Provisional Translation (as of July 2026)*

Administrative Notice

March 31, 2026

To: Division of Pharmaceutical Affairs, Prefectural Health Department (Bureau)

Pharmaceutical Evaluation Division,
Pharmaceutical Safety Bureau,
Ministry of Health, Labour and Welfare

Medical Device Evaluation Division,
Pharmaceutical Safety Bureau,
Ministry of Health, Labour and Welfare

Partial Revision of "Questions and Answers (Q&A) on the Operation of the Standards for Biological Raw Materials"

The operation of the Standards for Biological Raw Materials (MHLW Notification No. 210 of 2003) has been indicated by the "Standards for Biological Raw Materials, Operational Guideline" (PFSB/ELD Notification No. 1002-1 and PFSB/MDRMPE Notification No. 1002-5, dated October 2, 2014, issued by the Director of the Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, and the Counsellor of Minister's Secretariat, Ministry of Health, Labour and Welfare (Person in charge of review control of medical devices, regenerative medical products, etc.). In addition, the related Questions and Answers (Q&A) have been provided by the administrative communication entitled "Questions and Answers (Q&A) on the Operation of the Standards for Biological Raw Materials" (administrative notice, dated June 30, 2015, issued by the Evaluation and Licensing Division and the Office of the Counsellor for Medical Devices and Regenerative Medical Products, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare).

In line with the enforcement of the "Partial Revision of the Standards for Biological Raw Materials, Operational Guideline" ((PSB/PED Notification No. 0331-1 and PSB/MDED Notification No. 0331-1, dated March 31, 2026, issued by the Director of the Pharmaceutical Evaluation Division and the Director of the Medical Devices Evaluation Division, Pharmaceuticals Bureau, Ministry of Health, Labour and Welfare), the Questions and Answers (Q&A) on the operation of the Standards for Biological Raw Materials have been revised as attached. Please take note of this revision and ensure dissemination to relevant stakeholders under your jurisdiction.

With the issuance of this administrative communication, the administrative communication entitled "Handling of Drugs, etc. Using Master Cell Banks or Master Seeds that Do Not Meet the Standards for Biological Raw Materials" (dated March 27, 2009, issued by the Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare) is hereby abolished.

In addition, a copy of this administrative notice will be provided to the relevant organizations listed separately, for your information.

Attachment

Q&A on the operation of the Standards for Biological Raw Materials

Q1 In Section 1(2) of the "Standards for Biological Raw Materials, Operational Guideline" (PFSB/ELD Notification No. 1002-1 and PFSB/MDRMPE Notification No. 1002-5, dated October 2, 2014, issued by the Director of the Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, and the Counsellor of Minister's Secretariat, Ministry of Health, Labour and Welfare (Person in charge of review control of medical devices, regenerative medical products, etc.); hereinafter referred to as the "Operational Guideline"), it is stated that: "Source materials that are the master cell bank or master seed used for manufacture of drugs, etc. for which sufficient characteristic analysis of pathogens and denial of contamination with pathogens have been done, and that have been used in the process of establishing them. However, it is limited to those for which the applicability to source materials specified in the relevant standards has been confirmed in the approval review for drug, etc." Source materials used in the establishment of master cell banks (MCB) or master seeds (MS) for vaccines or viral vectors that were prepared relatively long ago fall under the scope of the Standards for Biological Raw Materials; however, due to the unavailability of detailed information, it is difficult to confirm their compliance with the Standards for Biological Raw Materials. How should such cases be handled?

A1 Based on past product-specific risk assessment results reviewed by the Pharmaceutical Affairs and Food Sanitation Council (currently the Pharmaceutical Affairs Council), the theoretical risk of source materials used in master cell banks or master seeds (hereinafter referred to as "MCB, etc.") has been evaluated to be extremely low. Therefore, if either (a) or (b) below is satisfied, the regulatory handling of source materials used in MCB, etc. may be processed solely by the administrative office without reporting to the Pharmaceutical Affairs Council. In such cases, the appropriateness should be described in the approval document pursuant to the provisions of Paragraph 9 of Chapter I or Paragraph (4) of Section 1, Chapter IV of the "Standards for Biological Raw Materials", and the use of such raw materials may be permitted. In addition, no information disclosure measures, such as those in package inserts, will be required.

It should be noted that the raw materials used in the establishment of MCB, etc. must be described in the manufacturing method section of the approval document. In principle, source materials that comply with the "Standards for Biological Raw Materials" should be used. Even for drugs, etc. that fall under the categories described above, when MCB, etc. are re-established, efforts should be made to switch to source materials that comply with the "Standards for Biological Raw Materials".

(a) In cases where some information on safety assurance measures can be obtained through retrospective investigation, all of the following seven conditions must be satisfied:

(1) Through retrospective investigation, it can be confirmed that, at the time of manufacture of the relevant MCB, etc., safety assurance measures against bacteria, viruses, and other adventitious pathogenic microorganisms were implemented, or there is a high probability that such measures were

implemented, for raw materials that did not comply with the provisions of the “Standards for Biological Raw Materials” that were used at that time.

(2) In purity tests conducted on the MCB, etc., contamination by bacteria, viruses, or other adventitious pathogenic microorganisms that could be assumed to originate from source materials not complying with the “Standards for Biological Raw Materials” has been ruled out.

(3) Sufficient virus clearance has been demonstrated in the manufacturing process of the drug substance or drug product. However, this condition does not apply where the MCB, etc. consist of a cellular substrate in which viruses cannot proliferate through culture during the manufacturing process (e.g., bacteria, yeast, etc.). In addition, for MCB, etc. of live vaccines, where sufficient safety information is available based on clinical use experience (including overseas use and clinical trial experience) of other live vaccines manufactured using MCB, etc. derived from a common seed strain, this condition does not apply, provided that it is confirmed that adequate quality and manufacturing controls were implemented during the establishment process of the relevant MCB, etc.

(4) If ruminant-derived raw materials, etc. that do not comply with the Standards for Ruminant-Derived Raw Materials were used, it can be confirmed, based on the geographical BSE risk (GBR) of the country of origin at the time of manufacture of the source materials and at the time of preparation of the MCB, etc., as well as the global epidemiological situation, that source materials derived from animals affected with transmissible spongiform encephalopathies (TSE) were not used, or there is a high probability that they were not used.

(5) If ruminant-derived raw materials that do not comply with the Standards for Ruminant-Derived Raw Materials were used, the criteria for safety assurance set forth in “Handling of Risk Evaluation, etc. in Application for Partial Change for Drugs, Medical Devices, etc. Using Bovine-Derived Raw Materials” (PFSB/ELD Notification No. 0801001 and PFSB/SD Notification No. 0801001, dated August 1, 2003) is satisfied.

(6) If human-derived raw materials were used, such materials comply with the provisions of the “Standards for Biological Raw Materials”.

(7) If there is an accumulation of safety information based on clinical use experience (including overseas use and clinical trial experience), no reports of infectious diseases considered to be attributable to the relevant source materials have been identified.

(b) In cases where it is difficult to obtain information on safety assurance measures through retrospective investigation, but clinical use experience (including overseas use and clinical trial experience) exists, all of the following five conditions must be satisfied:

(1) In purity tests conducted on the MCB, etc., contamination by bacteria, viruses, or other adventitious pathogenic microorganisms that could be assumed to originate from source materials not complying with the “Standards for Biological Raw Materials” has been ruled out.

(2) Sufficient virus clearance has been demonstrated in the manufacturing process of the drug substance or drug product. However, this condition does not apply where the MCB, etc. consist of a cellular substrate in which viruses cannot proliferate through culture during the manufacturing process (e.g., bacteria, yeast, etc.). In addition, for MCB, etc. of live vaccines, where sufficient safety information is available based on clinical

use experience (including overseas use and clinical trial experience) of other live vaccines manufactured using MCB, etc. derived from a common seed strain, this condition does not apply, provided that it is confirmed that adequate quality and manufacturing controls were implemented during the establishment process of the relevant MCB, etc.

(3) There is a sufficient accumulation of safety information based on clinical use experience (including overseas use and clinical trial experience), and no reports of infectious diseases considered to be attributable to the relevant source materials have been identified.

(4) If ruminant-derived raw materials that do not comply with the Standards for Ruminant-Derived Raw Materials were used, or may have been used, for example, safety information exists based on clinical use experience (including overseas use and clinical trial experience) over a period sufficiently exceeding the incubation period of prion diseases, and no reports of infection with pathogenic prions considered to be attributable to the relevant source materials have been identified.

(5) If human-derived raw materials that do not comply with the Standards for Biological Raw Materials were used, or may have been used, for example, safety information exists based on clinical use experience (including overseas use and clinical trial experience) over a period sufficiently exceeding the incubation periods of human-derived infectious diseases caused by contamination with hepatitis B virus, hepatitis C virus, human immunodeficiency virus, pathogenic prions, etc., and no reports of infectious diseases considered to be attributable to the relevant source materials have been identified.

Q2 Does the term “drugs, etc. that have obtained marketing authorization” as used in “General Notices 10” referred to in Section 1(3) of the Operational Guideline include “raw materials, etc. used in drugs, etc. that have obtained marketing authorization”?

A2 No, it does not. This is because the safety at the time of marketing authorization is evaluated for drugs, etc. as final products, and the viral safety of individual raw materials, etc. is not directly evaluated.

Q3 Section 3(3) of the Operational Guideline states that “it should be noted that”. Specifically, what measures should be taken?

A3 For example, the following may be considered: available information such as the viral infection history and infection status of the biological mother may be used to assess the risk of viral transmission from the mother to the donor.

If it is determined that the likelihood of transmission of hepatitis B virus, hepatitis C virus, human immunodeficiency virus, and human T-cell leukemia virus from the biological mother to the donor is sufficiently low even without testing the biological mother, serological tests and nucleic acid amplification tests of the biological mother may be omitted (refer to the table below).

	Donor age in months	1 month or younger	2 to 18 months	19 months or older
Donor	Viral testing	Can be omitted	Required	Required
Donor's biological mother	Evaluation of the risk of viral transmission to the donor	Required	Required	Can be omitted
	Viral testing	Required	Can be omitted depending on the case	Can be omitted

Note:

"Age in months" should be calculated by counting one month on the calendar day corresponding to the day of birth in the following month, with the last day of the month used when no corresponding day exists.

Q4 Under Section 3(3) of the Operational Guideline, in risk assessments for neonatal or infant donors, if infection of the biological mother with hepatitis B virus, hepatitis C virus, human immunodeficiency virus, or human T-cell leukemia virus is suspected, or if positive test results for the biological mother are obtained, are cells or tissues derived from such donors prohibited from use?

A4 Cells or tissues derived from such donors should not be used as human cell/tissue-derived raw materials, etc. If it cannot be confirmed that the biological mother is not infected, cells or tissues derived from the donor should not be used even when test results of donor-derived samples are negative, as the donor's immune system may be immature and the target viruses may be present below the detection limit of the tests.

Q5 In Section 3(6) of the Operational Guideline, what does "timing is not appropriate" specifically refer to?

A5 The term "timing is not appropriate", includes, for example, situations in which the donor has received blood transfusions or infusions after the collection of cells or tissues, resulting in dilution of infectious agents in blood samples and potential loss of reliability of test results. Therefore, if transfusion or infusion is anticipated for the donor, tests may be conducted using blood samples collected in advance, rather than samples collected at or after the time of the cell or tissue procurement.

Q6 In Section 3(6) of the Operational Guideline, how should "viral testing conducted at an appropriate stage of the manufacturing process" be specifically demonstrated?

A6 With regard to the appropriateness of test samples for viral testing, test items, and test methods, reference should be made to the following, among others:

"Partial Revision of Ensuring Quality and Safety of Products Derived from Human Processed iPS(-like) Cell (allogeneic cells)" (PMSB Notification No. 0117-11, dated January 17, 2025)

ICH Q5A(R2): "Partial Revision of Guideline of Viral Safety Evaluation of Biotechnology Products Derived

from Cell Lines of Human or Animal Origin" (PSB/PED Notification No. 0109-3, dated January 9, 2025) "Technical Guidance for Quality, Nonclinical Safety Studies and Clinical Studies of Regenerative Medical Products (Human Cell-Processed Products)" (Administrative Notice of Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare, dated June 27, 2016)

Q7 In Section 3(6) of the Operational Guideline, if "the qualifications of facilities and personnel for infection testing, and the reliability of test data are sufficiently ensured", is re-tests for human T-cell leukemia virus and parvovirus B19—whose absence of infection is required to be confirmed for donors of human (allogeneic) cell or tissue raw materials for human cell-processed products—necessary?

A7 The re-test is not necessarily required. Human T-cell leukemia virus (HTLV) has two types, HTLV-1 and HTLV-2, and Japan is known as an endemic area for HTLV-1. Almost all current HTLV infections in Japan are HTLV-1. The risk of HTLV-1 infection in human cell/tissue-derived raw materials can be sufficiently reduced by conducting interviews and medical examinations, performing antibody screening tests on samples collected at or around the time of collection of such raw materials, and conducting viral testing at appropriate stages of the manufacturing process, such as at the cell bank stage; therefore, the re-test for HTLV is not considered necessary. Parvovirus B19 infection generally does not cause symptoms as severe as those caused by hepatitis B virus, hepatitis C virus, human immunodeficiency virus, or HTLV-1 infection.

For parvovirus B19, interviews and medical examinations combined with testing of samples collected at or around the time of collection of the human cell/tissue-derived raw materials are generally sufficient. However, considering the background of patients receiving the final drug product, if particular caution is deemed necessary regarding parvovirus B19 infection, it is necessary to separately evaluate the need for additional risk-reduction measures and to consider post-administration infection risk management plans.

Q8 In Sections 3(6) and (7) of the Operational Guideline, how should it specifically be demonstrated that "the qualifications of facilities and personnel for infection testing, and the reliability of test data are sufficiently ensured"?

A8 To demonstrate that "the qualifications of facilities and personnel for infection testing, and the reliability of test data are sufficiently ensured," all of the following requirements must be satisfied:

(1) Where the intended test can be performed appropriately, based on the latest scientific knowledge, by using medical devices or in vitro diagnostic reagents that have obtained marketing authorization in Japan in accordance with the instructions for use provided in the package insert, either such devices or reagents should be used in accordance with the instructions for use in the package insert, or testing equipment or reagents that have been verified to have specificity and sensitivity equivalent to or greater than those devices or reagents should be used in accordance with the conditions applied at the time of such verification.

Conversely, where the intended test cannot be appropriately performed by using medical devices or in vitro diagnostic reagents that have obtained marketing authorization in Japan in accordance with the instructions for use provided in the package insert, testing equipment or reagents that have been verified to have

appropriate specificity and sensitivity based on the latest scientific knowledge, should be used in accordance with the conditions applied at the time of such verification.

(2) The intended test should be conducted by entities falling under Item 1, 2, or 4 of Section I of the "Notification on the Enforcement of the Ministerial Ordinance for the Maintenance of MHLW-Related Ministerial Ordinances in connection with the Partial Enforcement of the Act for Partial Revision of the Medical Care Act, etc." (HPB Notification No. 0810-1, dated August 10, 2018, issued by the Director-General of the Health Policy Bureau, Ministry of Health, Labour and Welfare; hereinafter referred to as the "Ministerial Ordinance Enforcement Notification"), such as hospitals, contractors engaged in specimen testing services, or clinical laboratories.
In addition, clinical laboratories should, in principle, be those that have been registered with the prefectural governor of their location in accordance with the "Guidelines for Clinical Laboratories" (HPB Notification No. 0329-24, dated March 29, 2021, issued by the Director-General of the Health Policy Bureau, Ministry of Health, Labour and Welfare, Attachment 1).
(3) In accordance with the Ministerial Ordinance Enforcement Notification, it is required that a quality management system for the testing institution with respect to the intended test be properly established, and that "third-party accreditation of testing facilities, such as ISO 15189", which is recommended in the said Ministerial Ordinance Enforcement Notification, has been obtained. In this context, "ISO 15189, etc." includes not only ISO 15189 but also, for example, CLIA (Clinical Laboratory Improvement Amendments) and CAP-LAP (the Laboratory Accreditation Program by the College of American Pathologists).
(4) Internal quality control and participation in external quality assessment programs, which are stipulated as efforts to be made by hospitals, etc. under the Ministerial Ordinance Enforcement Notification, are implemented with respect to the intended test. In this regard, external quality assessment programs should be those conducted under the leadership of a third-party organization accredited as a proficiency testing provider (e.g., CLIA programs, CAP surveys, or other inter-laboratory comparison programs conforming to the relevant requirements of ISO/IEC 17043).

Q9 For low-risk raw materials, etc.[1)] , is it permissible to omit to describe a country of origin in an application form or registration form of a master file (MF) as indicated in Attachment 3 of the Standards for Biological Raw Materials, Operational Guideline?
In such cases, is it permissible to delete the description regarding a country of origin of low-risk raw materials, etc. from an approval letter or MF by submitting a minor change notification?

A9 Yes, to both questions. Refer to an example for the description of an application form for "low-risk raw materials, etc." in Attachment 3 of the Operational Guideline. In this case, it is acceptable to leave a country of origin field for bovine-derived source materials, etc. blank in sections of composition or manufacturing method in an application form or MF registration application form. It is not necessary to submit a minor change notification solely for this change. It is acceptable to make this minor

1) For definition, refer to the "Standards for Biological Raw Materials" (MHLW Notification No. 210, 2003).

change notification along with other minor change notification or partial change application.

Q10 For low-risk raw materials, etc., is it permissible to delete TSE information (data number) from an approval letter by submitting a minor change notification?

A10 Yes, it is.

Q11 As shown in Section II-5 (3) of the Partial Revision of the Standards for Biological Raw Materials (PFSB Notification No. 1002-27, October 2, 2014), low-risk raw materials, etc. are considered highly likely to have risk-causative agents inactivated or removed during the manufacturing process. Therefore, is it permissible to assume that the exemption, etc. indicated in the proviso of (2), and (3) of the Standards for Ruminant-Derived Raw Materials are applied even if the materials were manufactured before the date on which the countries were accredited as having "a negligible BSE risk" by the World Organization for Animal Health (WOAH, founded as OIE)?

A11 Yes, it is.

Q12 For ruminant-derived raw materials, is it still prohibited to use hazardous parts as the source of bone gelatin for the use of capsules, etc. in Japan?

A12 As before, the use of hazardous parts from ruminant animals is prohibited. Therefore, be aware of the differences from food regulations, and information about the country of origin, the parts and age in month of the ruminant animals should be checked when obtaining raw materials for gelatin and its source material.

Q13 In cases where any country of origin of low-risk raw materials, etc. is already described in an approval letter or MF, is a partial change application or a minor change notification required to add the new country of origin to those documents?

A13 No, it's not required. Since the restriction on a country of origin has been abolished for low-risk raw materials, etc., neither partial change application nor minor change notification is required to add a country of origin.

Q14 For ruminant-derived raw materials listed in the Operational Guideline 5 (2) a, is it permissible not to include the description indicated in Attachment 3 of the Operational Guideline in an application form or a MF registration application form? In this case, is it permissible to delete such information from the approval letter or MF by submitting a minor change notification?

A14 Yes, to both questions. It is not necessary to submit a minor change notification solely for this change. It is acceptable to make this minor change notification along with other minor change notification or partial change application. However, regarding ruminant-derived raw materials applicable to the Operational Guideline 5 (2) b, c and d, a partial change application is required to delete the description, as it is necessary to identify and review the raw materials and the treatment, etc.

Q15 Section 5(2) b of the Operational Guideline states: "for which it can be evaluated that the safety of the product is ensured based on the clearance values of prions that may contaminate raw materials, etc. calculated based on the simulation of the dilution rate in the manufacturing process of raw materials, etc. or the reduction rate of prions in the purification process." Is there any specific indicator for prion clearance values by which the safety of a product can be assessed as ensured?

A15 At present, there is no specific indicator for prion clearance values by which the safety of a product can be assessed as ensured. Section 5(2)b of the Operational Guideline has been described taking into account the possibility that such indicators or methodologies may be established in the future.

Q16 For ruminant-derived raw materials, etc., is it permissible to submit a minor change notification to add a country of origin newly accredited as having "a negligible BSE risk" by WOAH to an approval letter or MF?

A16 Yes, it is. However, this is limited to cases where the source of the raw materials, etc. were collected after the date on which the country was accredited and publicly recognized as having "a negligible BSE risk" by WOAH. For drugs, etc.[2)] that are manufactured using ruminant-derived raw materials, etc. from countries that were previously prohibited as countries of origin but are now accredited as such, and that have been approved under the condition that the ruminant-derived raw materials, etc. are required to be switched at the time of approval, the collection date of the source materials should be stated in the approval letter to ensure clarity in handling (Refer to Q17).

Q17 Regarding the drugs, etc. that were approved under the condition that the country of origin of ruminant-derived raw material is required to be switched from the United States (U.S.) to countries conforming to the Standards for Biological Raw Materials, there is no need to switch the U.S.-origin ruminant-derived raw materials on the basis of safety, since U.S. has become an accredited country. Is it not obligatory to comply with the requirement to switch the raw materials at the time of approval? Additionally, how should deleted the description regarding the timing of switch in the approval letter or the relevant information in the package insert or the MHLW website?

A17 The U.S. was recognized as a country with negligible BSE risk on May 29, 2013, by WOAH. Consequently, bovine-derived raw materials manufactured from source materials collected in the U.S. before the accreditation date must still be switched. However, bovine-derived raw materials manufactured from source materials collected in the U.S. after the accreditation date do not have to be switched as these materials conform to the "Standards for Biological Raw Materials".

Since the situation differs for each product, please consult with the Pharmaceuticals and Medical Devices Agency individually regarding the method for deleting the relevant description (e.g., timing of switch) from the application form, etc.

Q18 Do insect-derived cell banks fall under "a characterized animal-derived cell bank" in the Standards

2) For definition, refer to the "Standards for Biological Raw Materials" (MHLW Notification No. 210, 2003).

for Animal-Derived Raw Materials (2)?

A18 Yes, they do. While insect-derived cell banks have been used in the manufacturing processes of some products, it is not known whether viruses that persist and proliferate during the culture of insect-derived cell banks are the same as viruses that persist and proliferate in the original insect hosts. Therefore, as before, insect-derived cell banks are treated as being included in "a characterized animal-derived cell bank" in the Standards for Animal-Derived Raw Materials (2).

Q19 Are the conditions listed in Attachment 1 of the Operational Guideline applicable to "the treatment steps to inactivate or remove any pathogens including viruses, etc." in the Standards for Animal-Derived Raw Materials (4)?

A19 Yes, it is. Refer to ICH-Q5A(R2): "Partial Revision of Guideline of Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin" (PSB/PED Notification No. 0109-3, dated January 9, 2025) for evaluation when processing is not performed under the conditions listed in Attachment 1 or under more stringent conditions.

Q20 For animals-derived raw materials, etc., when it is confirmed in a review that donor animals are healthy, is it permissible to omit to describe a country of origin or a part of use in an application form or MF registration application form as described in Attachment 3 of the Operational Guideline?

A20 Yes, it is. However, this is not applicable to raw materials, etc. subject to the Standards for Ruminant-Derived Raw Materials. This does not apply either when it is deemed necessary during a review, for example, when treatment conditions are specified depending on a part of use.

Q21 For the animal-derived raw materials, etc., when the materials are processed under the conditions listed in Attachment 1 of the Operational Guideline or under more stringent conditions, is it permissible to omit to describe a country of origin or a part of use in an application form or a MF registration application form as indicated in Attachment 3 of the Operational Guideline, notwithstanding the Operational Guideline 7 (4)? In this case, is it permissible to delete such information from the approval letter or MF by submitting a minor change notification?

A21 Yes, to both questions. However, this is not applicable to raw materials, etc. subject to the Standards for Ruminant-Derived Raw Materials. It is not necessary to submit a minor change notification solely for this change. It is acceptable to make this minor change notification along with other minor change notification or partial change application.

Q22 It is stated that the name of ingredients derived from human or other living organisms, as well as the name of the origin of these ingredients and their part of use, etc. should be described in package insert "according to the description in the approval letter" in Section III-1 (3) ① and III-2 (2) ①, Attachment 1 of "Instructions for Package Inserts of Biological Products" (PFSB/SD Notification No. 0520004, May 20, 2003). In cases where it is deemed not necessary to describe the country of origin

or the part of use in an application form according to the Standards for Biological Raw Materials, is it permissible to omit to describe the country of origin or the part in the package insert?

A22 Yes, it is. However, from the perspective of providing appropriate information in the package insert, there may be cases where description of the part of use, etc. is required in the review to clarify the ingredients used.

Q23 With regard to the raw materials newly added in Attachment 2 of the Operational Guideline, is it permissible to delete the corresponding descriptions from the approval letter or MF for already approved products, which were described in Attachment 3 of the Operational Guideline, by submitting a minor change notification?

A23 Yes, it is. However, this is not applicable to raw materials, etc. subject to the Standards for Ruminant-Derived Raw Materials. It is not necessary to submit a minor change notification solely for this change. It is acceptable to make this minor change notification along with other minor change notification or partial change application.