# GLOSSARY OF TERMS

*The definitions given below have been selected and restricted to those that are likely to be useful to users of this OIE* Terrestrial Manual*.*

- **Absorbance or optical density**

Absorbance, also termed optical density (OD), describes the amount of light transmitted through a medium. Many assays are designed so that the absorbance is proportional to the amount of analyte. OD at a specific wavelength is determined with a spectrophotometer. It is calculated as OD = $\log_{10}$ (incident light/transmitted light)

- **Accuracy**

Nearness of a test value to the expected value for a reference standard reagent of known activity or titre.

- **Assay**

Synonymous with test or test method, e.g. enzyme immunoassay, complement fixation test or polymerase chain reaction tests.

- **Batch**

All vaccine or other reagent, such as antigen or antisera, derived from the same homogeneous bulk and identified by a unique code number.

- **Biohazard (CWA[1] 15793:2011)**

Potential source of harm caused by biological agents or toxins.

- **Biological agent (adapted from CWA 15793:2011)**

Any microorganism including those which have been genetically modified, cell cultures, and parasites, which may be able to provoke any infection, allergy, or toxicity in humans, animals or plants. *Note:* for the purpose of Biorisk Analysis, prions are regarded as biological agents.

- **Biosafety**

Laboratory biosafety describes the principles and practices for the prevention of unintentional exposure to biological materials, or their accidental release.

- **Biosecurity**

Laboratory biosecurity describes the controls on biological materials within laboratories, in order to prevent their loss, theft, misuse, unauthorised access, or intentional unauthorised release.

- **Biorisk (CWA 15793:2011)**

Combination of the probability of occurrence of harm and the severity of harm where the source of harm is a biological agent or toxin. Note: the source of harm may be an unintentional exposure, accidental release or loss, theft, misuse, diversion, unauthorised access or intentional unauthorised release.

1 CWA: CEN Workshop Agreement (2011). CEN: European Committee for Standardization

- **Biorisk analysis (adapted from the OIE *Terrestrial Animal Health Code*)**

The process composed of biohazard identification, biorisk assessment, biorisk management and biorisk communication.

- **Biorisk assessment (CWA 15793:2011)**

Process of evaluating the biorisks arising from biohazards, taking into account the adequacy of any existing controls, and deciding whether or not the biorisk(s) is acceptable.

- **Biorisk Managment Advisor (CWA 15793:2011)**

Individual who has expertise in the biohazards encountered in the organisation and is competent to advise top management and staff on biorisk management issues.

- **Biorisk Management (adapted from OIE *Terrestrial Animal Health Code*)**

Process of identifying, selecting and implementing measures that can be applied to reduce the level of biorisk.

- **Biorisk Management System (CWA 15793:2011)**

Part of an organisation's management system used to develop and implement its biorisk policy and manage its biorisks.

- **Cell line**

A stably transformed line of cells that has a high capacity for multiplication *in vitro*.

- **Centrifugation**

Throughout the text, the rate of centrifugation has been expressed as the Relative Centrifugal Force, denoted by '***g***'. The formula is:

$$\frac{(\text{RPM} \times 0.10472)^2 \times \text{Radius (cm)}}{980} = \boldsymbol{g}$$

where RPM is the rotor speed in revolutions per minute, and where Radius (cm) is the radius of the rotor arm, to the bottom of the tube, in centimetres.

It may be necessary to calculate the RPM required to achieve a given value of ***g***, with a particular rotor. The formula is:

$$\text{RPM} = \frac{\sqrt{g \times 980}\ /\text{Radius (cm)}}{0.10472}$$

- **Cross-reaction**

See 'False-positive reaction'.

- **Cut-off/threshold**

In immunoassays, cut-off or threshold values are those selected for distinguishing between negative and positive test results, and may include an indeterminate or suspicious zone.

- **Dilutions**

Where dilutions are given for making up liquid reagents, they are expressed as, for example, 1 in 4 or 1/4, meaning one part added to three parts, i.e. a 25% solution of A in B.

- v/v – This is volume to volume (two liquids).
- w/v – This is weight to volume (solid added to a liquid).

- **Dilutions used in virus neutralisation tests**

There are two different conventions used in expressing the dilution used in virus neutralisation (VN) tests. In Europe, it is customary to express the dilution before the addition of the antigen, but in the United States of America and elsewhere, it is usual to express dilutions after the addition of antigen.

These alternative conventions are expressed in the *Terrestrial Manual* as 'initial dilution' or 'final dilution', respectively.

- **Efficacy**

Specific ability of the biological product to produce the result for which it is offered when used under the conditions recommended by the manufacturer.

- **False-negative reaction**

Negative reactivity in an assay of a test sample obtained from an animal exposed to or infected with the organism in question, may be due to lack of analytical sensitivity, restricted analytical specificity or analyte degradation, decreases diagnostic sensitivity.

- **False-positive reaction**

Positive reactivity in an assay that is not attributable to exposure to or infection with the organism in question, maybe due to immunological cross-reactivity, cross-contamination of the test sample or non-specific reactions, decreases diagnostic specificity.

- **Final product (lot)**

All sealed final containers that have been filled from the same homogenous batch of vaccine in one working session, freeze-dried together in one continuous operation (if applicable), sealed in one working session, and identified by a unique code number.

- **Harmonisation**

The result of an agreement between laboratories to calibrate similar test methods, adjust diagnostic thresholds and express test data in such a manner as to allow uniform interpretation of results between laboratories.

- **Incidence**

Estimate of the rate of new infections in a susceptible population over a defined period of time; not to be confused with prevalence.

- **In-house checks**

All quality assurance activities within a laboratory directly related to the monitoring, validation, and maintenance of assay performance and technical proficiency.

- **In-process control**

Test procedures carried out during manufacture of a biological product to ensure that the product will comply with the agreed quality standards.

- **Inter-laboratory comparison (ring test)**

Any evaluation of assay performance and/or laboratory competence in the testing of defined samples by two or more laboratories; one laboratory may act as the reference in defining test sample attributes.

- **Laboratory biosafety**

See *Biosafety*.

- **Laboratory biosecurity**

See *Biosecurity*.

- **Master cell (line, seed, stock)**

Collection of aliquots of cells of defined passage level, for use in the preparation or testing of a biological product, distributed into containers in a single operation, processed together and stored in such a manner as to ensure uniformity and stability and to prevent contamination.

- **Master seed (agent, strain)**

Collection of aliquots of an organism at a specific passage level, from which all other seed passages are derived, which are obtained from a single bulk, distributed into containers in a single operation and processed together and stored in such a manner as to ensure uniformity and stability and to prevent contamination.

- **Methods comparison (equivalency testing)**

Determination of certain assay performance characteristics of new or different test methods by means of an inter-laboratory comparison to a standard test method; implied in this definition is that participating laboratories are using their own test methods, reagents and controls and that results are expressed qualitatively.

- **Optical density**

See absorbance.

- **Performance characteristic**

An attribute of a test method that may include analytical sensitivity and specificity, accuracy and precision, diagnostic sensitivity and specificity and/or repeatability and reproducibility.

- **Phylogeography**

Phylogeography is the study of the genetic and geographic structure of populations and species.

- **Potency**

The potency of a biological product is the concentration of the immunologically active component. For a vaccine it is the concentration of the specific immunogen, and for an antiserum it is the concentration of the specific antibody.

- **Precision**

The degree of dispersion (variance, standard deviation or coefficient of variation) within a series of measurements of the same sample tested under specified conditions.

- **Predictive value (negative)**

The probability that an animal is free from infection given that it tests negative; predictive values are a function of the DSe (diagnostic sensitivity) and DSp (diagnostic specificity) of the diagnostic assay and the prevalence of infection.

- **Predictive value (positive)**

The probability that an animal has been infected given that it tests positive; predictive values are a function of the DSe and DSp of the diagnostic assay and the prevalence of infection.

- **Prevalence**

Estimate of the proportion of infected animals in a population at one given point in time; not to be confused with incidence.

- **Primary cells**

A pool of original cells derived from normal tissue up to and including the tenth subculture.

- **Production seed**

An organism at a specified passage level that is used without further propagation for initiating preparation of a production bulk.

- **Proficiency testing**

One measure of laboratory competence derived by means of an inter-laboratory comparison; implied in this definition is that participating laboratories are using the same test methods, reagents and controls and that results are expressed qualitatively.

- **Purity**

Quality of a biological product prepared to a final form and:

a) Relatively free from any extraneous microorganisms and extraneous material (organic or inorganic) as determined by test methods appropriate to the product; and

b) Free from extraneous microorganisms or material which could adversely affect the safety, potency or efficacy of the product.

- **Qualitative Risk Assessment (*Terrestrial Animal Health Code*)**

An assessment where the outputs of the likelihood of the outcome or the magnitude of the consequences are expressed in qualitative terms such as high, medium, low or negligible.

- **Quantitative Risk Assessment (*Terrestrial Animal Health Code*)**

An assessment where the outputs of the of the risk assessment are expressed numerically.

- **Reference Laboratory**

Laboratory of recognised scientific and diagnostic expertise for a particular animal disease and/or testing methodology; includes capability for characterising and assigning values to reference reagents and samples.

- **Repeatability**

Level of agreement between replicates of a sample both within and between runs of the same test method in a given laboratory.

- **Reproducibility**

Ability of a test method to provide consistent results when applied to aliquots of the same sample tested by the same method in different laboratories.

- **Risk (*Terrestrial Animal Health Code*)**

The likelihood of the occurrence and the likely magnitude of the biological and economic consequences of an adverse event or effect to animal or human health.

- **Risk Communication (*Terrestrial Animal Health Code*)**

The interactive transmission and exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions among risk assessors, risk managers, risk communicators, the general public, and other interested parties.

- **Room temperature**

The term ‘room temperature’ is intended to imply the temperature of a comfortable working environment. Precise limits for this cannot be set, but guiding figures are 18–25°C. Where a test specifies room temperature, this should be achieved, with air conditioning if necessary; otherwise the test parameters may be affected.

- **Safety**

Freedom from properties causing undue local or systemic reactions when used as recommended or suggested by the manufacturer and without known hazard to in-contact animals, humans and the environment.

- **Sample**

Material that is derived from a specimen and used for testing purposes.

- **Sensitivity (analytical)**

Synonymous with 'Limit of Detection', smallest detectable amount of analyte that can be measured with a defined certainty; analyte may include antibodies, antigens, nucleic acids or live organisms.

- **Sensitivity (diagnostic)**

Proportion of known infected reference animals that test positive in the assay; infected animals that test negative are considered to have false-negative results.

- **Sensitivity (relative)**

Proportion of reference animals defined as positive by one or a combination of test methods that also test positive in the assay being compared.

- **Specific pathogen free (SPF)**

Animals that have been shown by the use of appropriate tests to be free from specified pathogenic microorganisms, and also refers to eggs derived from SPF birds.

- **Specificity (analytical)**

Degree to which the assay distinguishes between the target analyte and other components in the sample matrix; the higher the analytical specificity, the lower the level of false-positives.

- **Specificity (diagnostic)**

Proportion of known uninfected reference animals that test negative in the assay; uninfected reference animals that test positive are considered to have false-positive results.

- **Specificity (relative)**

Proportion of reference animals defined as negative by one or a combination of test methods that also test negative in the assay being compared.

- **Specimen**

Material submitted for testing.

- **Standard Reagents**

- **International Standard Reagents**

  Standard reagents by which all other reagents and assays are calibrated; prepared and distributed by an International Reference Laboratory.

- **National Standard Reagents**

  Standard reagents calibrated by comparison with International Standard Reagents; prepared and distributed by a National Reference Laboratory.

- **Working Standards (reagents)**

  Standard reagents calibrated by comparison with the National Standard Reagent, or, in the absence of a National Standard Reagent, calibrated against a well-characterised in-house standard reagent; included in routine diagnostic tests as a control and/or for normalisation of test results.

- **Sterility**

Freedom from viable contaminating microorganisms, as demonstrated by approved and appropriate tests.

- **Test method**

Specified technical procedure for detection of an analyte (synonymous with assay).

- **Tests**
- **Prescribed**

  Test methods that are required by the OIE *Terrestrial Animal Health Code* for the international movement of animals and animal products and that are considered optimal for determining the health status of animals.

- **Screening**

  Tests of high diagnostic sensitivity suitable for large-scale application.

- **Confirmatory**

  Test methods of high diagnostic specificity that are used to confirm results, usually positive results, derived from other test methods

- **Thermotolerant**

  The term used to describe the ability of a vaccine and/or the parent virus/strain to retain a level of infectivity after exposure to heat, that is, the delayed heat degradation of the virus. For example, for the thermotolerant I-2 Newcastle disease vaccine, it is defined by the length of time the vaccine will retain an infectivity titre sufficient to induce a protective immune response, at a particular temperature. The term “delayed heat degradation” may also be encountered, but the term “thermotolerant” is preferred. The terms “heat resistant” and “thermostable” are considered to create unrealistic expectations of a vaccine’s properties and should be avoided.

- **Vaccine**

  Includes all products designed to stimulate active immunisation of animals against disease, without regard to the type of microorganism or microbial component or toxin from which they may be derived or that they contain.

- **Working seed**

  Organism at a passage level between master seed and production seed.

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