

**United States Department of Agriculture
Center for Veterinary Biologics
Standard Operating Procedure**

**General Risk Analysis Process and Procedure for the Center for Veterinary
Biologics Pharmacovigilance Monitoring Committee**

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**General Risk Analysis Process and Procedure for the Center for Veterinary Biologics Pharmacovigilance
Monitoring Committee**

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1. Purpose

This standard operating procedure (SOP) describes the process whereby the Center for Veterinary Biologics (CVB) determines whether action shall be taken on a real, perceived, or potential adverse event.

2. Scope

The policy and processes described in this document apply to issues that are brought to the attention of the Pharmacovigilance Monitoring Committee (PMC). See the current version of [ICSOP0040](#), Section 4.

3. Objective

To provide a uniform, visible process, based on the principles of risk assessment, by which the CVB determines whether action shall be taken on knowledge or data that suggest there is a real, perceived, or potential risk concerning the use of a biological product.

4. Policy

It is the policy of the CVB that action taken on real, perceived or potential adverse events shall be based on a consistent process and accepted principles of risk analysis.

It is also CVB policy that the process for the analysis and that decisions taken shall be adequate to ensure that adequate, appropriate action and precautions are taken to ensure against loss or suffering via regulatory action. The action may include the implementation of new CVB guidance, CVB policy, or regulations, requests for label warnings, action to ensure compliance with regulations, or any other action within our mandate to so ensure.

5. Definitions

The definitions and procedure that follow are based upon the contents of the OIE Handbook on Import Risk Analysis for Animals and Animal Products, Volume 1 (see **Section 8**).

5.1 Risk Analysis: The process composed of risk assessment, risk management, and risk communication

5.2 Risk Assessment: The evaluation of the likelihood and the biological, environmental, perceptual, or political consequences of a licensed product being unsafe

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5.3 Risk Management: The process of identifying, selecting, and implementing measures that can be applied to reduce the level of risk

6. General Procedures

6.1 Incoming information signals the need for analysis and possible remedial action.

Incoming information may include:

- Adverse Event Reports
- A complaint from a member of the public
- A news item
- Data from submissions for licensure
- Peer reviewed literature
- APHIS Programs

6.2 The recipient of the information informs the PMC via the Biologics Epidemiologist (PMC Chairperson). The Biologics Epidemiologist will decide on whether the issue warrants a Risk Assessment.

6.3 The PMC or designee(s) gather(s) information as indicated and appropriate and evaluates the need for action based on a documented Risk Analysis. The PMC or designate(s) first conducts a Risk Assessment:

6.3.1 The Risk Assessment portion of the Risk Analysis shall include, as indicated and appropriate, consideration of:

- Hazard identification
- Hazard characterization
- Exposure assessment
- Risk characterization

The gathered information (see above) may include any information or data pertinent to the issue (e.g., letters, adverse event reports, journal articles, data from studies).

The outcome of the assessment may be quantitative or qualitative. If the outcome is qualitative, the result shall be noted as high, medium, low, or negligible risk. Based on the result, the process may continue to the risk management process (e.g., the result is high) or go to Section 4 of this document (e.g., if the result is negligible and other data indicate action is not warranted).

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6.3.2 The Risk Management portion of the Risk Analysis shall include:

- Risk Evaluation
- Option Assessment
- Monitoring Plan
- Review Plan (as indicated and appropriate)

6.4 The PMC or designee(s) shall document, list, and file the information and the Risk Analysis, formulating a recommendation for action (see the current version of [ICSOP0041](#)). The recommendation shall be documented as a part of a detailed Decision Memorandum to the Compliance Section Leader and CVB Management Teams via the applicable CVB Director; copies of pertinent filed information and the Risk Analysis shall be appended to the decision memo. The Decision Memorandum shall include pro and con statements (see the current version of [ICSOP0041](#)) and function as the Risk Management portion of the Risk Analysis and include the Risk Evaluation, Option Assessment, and Monitoring and Review Plans noted above. The recommendation shall serve as the Monitoring and Review Plans (i.e., the action to be taken and the means by which the action is to be executed, monitored, and/or reviewed).

Examples of a Monitoring Plan:

- An addition or change to the 9 CFR regarding a required label warning for a particular class of products. The action is ultimately executed by CVB-Policy, Evaluation, and Licensing (PEL) Reviewer request, and Inspection and Compliance (IC) monitors the labels at inspection. The execution of the action may include feedback from stakeholders prior to the request.
- An unannounced inspection by IC, with documentation of the inspection and any follow up actions to be taken
- A hold on product, with documentation of remedial action and follow up actions to be taken

6.5 The applicable Director shall respond by signed letter to the PMC regarding the Decision Memorandum. The letter shall indicate the actions to be taken, if any, and by whom (e.g., IC, PEL).

7. Records to be Retained

For each incoming event, the following records shall be retained with the appropriate Directorate, with a copy to be kept by the Chair of the PMC:

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- Documentation of Incoming Event
- The Risk Analysis and Supporting Materials
- The Decision Memorandum
- Meeting Agendas and Minutes (see the current version of [ICSOP0041](#))
- Letter from CVB Director
- Record of Action Taken
- Record of Follow-up Action, including Monitoring and/or Review Plans, as indicated

8. References

World Organization for Animal Health, 2004: OIE Handbook on Import Risk Analysis for Animals and Animal Products, Volume 1.