

## SOURCES OF AUTHORITY TO REGULATE

### **1) Congress - Legislation**

- A law requires a regulator to regulate in a specific area, usually without providing specific guidance on how to do so.

### **2) Self-Initiation**

- A regulator proposes and adopts regulations under its general authority.

Proposed technical regulations (“RT”) are developed by regulators and must be put before the Technical Secretariat (Secretaría Técnica or “ST ORT”) of Costa Rica’s Technical Regulation Body’s (Organo de Reglamentación Técnica or “ORT”) for examination. Note that the ORT is an inter-ministerial commission attached to MEIC.

The main developers of RTs include: the Ministry of Economy, Industry, and Commerce (“MEIC”), the Ministry of Science, Technology, and Telecommunications, the Ministry of Agriculture and Livestock, the Ministry of Health, the Ministry of the Environment and Energy, the Ministry of Public Works and Transport, and the Ministry of Foreign Trade. The private sector is encouraged to participate in the RT development process, including in developing proposals in coordination with governmental authorities.

## STEP 1: Analysis of the Problem

The regulator must analyze whether an RT is the only solution to the problem or if there are non-regulatory, more efficient, and/or less costly alternatives capable of solving the problem. Once it has identified the problem, the regulator must clearly and precisely outline the purpose and objective of the proposed RT. (Throughout the RT development process, the purpose and objective of the proposed RT must always be taken into consideration so that the requirements and administrative burden that the RT creates are directly related to the objectives. Although it does not provide specifics, MEIC’s domestic RT development guide encourages the agency that is proposing the RT to make the proposal available to interested stakeholders and involve other regulators that would be affected by the proposed RT.)

## STEP 2: Analysis of Legal Authority

As part of its analysis, the regulator must research:

- 1) Existing RTs by:
  - a. Determining the scope of its regulatory authority;

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- b. Identifying if other agencies have regulatory authority over the same matter;
  - c. Reviewing existing RTs to determine whether an RT already regulates the matter
    - i. If an existing RT covers the same matter as the proposed RT and the existing RT solves the previously identified problem, then the proposed RT is unnecessary.
    - ii. If an existing RT covers a similar, but not the same, matter or is out-of-date, then the regulator must examine whether to modify the existing RT, rather than develop a new one.
    - iii. If there is no existing RT that covers the same matter, the regulator must develop a new RT.
- 2) Existing domestic laws, including attorney general and Supreme Court opinions.
  - 3) Existing foreign RTs by reviewing existing RTs of countries similar to Costa Rica or any comparative studies of existing RTs done by an international organization.

Note: MEIC’s domestic RT development guide encourages the regulatory agency proposing the RT to maintain a database of all information collected during this step for future reference.

### STEP 3: The Regulator Drafts a Technical Regulation

If the regulator determines that an RT is necessary, it must follow the process set out below to draft the RT. However, before starting the process, the regulator must identify the areas in which the proposed RT will potentially have an impact to determine which stakeholders should be involved in the process. The list of interested stakeholders is as follows:

- Ministries: participation by a Ministry will depend on the Ministry’s legal authority and the type of RT proposed. For example, if the proposed RT will regulate quality and consumer information, then MEIC will be involved.
- Private Sector (Chambers and Associations): the members of the Chamber or Association selected must comprise at least 80% of the represented sector.
- Academia: members of academic institutions should be included when they possess extensive knowledge on the product that will be regulated.
- Consumer groups

#### **Process to Draft the RT:**

- 1) Technical and Scientific Analysis
  - (a) To research the technical and scientific support for the proposed RT, the regulator must avail itself of all possible sources of information, including:

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- i. the Internet (i.e., Google and other search engines);
    - ii. university research; and
    - iii. public or private research.
  - (b) Additionally, it should always be a priority for the regulator to select a standard that has been internationally accepted – for example, standards developed by: Codex Alimentarius; the World Organisation for Animal Health; the International Plant Protection Convention; and other organizations in which Costa Rica has membership.
  - (c) For proposed RTs, the regulator must prepare a study to determine whether the standard should be adopted in its entirety or only partially.
    - i. If the standard is adopted in its entirety, it is unnecessary to find technical and scientific support for the proposed RT and the proposed RT must only comply with the rules of Decree 36214-MEIC.
    - ii. If the standard is partially adopted, the regulator must identify the technical and scientific support that justifies and explains why the international standard is not an adequate solution to the problem to be solved by the proposed RT. In these cases, the regulator must:
      1. analyze existing scientific studies regarding the product that will be regulated, with a view towards using the studies as the basis for the proposed RT;
      2. study and verify the market – for example, by visiting producers; and
      3. perform a statistical analysis of the market studies to determine their reliability.
- 2) Determining whether the new requirements, administrative burdens, or procedures are legally permissible.
  - (a) The proposed RT must be permissible under Law 8220.
    - i. Any new requirements or administrative burdens established by the proposed RT must not be unnecessary or duplicative.
  - (b) The proposed RT must be permissible under Law 6227.
    - i. All regulatory processes must follow the rules of transparency and publication established by Article 361.
  - (c) Any new requirements, administrative burdens or procedures established by the proposed RT must be strictly necessary to ensure the proposed RT's objective is fulfilled.
  - (d) Any new requirements, administrative burdens or procedures established by the proposed RT must not limit free market competition or create a barrier to trade and entry.

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- (e) Any new requirements, administrative burdens or procedures established by the proposed RT must be supported by a scientific, legal, and technical basis. Additionally, the regulatory agency must demonstrate that it has adequate staff and budget to enforce the requirements of the proposed RT.
  - (f) The regulator must presume that the regulated person/agency will act in accordance with the proposed RT's requirements.
  - (g) The regulator must determine how the proposed RT will be enforced and which government authorities will enforce it.
- 3) Summoning interested stakeholders to form a technical working group and reach a consensus.
- (a) In cases where a technical working group is not necessary, the regulator must justify its decision by providing an explanation as to why it was not necessary to do so.

### STEP 4: ORT Analyzes the Draft RT

The regulator must submit the draft RT to ST ORT for review. After review, ST ORT opines on the draft RT. If the draft is legally permissible (including with respect to Costa Rica's international obligations, such as the World Trade Organization's ("WTO") Technical Barriers to Trade Agreement ("TBT Agreement")), ST ORT recommends that ORT propose the draft RT for public comment. If ST ORT opines that the draft RT will not adhere to the TBT Agreement, the regulator must modify the proposed RT accordingly.

In either case, ORT members may send comments on the draft RT to ST ORT, and ST ORT must respond to the comments.

### STEP 5: Domestic Public Comment Period

Once ORT approves the draft RT and interested stakeholders reach a consensus, the regulator publishes notice of the proposed RT on Costa Rica's Official Gazette. The notice must:

- 1) identify the regulatory agency;
- 2) include the name of the proposed RT;
- 3) include the physical and electronic address where the relevant public comment documents are located; and
- 4) include the physical and electronic address where public comments can be submitted.

The comment period must be open for a minimum of ten (10) business days.

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### STEP 6: The Regulator Reviews and Responds to Domestic Public Comments

Once the domestic comment period ends, the regulator reviews and analyzes all of the comments. If the regulator agrees with a comment, the agency incorporates it into the proposed RT. If the agency does not agree with the comment, it must justify why it rejected the comment. All responses are organized in a matrix that includes all comments and their corresponding responses, as follows:

- 1) Source of the comment;
- 2) Date when the comment was received;
- 3) Text of the comment (translations may be also included);
- 4) Response to the comment (whether the comment was accepted or rejected); and
- 5) Justification for rejecting the comment.

If complex comments are received, ST ORT transmits them to the technical working group for examination and responds to those that are duly substantiated.

### STEP 7: International Public Comment Period (If Necessary)

After the domestic public comment period ends, MEIC determines whether the proposed RT needs to be notified to the WTO. If the answer is yes, ST ORT notifies the WTO (and other countries with which Costa Rica has agreements with) of the proposed RT, and a sixty (60) day international public comment period begins. WTO members may comment on the proposed RT and may also request to extend the comment period through the WTO website.

### STEP 8: The Regulator Reviews and Responds to International Public Comments

Once the international comment period ends, ST ORT compiles the comments received and submits them to the regulator. The regulator reviews and analyzes all of the comments. If the regulator agrees with a comment, the agency incorporates it into the proposed RT. If the agency does not agree with the comment, it must justify why it rejected the comment. All responses are organized in a matrix that includes all comments and their corresponding responses, as follows:

- 1) Source of the comment;
- 2) Date when the comment was received;
- 3) Text of the comment (translations may be also included);
- 4) Response to the comment (whether the comment was accepted or rejected); and
- 5) Justification for rejecting the comment.

The regulator must reply to the comments within thirty (30) business days and submit the matrix to ST ORT so that ST ORT can make the matrix available on MEIC's website.

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### STEP 9: Final RT is Signed and Published

The final RT must be signed by the head of the regulator and the President. (Note: all RTs must be Decrees.) The RT is published in Costa Rica's Official Gazette and enters into force.