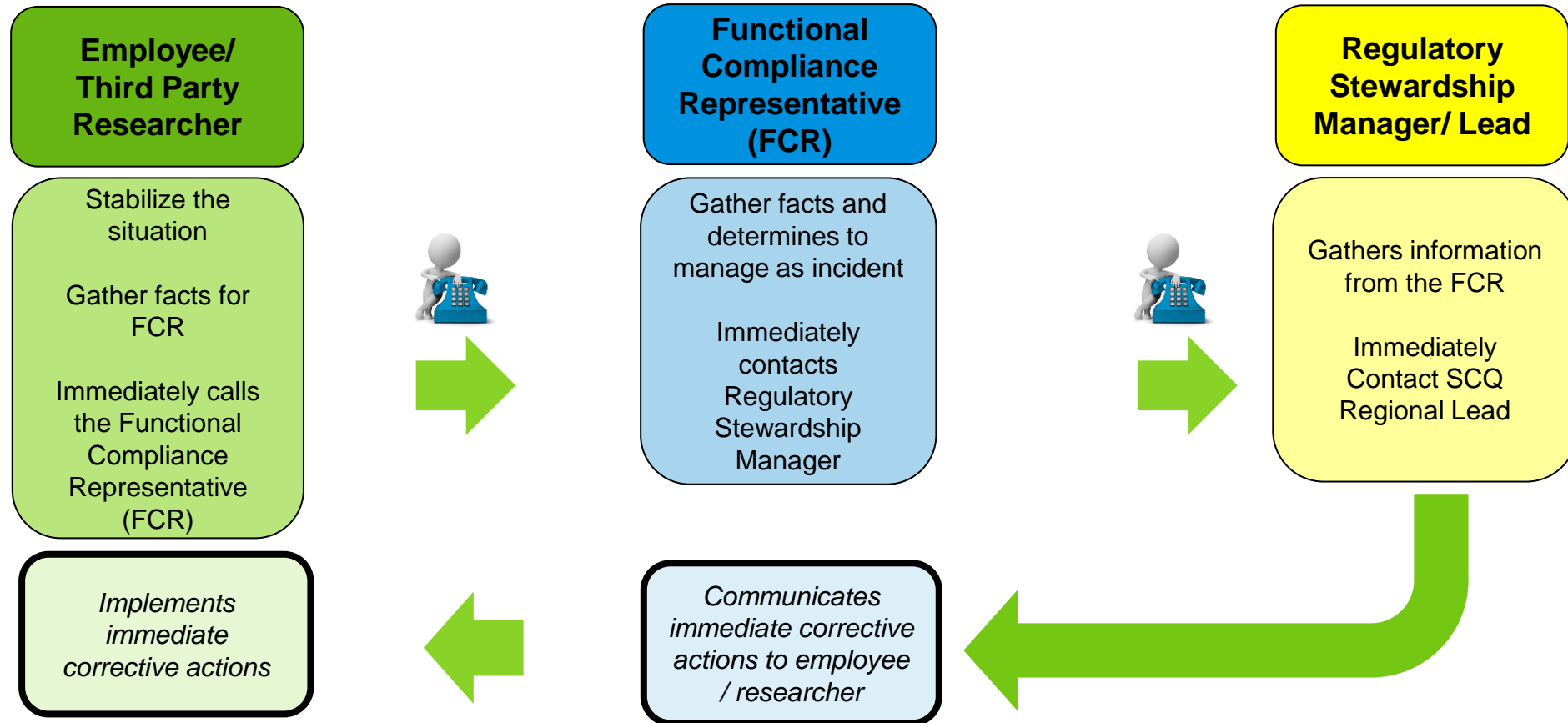
Biosafety

Biological products or microorganisms and insects

*An Incident is an **unintended event** or **occurrence** that **disrupts** or has the **potential to disrupt** operations, commerce, health and safety, the environment, and/or result in non-compliance with relevant regulations or standards for the industry or product.*



Stewardship & Compliance Incident Communication Workflow



If contact not available, call next level

Bayer Determines if escalation of the incident is required and should be the only party communicating the escalation and required corrective actions.



Situations that Require to Manage as Incident

Incidents that involve or potentially involve:

- // a violation of a permit condition, product registration or regulation:
 - // missing or incorrect documentation or labels when shipping
 - // isolation breaches
 - // flowering volunteers in the field
 - // weather damage to confined trials (ex: flooding, run-off, hail, wind, typhoon)
 - // unauthorized, misdirected or lost shipments
 - // animal feeding in confined trial
 - // Introduction of unauthorized chemical treatment in seed
- // loss of containment (ex: trials, labs, shipments)
- // low level presence / adventitious presence - detection of GM event in conventional seed
- // situations that could affect our company reputation, license to operate or product flow to customers
- // stewarded material that has the potential to enter global channels
- // suspected resistance issues
- // product failure

In these situations, call immediately

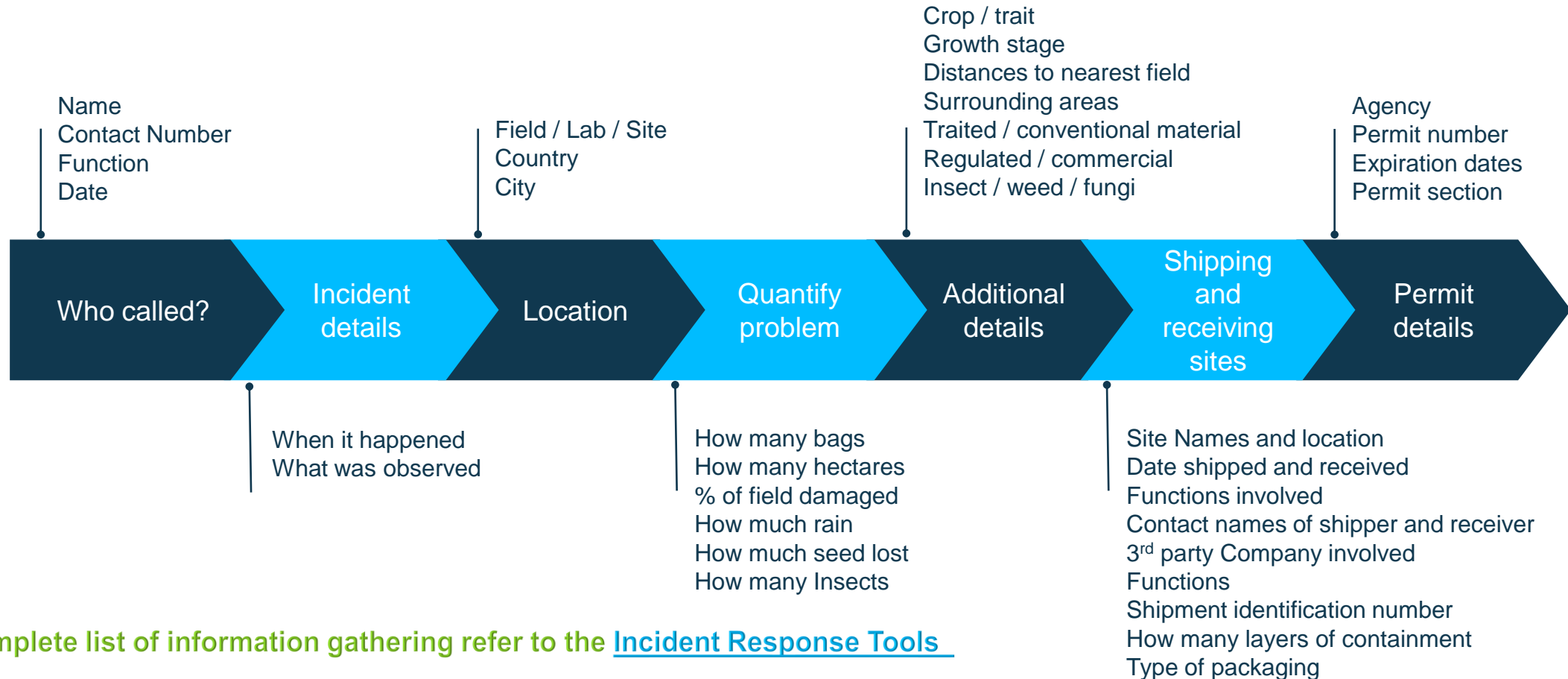


**When in doubt about a situation,
CALL**



Gathering Facts

Examples of initial information gathering for **Seeds, Traits and Biologics** related incidents

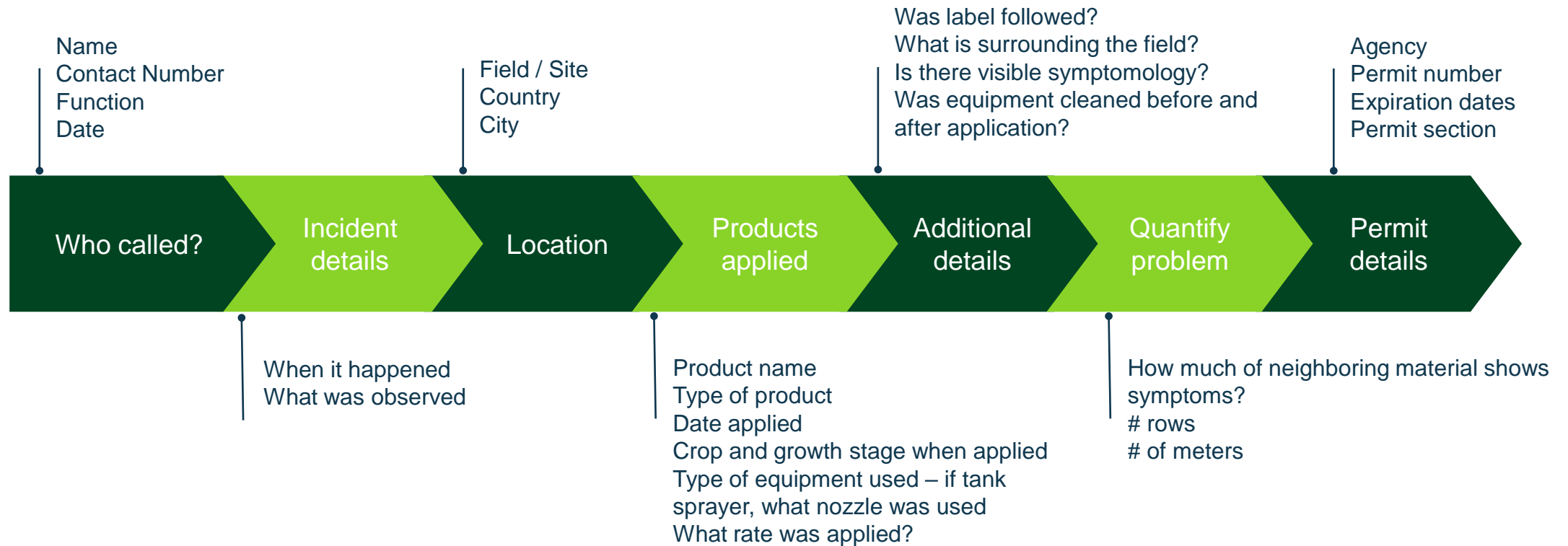


For complete list of information gathering refer to the [Incident Response Tools](#)



Gathering Facts

Examples of initial information gathering for incidents involving **Crop Protection**



For complete list of information gathering refer to the [Incident Response Tools](#)



Important

- Incidents are **confidential** and should be not shared with others without prior approval
- When gathering facts go to a quiet place so people around you do not overhear conversations
- Don't share information with others outside Bayer
- Don't send emails about the issue unless instructed by Bayer
- Don't send pictures unless instructed by Bayer
- After the investigation and/or corrective actions are implemented, don't share information about the issue

FUNCTIONAL COMPLIANCE REPRESENTATIVES

Vegetables – David Campbell – 0400 304 766

Market Development – Ian McMaster – 0400 191 971

Field Solutions – Thomas McGuire - 0408 914 735

STEWARDSHIP LEAD – THERESA DOYLE – 0419 903 506

By completing this training, you understand and agree to comply with Bayer's Incident Management reporting process.



Responsibilities

Employee / Researcher

- // Communication of incidents to Functional Compliance Representative (FCR)
- // Gather facts of the incident
- // Participate in incident investigation and implementation of corrective actions

Functional Compliance Representative - FCR

- // Train employees, researchers, third parties
- // Communication of incidents to Regulatory Stewardship Managers
- // Support incident investigation
- // Ensure implementation of response plan

Regulatory Stewardship Manager/ Lead

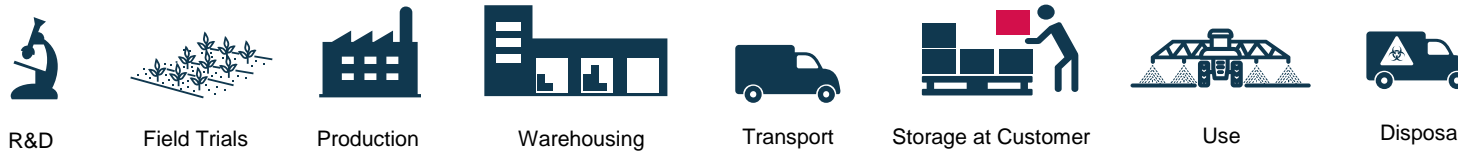
- // Train Functional Compliance Representatives
- // Communicate incidents to Regional Regulatory Stewardship Leads
- // Support incident investigation



Contracted Third Parties

Internal: Before leaving Bayer's Control

External: After leaving Bayer's Control



Warehousing and Transport may be considered internal or external context depending on the case

**Crop protection
Biologicals
Seed Treatment**



**External
Adverse
Incidents for
CCPs**

**Seeds
Traits
Treated Seed**



**Stewardship
and
Compliance
Incident**



*Thank
you*

