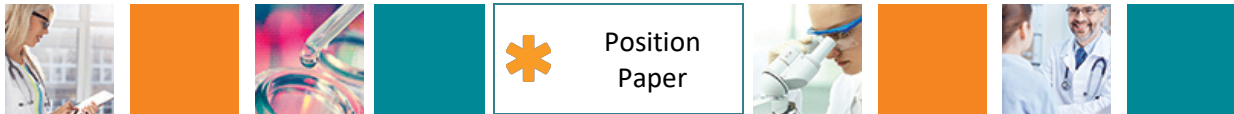


Rules of Origin in Free Trade Agreements (FTAs) and Economic Partnership Agreements (EPAs)

EFPIA Position * December 2019



This position paper aims to update previous EFPIA papers on customs and preferential rules of origin.



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1. Introduction

The EU-Japan Economic Partnership Agreement (EPA) has considerably changed the set of Rules of Origin (RoO), notably about the origin statement and verification. These changes partly initiated in the EU-Canada Comprehensive Economic and Trade Agreement (CETA), require an update of our previous position paper, issued in May 2017.

In order to facilitate the reading in relation to the current approach of origin rules pursued by the European Commission (EC), the present position paper is structured by following the frame of the EU-Japan EPA.

Even though some comments or requests are answers to questions and standpoints triggered by this EPA, this position paper aims to cover all important topics comprised in recent Protocols of origin or Protocols under negotiation with trade partners.

The proposed list rules in this paper have been widely based on the former version of this position paper without major change, rather by adding further precisions.

EFPIA observed with high satisfaction that the European Commission has widely considered the input given by the pharmaceutical industry in this field.

Considering the additional work done for the enforcement of the EU-Japan EPA, EFPIA advocates that all **EPAs and Free Trade Agreements (FTAs) should be negotiated in a way that no explanatory guidelines are required.** This notably concerns the origin statement for which the protocol added “including information on the originating status of materials used in the production of the product”, the verification process entirely in the hand of the authority of the importing party, the administrative cooperation which should not be optional and the business confidentiality which must be secured.

2. Wholly obtained products

EFPIA agrees with the definition coming from the EU-Japan EPA.

3. Insufficient Working or Processing.

While EFPIA understands and supports the concept of Insufficient Working and Processing, the word “simple” in “(I) *simple placing in bottles, cans, flasks, bags, cases or boxes, simple fixing on cards or boards and all other simple packaging operations*” can be misleading for industries that require investment in sterile rooms, temperature-controlled environments and expensive equipment for pharmaceutical filling operations, all of which are subject to strict controls under Good Manufacturing Practice (GMP) and medicines agencies’ rules. The picture below depicts the immense investment that far exceeds “simple filling.”

EFPIA suggest the word “simple” to be further defined and clarified to make the necessary distinctions based on the above one.



Filling process in the pharmaceutical industry: This is not simple

4. Non-Alteration

§ 1 of art. 3.10 of the EU-Japan EPA entirely satisfies the needs of the operational activity:

*An originating product declared for home use in the importing Party shall not have, after exportation and prior to being declared for home use, been altered, transformed in any way or subjected to operations other than to preserve them in good condition or than **adding or affixing marks, labels, seals or any other documentation to ensure compliance with specific domestic requirements of the importing Party.***

The challenge when maximizing distribution routes are the markets with low import volumes. The additional task of artwork preparation for cartons and leaflets, which indicate use, in a specific language, is often performed in warehouse facilities outside of an EPA/FTA territory before importing to the targeted countries of destination. None of these tasks alter the medicinal product.

This definition improves upon the former one and is proposed by the EC in all new EPAs/FTAs. This entirely satisfies the expectations of our industry.

The proof of non-alteration of the medicinal product, only in case the customs authority of the importing Party is requesting evidence of compliance, is in accordance with our expectations.

5. Returning products

Contrary to the rule on non-alteration above, art. 3.11 of the EU-Japan EPA obliges the importer to demonstrate each time products are returned that they are the same as the one subject to prior exportation. As a tolerance is given to operations made in order to preserve the goods and because it is the operation of identical kind we have for alteration rule, the same principle should govern the benefit of preferential origin status: goods returned should be considered as originating goods unless the authority of the importing country demonstrates that the originating status of the goods has changed.

6. Claim for preferential tariff treatment

In addition to the usual statement on origin issued by the exporter, the EC has introduced the notion of “importer’s knowledge”. Depending on the organization of the involved operators, this new possibility might be used, however within the pharmaceutical industry, we would advise caution about this requirement. In principle we do not oppose this new approach, if the statement issued by the exporter remains in all EPAs/FTAs, and the risk and liability falls on the claimant. Nevertheless, EFPIA considers this new possibility as risky because it may create uncertainties if the importer claims the preferential treatment without having the exporter's origin statement.

Under importer’s knowledge, liability should exclusively fall on the claimant without the possibility of the manufacturer or supplier incurring damages. The standard is that the claimant obtains a preferential statement from manufacturer or supplier.

7. Statement on origin

The EC has introduced a major change to the content of the statement. In previous EU FTAs, the exporter only had to inform the importer about the origin status of the goods.

According to § 1 of Art. 3.17 of the EU-Japan EPA, ‘A statement on origin may be made out by an exporter of a product on the basis of information demonstrating that the product is originating, **including information on the originating status of materials used in the production of the product.** The exporter is responsible for the accuracy of the statement on origin and of the information provided.’

Under this provision, not only does the origin status of imported goods have to be provided, but also the originating status of all materials used for producing them, at the time of importation.

EFPIA’s view is that the disclosure of business confidential information, such as the originating status of materials used, should not be shared with anyone other than the exporting authority in an audit request. It is therefore not acceptable to our industry to be requested to share the bill of materials for products, especially due to the new verification process that has been introduced by the EC.

A statement for multiple shipments is an appropriate new rule that allows the exporter to demonstrate the origin status of the goods well ahead of the importation.

EFPIA is also in favor of the withdrawal of the REX number, because it has no practical use, for the following reasons:

- It is not a requirement for benefiting from preferential origin under the claim and verification processes.
- It is only mentioned in the footnote of annex 3: *(2) Indicate the reference number through which the exporter is identified. For the European Union exporter, this will be the number assigned in accordance with the laws and regulations of the European Union. For the Japanese exporter, this will be the Japan Corporate Number. **Where the exporter has not been assigned a number, this field may be left blank.***

- Contrary to former EPAs/FTAs it is not linked - in the protocol of origin itself – to a value threshold above which a reference for granting a status is required.
- It does not provide any certainty about the quality of the registration.

EFPIA instead requests to maintain the Approved Exporter status because:

- In all EPAs/FTAs in which it is included, the registration comes from a shared process with the other party;
- It is a certification of conformity of the exporter's knowledge in rules of origin;
- It requires to obtain statements from suppliers prior to launching the registration process;
- It gives more certainty to the country of importation that the statement of origin has been issued under the control of the customs of the exporting party.

In addition, EUR1 certificate should be proposed to allow non-approved exporters to benefit from origin preferences.

8. Record keeping requirements

Rather than defining a minimum period of time under which operators must keep records necessary to demonstrate the origin status of the goods, as under art. 3.19 of the EU-Japan EPA, our sector requests for legal certainty and reduction of administrative cost, a well-defined fixed period that can take into account ex-post controls.

A minimum period leads to insecurity for exporters, as it is related to each national regulation. Some importing countries allow controls on origin for indefinite periods. A maximum period might also lead to enable the destruction of record keeping before 5 years. EFPIA is in favor of a fixed 5 years period.

9. Verification

The list of information elements in § 2 of art. 3.21 of the EU-Japan EPA can be requested from importers especially if they have claimed for preference under the Importer's knowledge process.

If the importer does not have the answers to these questions, or does not have the ability to provide them under the internal organization of the company, the proofs of preferential origin are on the exporter's side.

EFPIA considers that such information, for an industry driven by innovation, falls under business confidentiality and should only be disclosed to the authority of the exporting trade partner (see point 10 below).

This position is in line with the communication of the EC that the control must be performed by the authority of the exporting party (despite the fact the protocol of origin never obliges the importing party to do so). Besides the issue of confidentiality, it is also a high additional administrative burden and cost to provide such information to a foreign customs office, which may prevent the exporter to use the benefit of the EPA.

The scheme of verification of preferential origin by the authority of the importing country leads the exporter to face many authorities instead of having one single customs point of contact.

10. Administrative cooperation

EFPIA's position is that the authority of the importing country should ask the authority of the exporting party to proceed with the verification of the status of the goods. It must be clear that no information listed under §2 of art. 3.21 (verification process) can be dispatched to the authority of the importing country without consent of the exporter (see point 12 of this paper).

Regarding controls in exporters' premises, only the authority of the exporting country shall be authorized to do so. If the manufacturer is not the exporter, the latter must be informed by the authority of the exporting country that such checks will be performed.

The sharing of information by the exporter with the authority of the exporting country and with the authority of the importing country should follow the rules described here after:

2. The request for information in paragraph 1 of art. 3.21 shall contain no more than the following data elements:

Nr	Data Elements	Confidential (C) or not confidential (NC)	Proposal to deliver information in case C, to the authority of the exporting country (AEC) and transfer of information to the authority of the importing country (AIC)
1	- The statement on origin, where such a statement was the basis of the claim referred to in paragraph 2(a) of Article 16.	NC	
2	- The HS-code of the final product and origin criteria used.	NC	
3	- A brief description of the production process.	C	General information, i.e. the kind we find in technical literature easily accessible and not protected by a patent.
4	- Where the origin criterion was based on a specific production process, a specific description of that process.	C	Simply mention the process that has been retained for the heading: e.g. for chemistry: chemical reaction; purification; biotechnological process.
5	- Where applicable a description of the originating and non-originating materials used in the production process.	C	This is highly confidential: This falls under the confidentiality paragraph. This information should only be delivered to the authority of the exporting party, the latter certifies to the authority of the importing country that the manufacturing process used is in line with the one listed in the protocol of origin.
6	- Where the origin criterion was 'wholly obtained', the applicable category (such as harvesting, mining, fishing and place of production).	NC	

7	- Where the origin criterion was based on a value method, the value of the final product as well as the value of all the non-originating or, as appropriate to establish compliance with value requirement, originating materials used in the production.	C	This is highly confidential for materials (value of final product is filled in the import clearance document). Elements of calculation are provided by the exporter to the authority of the exporting country, the latter certifies to the authority of the importing country that the criterion is fulfilled. From AEC to AIC: only information about thresholds: e.g. for chemistry (non-originating material part < 40 % EXW value).
8	- Where the origin criterion was based on weight, the weight of the final product as well as the weight of the relevant non-originating materials or, as appropriate to establish compliance with weight requirement, originating materials used in the final product;	C	Information not concerning Pharmaceutical activity.
9	- Where the origin criterion was based on changes in tariff classification, a list of all the non-originating materials including their tariff classification (in 2-, 4- or 6-digit format depending on the origin criteria).	C	This is highly confidential: Complete information is provided by the exporter to the authority of the exporting country, the latter certifies to the authority of the importing country that the criterion is fulfilled. From AEC to AIC: CTH rule correctly (or not) used by the exporter.
10	- The information relating to the compliance with the provision on non-alteration referred to in Article X10.	NC	

11. Denial of preferential tariff treatment

Considering the information requirements in § 2 of art. 3.21 of the EU-Japan EPA and the EFPIA position to disclose this information to the authority of the exporting party, it is doubtful the authority of the importing party may receive all required information within the timeframe of 3 months, the timeframe for such enquiries should be extended in order to comply with the time required for administrative cooperation.

By experience, the period during which administration in charge of control must answer to the administration in charge of notifying the result of inspection is very short. A fixed period is not adequate, especially when several administrations are involved, which is often the case for the pharmaceutical sector as distribution of products is not managed by manufacturing plants.

The audit period should be extended upon request of the authority in charge of the checks, when the control could not be finalized in the specified time period. As per the EU-Japan EPA, the specified period is two years, which is acceptable for EFPIA.

12. Confidentiality

The Guidance on confidential information for the EU-Japan EPA, published by DG TAXUD, states that: *“Paragraph 3 complements in particular Article 3.22(5) by prohibiting the disclosure of information by the exporting or importing Party without the consent of the exporter.”*

The consent of the exporter should be written in the EPA/FTA itself and not only in a guideline issued by the Commission. The concern for companies is that a guideline is not legally binding. In addition, depending on the contract between importer and exporter, the exporter’s consent could be a difficult decision. If the parties are bound by a contract, the exporter would have to choose between disclosing confidential business information to the authority of the importing country in order to participate in an FTA, or breaching the contract with the importer by not enabling him to participate in the EPA and lose the competitive advantage offered to FTA participating countries.

EFPIA therefore requests the exporter’s consent to be integrated into the EPA/FTA itself.

13. List rules: chapters 28, 29 and 30

The following alternative rules consist of the latest technical review of the pharmaceutical and biotechnology sectors. Rules of origin for chemical and pharmaceutical chapters 28 to 30 are based on “last substantial transformation” which is understood to confer origin if one of the following rules applies, **IN A NON-HIERARCHICAL ORDER.**

In particular, EFPIA proposes the following:

13.1. Change of tariff subheading as the most widely accepted method to confer origin

One of the methods for determining origin should be the rule of Change in Tariff Heading (CTH) on a heading (4-digit HS Code) or of Change in Tariff Sub-Heading (CTSH) on a sub-heading level (6-digit HS Code), particularly for chapters 28 and 29.

Even though these chapters are covered by the activity of the chemical industry, some headings are typically headings of active pharmaceutical ingredients (such as 2932; 2933; 2934; 2935; 2936; 2937; 2938; 2939; 2941). Successive substantial transformation steps may be performed within the same heading or subheading.

For Chapter 30, the CTSH criterion is not always applicable*, therefore the rule should be “manufacture¹ from any heading.”

* Examples:

¹ “Manufacture” means any kind of working or processing, including assembly or specific operations that results in a new and different article of commerce.

- Mexico has not implemented the Subheading changes from the WCO for biologics in chapter 30.
- Additionally, some families of products have successive and substantial manufacturing steps, which are performed inside the same subheading. The new WTO HS structure, enforced in January 2017, broadens the ability to use the CTS rule but not globally, for the additional reasons, concerning 3001 and 3002:
 1. In subheading 3001: Some important products, at least in the Heparin family of 3001.90 have several industrial steps up to the production of exonaparin sodium or semuloparin sodium, for instance.
 2. In subheading 3002: vaccines are products that cover cell development up to vaccines for retail sale. These different steps may be manufactured in different places prior to the final step within the FTA region.

For 3003 and 3004: as these headings do not cover products from 3002 (heading definitions), all these products are produced with active ingredients (classified in chemical chapters or 3001) and from excipients that are classified in chemical or agricultural chapters. Therefore “Manufacture from any heading” or CTH suffices for these two headings.

The aim of this is to take into consideration that the country where the pharmaceutical drug products are formulated, determines the country of origin, as well as consider the significant manufacturing investment of labor and overhead in these countries at this final step of medicinal production.

Contrary to non-preferential rules of origin, which consider the tariff shift between 3003 and 3004 non-origin conferring, EFPIA advocates that this manufacturing step should be considered as a substantial step to be taken into account. Various reasons lead to this conclusion:

- Simplification of the rule of chapter 30;
- Low level of trade under 3003 compared to 3004;
- Increasing costs for the last industrial steps (transportation, industrial investment in protected atmosphere, quality check and pharmaceutical release, and additional investments needed for filling and packaging activities);
- Deliveries of 3003 to countries that require industrial steps in their countries, in relation to the capability to maintain trade of finished products. These products are consequently processed into 3004 products, for domestic consumption as a requirement of the importing government.

13.2. De Minimis Clause

Goods that do not undergo a change in tariff classification are nonetheless originating goods if the value of all non-originating materials that have been used in the production of the good and do not undergo the applicable change in tariff classification, does not exceed 20% of the adjusted value of the good.

13.3. Manufacturing processes

If companies are unable to qualify their product through the tariff shift rule, then the rules below (non-hierarchical order) may be considered as origin conferring processes.

a. Chemical reaction

A “chemical reaction” is a process (including a biochemical process) which results in a molecule with a new structure by breaking intramolecular bonds and by forming new intramolecular bonds, or by altering the spatial arrangement of atoms in a molecule. **A chemical reaction may also be expressed by a change of the CAS (Chemical Abstract Service) number.**

The following processes should not be considered for purposes of origin:

- (a) dissolving in water or other solvents;
- (b) the elimination of solvents including solvent water or
- (c) the addition or elimination of water of crystallization.

A chemical reaction as defined above is to be considered as origin conferring.

b. Mixtures and blends

The deliberate and proportionally controlled mixing or blending (including dispersing) of materials, other than the addition of diluents, to conform to predetermined specifications which results in the production of a good having physical or chemical characteristics which are relevant to the purposes or uses of the good and are different from the input materials is to be considered to be as origin conferring.

c. Purification

Purification is to be considered as origin conferring provided that purification occurs in the territory of one or both of the Parties results in one of the following criteria being satisfied:

- (a) purification of a good resulting in the elimination of 80 percent of the content of existing impurities; or
- (b) the reduction or elimination of impurities resulting in a good suitable for one or more of the following applications:
 - (i) pharmaceutical, medical, cosmetic, veterinary or food grade substances;
 - (ii) chemical products and reagents for analytical, diagnostic or laboratory uses;
 - (iii) elements and components for use in micro-electronics;
 - (iv) specialized optical uses;
 - (v) biotechnical use (e.g., in cell culturing, in genetic technology, or as catalyst);
 - (vi) carriers used in a separation process; or
 - (vii) nuclear grade uses.

d. Change in Particle size

The deliberate and controlled modification in particle size of a good, other than by merely crushing or pressing, resulting in a good having a defined particle size, defined particle size distribution or defined

surface area, which is relevant to the purposes of the resulting good and having different physical or chemical characteristics from the input materials is to be considered as origin conferring.

e. Standard Materials

Standard materials (including standard solutions) are preparations suitable for analytical, calibrating or referencing uses having precise degrees of purity or proportions which are certified by the manufacturer. The production of standard materials is to be considered as origin conferring.

f. Isomer Separation

The isolation or separation of isomers from a mixture of isomers is to be considered as origin conferring.

g. Biotechnological Processes

- (a) Biological or biotechnological culturing, hybridization or genetic modification of
 - (i) micro-organisms (bacteria, viruses (including phages) etc.) or
 - (ii) human, animal or plant cells; and
- (b) Production, isolation or purification of cellular or intercellular structures (such as isolated genes, gene fragments and plasmids) are to be considered as origin conferring;
- (c) Products shall be as originating if
 - (i) products of Chapter 30 are obtained by using cell cultures;
 - (ii) products of chapter 29 to 39 are obtained by fermentation.

Cell culture is defined as the cultivation of human cells, animal cells and plant cells under controlled conditions (such as defined temperatures, growth medium, gas mixture, pH) outside a living organism. Biotechnological processes are defined in heading 3002.

Fermentation is a biotechnological process in which bacteria, yeasts, fungi or enzymes are used to produce products falling within chapter 29 to 39.

13.4 Added Value Rule

Added-value criteria can be calculated with one of the following options:

- Value of all the non-originating materials used, does not exceed 60% of the ex-works price of the product², or
- Net Cost³ where the value of all non-original material does not exceed 70%, or

² Ex-Works (EXW) as defined by Incoterms® 2010

³ Net cost: The net cost is the cost to produce a good. It excludes sales promotion costs, marketing and aftersales service costs, royalties, shipping and packing costs and non-allowable interest costs. Similarly, to the transaction

- Transaction value (CIF or FOB) of the imported goods or of identical or similar imported goods⁴ for the purpose of origin calculation. The value of all the non-originating materials used does not exceed 60%.

Introduction of FOB value in the EU-Japan EPA is highly appreciated, as manufacturing activity is not enough to capture all costs before sales and deliveries to third countries and does not accommodate the many manufacturing scenarios in today's environment, such as toll-manufacturing, third party manufacturing and sales, or consigned material management. The definition of FOB value mention in the EU-Japan EPA fits with EFPIA members' expectations:

(a) 'FOB' means:

- (i) the free on board price of the product paid or payable to the seller regardless of the mode of shipment, provided that the price includes the value of all the materials used and all other costs incurred in the production of a product and its transportation to the exportation port in the Party, minus any internal taxes which are, or may be, repaid when the product obtained is exported; or
- (ii) if there is no price paid or payable or if the actual price paid does not reflect all costs related to the production of the product which are actually incurred in the production of a product, the value of all the materials used and all other costs incurred in the production of the product in the exporting Party, and its transportation to the exportation port in the Party which:
 - (A) include selling, general and administrative expenses, as well as profit, that can be reasonably allocated to the product, the costs of freight and insurance; and exclude any internal taxes of the exporting Party which are, or may be, repaid when the product obtained is exported.

value method, the difference between the net cost of a good and the value of its non-originating materials is calculated as a percentage of the net cost in order to yield the good's regional value content.

⁴ The transaction value is the amount paid for the good adjusted to an FOB (Free On Board) basis.

14. Country of Origin Marking

Whether marking is optional or imposed by the regulation of the importing country, the above rules of origin have the preference over any other rule relating to the establishment of the country of origin, so noted as an EPA override provision.

15. Blueprint for other EPAs/FTAs

EFPIA considers that the present position paper on rules of origin should be applied to all negotiations of new EPAs/FTAs and for the modernization of EPAs/FTAs already in force.

The proposal made by the EC for PAN-EUROMED Rules is the one that complies with all requests of pharmaceutical industry.

