# Summary Information Format for Environmental Releases

## I. INTRODUCTION

The information requested in the "Summary Information Format for Environmental Releases" is used by the Center for Veterinary Biologics (CVB) to evaluate the safety characteristics of the vaccine microorganism within the context of the target environment. This information is provided to determine: 1) the location and characteristics of the release site; 2) the test dose and total amount of the experimental biologic to be used in the proposed study; 3) the frequency and duration of exposure to the test material; 4) potential escapes into occupational, residential, or outdoor environments; and 5) the individuals, populations, or ecosystems that will be, or may be, exposed to the experimental biologic.

An Environmental Release refers to the release of an experimental vaccine microorganism to the accessible environment. The Accessible Environment is defined as the environment that can be reached by the vaccine microorganism and its progeny.

## II. ENVIRONMENTAL RELEASE

The progression to determine the safety characteristics of an experimental vaccine microorganism eventually requires research involving planned introductions into the environment. Planned Introductions into the Environment refers to the deliberate release of live microorganisms from contained facilities to the environment. CVB recommends and encourages the use of small-scale field tests, when appropriate.

### A. Location of test site

Identify the exact location of the test site. For proposed commercial uses, the conditions under which the vaccine will be used should be identified; e.g., unlimited commercial distribution and use, restricted for use by veterinarians only, small animal veterinary hospitals, commercial poultry houses, etc.

### B. Characteristics of the test site

Identify the size of the test site, including relevant geographical and environmental information. A description of the area surrounding the test site should be provided, including the presence of non-target animal species. The condition of the test site should be documented, as well as previous studies conducted on the test site.

C. Personnel

Identify the personnel conducting the study, including their qualifications, training, and specific role in the study. Appropriate safeguards, education, and training should be provided as needed.

D. Experimental design

Identify the objectives of the release. For small-scale field tests, the protocol of study should include the following information, as appropriate: 1) the number of animals; 2) a description of the animals; 3) the route of administration; 4) the dose; 5) the total amount of test material; 6) frequency and duration of exposure; 7) the method of disposing waste; and 8) decontamination of the test site.

CVB recommends the application of Good Developmental Practices (GDP) in the design of the study. These guidelines were specifically devised by the Organization for Economic Co-Operation and Development (OECD) for small-scale field research with genetically modified plants and microorganisms. The GDP concept is applicable to field tests conducted with vaccine microorganisms. The goal is to design an experiment that will minimize the dissemination of the microorganism, and control the transfer of heterologous genetic material.

E. Potential for escape and dispersal in the environment

The potential for escape and dispersal from the release site should be assessed. Possible exposure to the area surrounding the test site should be considered and evaluated, including the probability of non-target animal exposure.

F. Potential for establishment in the environment

The habitability of the test site and/or environments for the introduced vaccine microorganism is appraised. The following environmental characteristics are evaluated, as appropriate: 1) the presence of other biological organisms; 2) the nutrient status; 3) physicochemical factors; and 4) the presence of toxic chemicals and metabolites.

G. Monitoring

Environmental monitoring is crucial for the success of the risk analysis process; monitoring is an essential part of ensuring that unacceptable or unexpected adverse events do not occur. Thus, appropriate methods and procedures for monitoring the released vaccine microorganism in and around the test site should be identified prior to initiating the study. The monitoring methods should be sensitive and specific. Provisions for recording the results of the monitoring should be in place.

H. Contingency plans in case of adverse event

The sponsor of the proposed study should identify contingency plans in case an adverse event occurs. Contingency plans should include procedures for terminating the study as quickly as possible, and identify methods to stop the shed, spread, or dispersal of the vaccine microorganism once released in the environment.