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Body: Ministry of Agriculture and Livestock/Secretariat of Agricultural Defense

ORDINANCE SDA/MAPA NO. 1,136, OF JUNE 25, 2024

Establishes guidelines for rework, revalidation and reprocessing procedures for formulated products, technical products and pre-mixtures, of a chemical nature, provided for by Law No. 14,785, of December 27, 2023, in accordance with the provisions of art. 38.

THE SECRETARY OF AGRICULTURAL DEFENSE OF THE MINISTRY OF AGRICULTURE AND LIVESTOCK, in the use of the powers conferred on him by arts. 22 and 49 of Annex I of Decree No. 11,332, of January 1, 2023 and in view of the provisions of Law No. 14,785, of December 27, 2023 and what appears in Process No. 21000.078206/2023-10, resolves:

Art. 1º The guidelines for the procedures for reworking, revalidation and reprocessing of formulated products, technical products and premixes of a chemical nature are hereby established in accordance with the provisions of art. 38 of Law No. 14,785, of December 27, 2023.

Art. 2 For the purposes of this Ordinance, the definition of traceability is applied as the set of procedures that allows the verification of all stages of rework, revalidation or reprocessing of formulated products, premixes and technical products, through informative and documentary elements registered;

Sole paragraph. The definitions of reprocessing, rework and revalidation are established in Law No. 14,785 of 2023.

Art. 3 Formulated products, pre-mixes and technical products may be subjected to rework within the validity period and which present:

I - primary or secondary packaging that is damaged or requires changing packaging to another packaging capacity, as long as there has been no leakage or contact of its contents with the external environment;

II - compromise of information about the batch, production date or expiration date on the packaging; or

III - damaged label or leaflet or that presents incorrect information.

§ 1 When reworking, the original batch number, manufacturing date and expiration date must be maintained.

§ 2 The rework procedure may only be carried out by manufacturers, formulators and handlers authorized in the registration, under the responsibility of the registration holder.

Art. 4 Technical products with expiry date or expired for a maximum of 1 (one) year and which preserve the registration specifications may be subject to revalidation.

§ 1 Verification regarding the preservation of registration specifications, for each batch, must follow the flow of steps set out in Annex I.

§ 2 The preservation of registration specifications must be guaranteed by maintaining the minimum active ingredient content and maximum impurity content, in accordance with the qualitative and quantitative composition declaration registered for the product.

§ 3 Lots that meet the criteria established in § 2 will be considered suitable for conducting an accelerated stability study and, provided that the variation in active ingredient content meets the limits specified in the "Collaborative International Pesticides Analytical Council" - CIPAC MT method 46.4 or other reference protocols, the validity period may be extended for an additional period of a maximum of 2 (two) years.

§ 4 In batches submitted for revalidation, the original batch number and date of manufacture must be maintained.

§ 5 The revalidation procedure for technical products may be carried out by manufacturers approved in the registry or registered formulators for the production of formulations or premixes based on the technical product to be revalidated, under the responsibility of the registration holder.

Art. 5 Formulated products and pre-mixtures, with expiry date or expired for a maximum of 2 (two) years and which preserve the registration specifications, may be subject to revalidation.

§ 1 Verification regarding the preservation of registration specifications, for each batch, must follow the flow of steps set out in Annex II.

§ 2 The preservation of registration specifications must be guaranteed by meeting the following criteria:

I - the results of the active ingredient contents must be in accordance with the qualitative and quantitative composition declaration registered for the product;

II - the parameters of the physical characteristics provided for by the Brazilian Association of Technical Standards - ABNT in the Brazilian Standard - NBR/ABNT nº 8510, when applicable, must be met;

III - exclusively for expired products, the results of the following physical-chemical studies must be in accordance with the results of studies supporting registration, when applicable:

a) physical condition, appearance and color;

b) pH;

c) density;

d) volatility;

e) viscosity;

f) distribution of particles by size;

g) solubility/miscibility;

h) flash point; It is

i) surface tension.

§ 3 The batches that meet the criteria established in § 2 will be considered suitable for conducting an accelerated stability study and, as long as the variation in the active ingredient content meets the limits specified in the CIPAC MT 46.4 method or other reference protocols, the The validity period may be extended for an additional period of a maximum of 2 (two) years.

§ 4 In batches submitted for revalidation, the original batch number and date of manufacture must be maintained.

§ 5 The revalidation procedure for formulated products and premixes must be carried out only by manufacturers and formulators approved in the registration, under the responsibility of the registration holder.

Art. 6 Formulated products and premixes with expiry date or expired for a maximum of 2 (two) years and which do not comply with items I, II and III of §2 of art. 5th may be subjected to reprocessing, according to the flow of steps provided for in Annex III, to reestablish the registration specifications.

§ 1 Reprocessing may also be carried out for batches whose studies provided for in items I, II and III of §2 of art. 5th, they have not been conducted.

§ 2 The reprocessing procedure may occur:

I - by adding installments of batches that are due or expired, in the process of manufacturing a new batch of the same product; or

II - by the addition of other ingredients of the registered formulation, with the purpose of physical-chemical correction or the qualitative and quantitative composition of a batch outside the registration specifications.

§ 3 When reprocessing involves the addition of a portion of a batch, as per item I of § 2, the quantity of product to be added cannot exceed 20% (twenty percent) of the final product.

§ 4 The new batch of formulated product, resulting from the reprocessing procedure, must meet the criteria established in items I, II and III of §2 of art. 5th.

§ 5 The accelerated stability study must be conducted for the new batch of formulated product, resulting from the reprocessing procedure and, as long as the variation in the active ingredient content meets the limits specified in the CIPAC MT 46.4 method or other reference protocols, it may a maximum validity period of 2 (two) years must be established.

§ 6 The reprocessing procedure must be carried out only by formulators approved in the registry, under the responsibility of the registration holder.

Art. 7 Studies to verify the preservation of the registration specification must be validated or conducted in accordance with nationally or internationally recognized protocols.

Art. 8 The batch submitted for revalidation or reprocessing cannot be used again for such procedures.

Art. 9 The use of the procedures indicated in this Ordinance is prohibited when fraud or modification not authorized by federal agricultural, health and environmental bodies is found, in the qualitative and quantitative composition and in the manufacturing conditions of the product.

Art. 10. The reprocessing procedure does not require prior authorization from the registration bodies and, in itself, does not constitute a change in the conditions of the production process approved in the product registration.

Art. 11. The import of expired products, as well as those outside the registration specifications, for the purposes set out in this Ordinance is prohibited, subjecting offenders to applicable responsibilities.

Art. 12. In rework, revalidation and reprocessing procedures, the necessary records must be made to guarantee the traceability of the actions.

§ 1 Information records must be kept available to the competent authorities for a period of 5 (five) years after carrying out the procedures referred to in the caput.

§ 2 The numbering of lots submitted for revalidation must enable the verification of records by the competent authorities, with the following minimum information:

I - batch identification;

II - quantity of revalidated product;

III - original expiration date;

IV - new expiration date;

V - date of completion of each stage of the revalidation procedure;

VI - details of the procedure performed; and

VII - results of tests carried out for revalidation.

§ 3º The numbering of batches submitted for reprocessing must enable the verification of records, by the competent authorities, with the following minimum information:

I - identification of batches to be reprocessed;

II - quantity of product from each batch to be reprocessed;

III - original expiration date of the batches to be reprocessed;

IV - identification of the batch resulting from reprocessing;

V - batch quantity resulting from reprocessing;

VI - expiration date of the batch resulting from reprocessing;

VII - date of completion of each stage of the reprocessing procedure;

VIII - details of the procedure performed; It is

IX - results of tests carried out for reprocessing.

§ 4 Only products subjected to such procedures will be considered revalidated or reprocessed, and their packaging must express the new expiration dates, under penalty of being considered unfit for use.

Art. 13. At the end of the revalidation or reprocessing procedures, a report must be issued, signed by the technician responsible, attesting that the product maintains registration specifications and maintains quality and safety regarding aspects of agronomic efficiency, human health and the environment .

Art. 14. In cases where the revalidation or reprocessing procedures for expiring or expired batches are not viable or when the batch resulting from one of the processes does not demonstrate the preservation of the registration specifications and quality assurance of the final product, the product it must be destined for the appropriate deactivation process.

Art. 15. Federal bodies responsible for the agriculture, health and environment sectors, upon justification, may request agronomic, toxicological or ecotoxicological efficacy tests for batches submitted for revalidation or reprocessing.

Art. 16. The procedures provided for in this Ordinance must be carried out in compliance with the principles of good manufacturing practices.

Art. 17. The registration holder will be responsible for guaranteeing the quality of products submitted to the procedures provided for in this Ordinance.

Art. 18. Failure to comply with the conditions established in this Ordinance may result in administrative, civil and criminal liability in accordance with the provisions of Law No. 14,785, of 2023, its regulatory decree, and other pertinent rules.

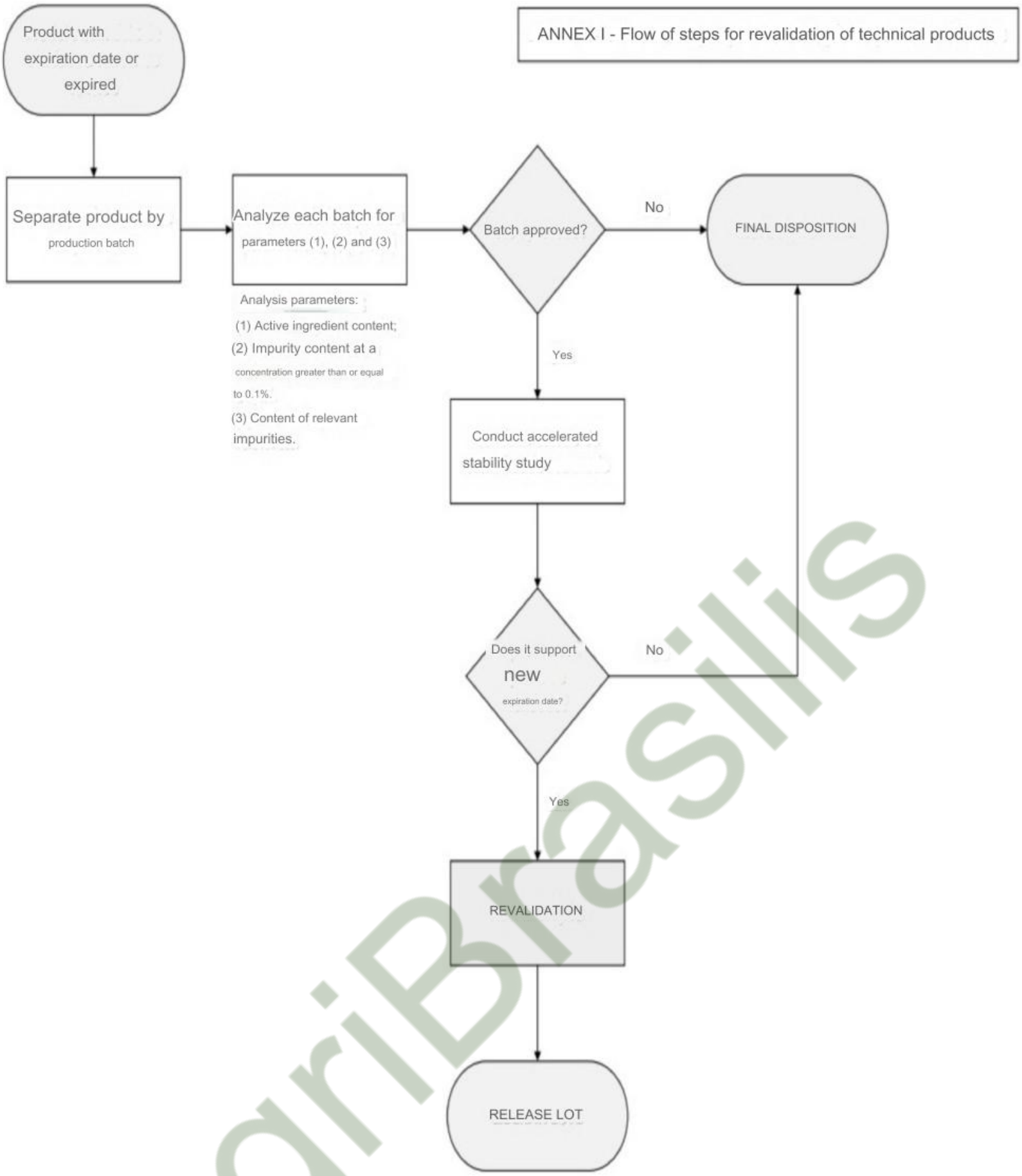
Art. 19. This standard does not apply to environmental control products covered by Law No. 14,785, of 2023.

Art. 20. This Ordinance shall come into force on the date of its publication.

CARLOS GOULART

ANNEX I

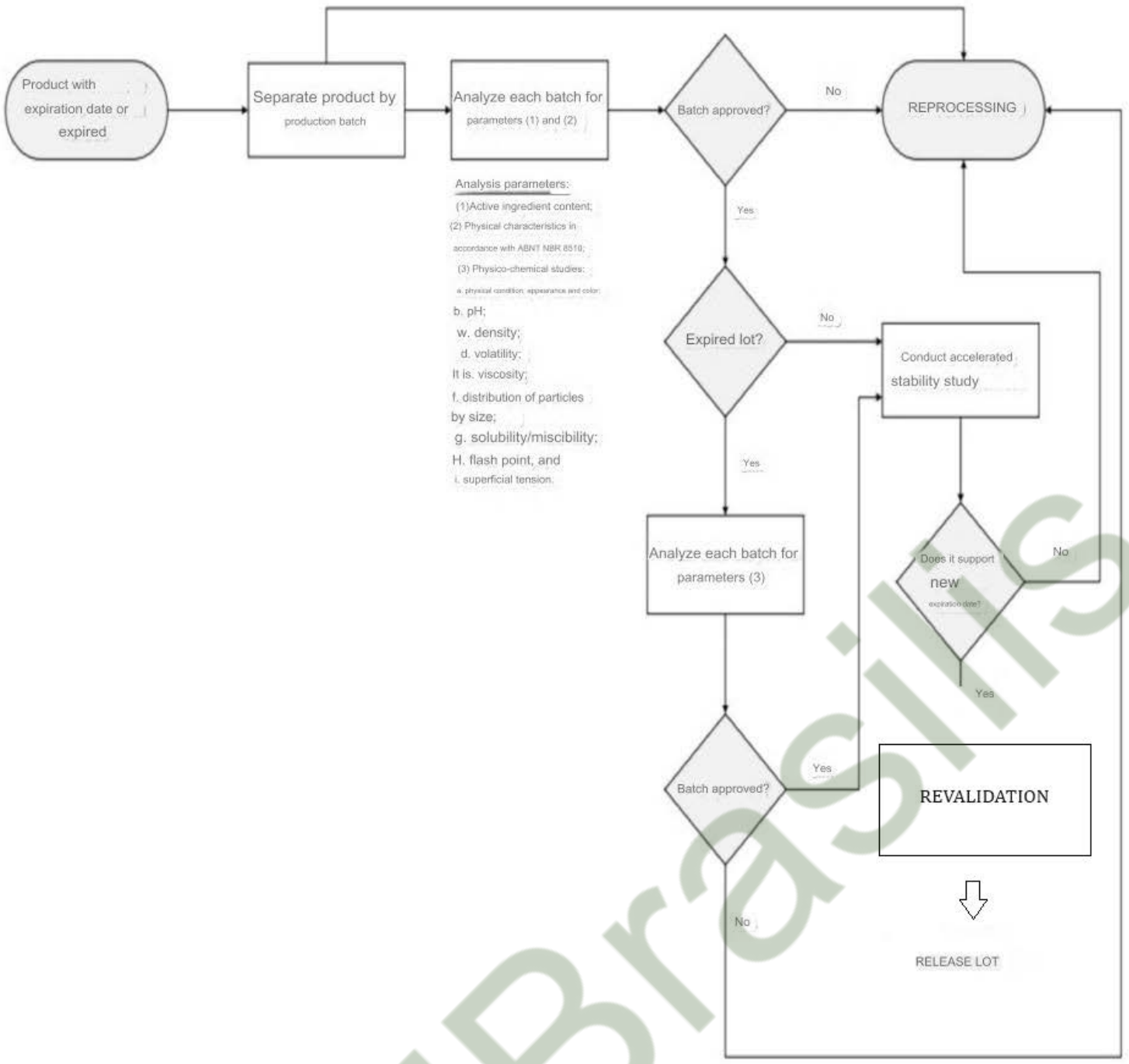
FLOW OF STEPS FOR THE REVALIDATION PROCEDURE OF TECHNICAL PRODUCTS



ANNEX II

FLOW OF STEPS FOR REVALIDATION OF FORMULATED PRODUCTS AND PREMIXES

ANNEX II - Flow of steps for revalidation of formulated products and premixes



ANNEX III

STEP FLOW FOR REPROCESSING FORMULATED PRODUCTS AND PREMIXES

ANNEX III - Flow of steps for reprocessing formulated products and premixes