

Draft Recommendation on US/EU Equivalency
NOSB International Committee
April 15, 2002

I. Background:

The National Organic Program Final Rule provides 3 options for organic products produced in foreign countries to be imported into the United States. As shown below in section 205.500, these are: 1) direct accreditation by the USDA; 2) accreditation of a foreign certifying agent by a government whose standards meet the requirements of the NOP Final Rule; or 3) accreditation of a foreign certifying agent by a government that has negotiated an equivalency agreement with the US. The Final Rule states:

“§ 205.500 Areas and duration of accreditation.

(a) The Administrator shall accredit a qualified domestic or foreign applicant in the areas of crops, livestock, wild crops, or handling or any combination thereof to certify a domestic or foreign production or handling operation as a certified operation.

(b) Accreditation shall be for a period of 5 years from the date of approval of accreditation pursuant to § 205.506.

(c) In lieu of accreditation under paragraph (a) of this section, USDA will accept a foreign certifying agent's accreditation to certify organic production or handling operations if:

(1) USDA determines, upon the request of a foreign government, that the standards under which the foreign government authority accredited the foreign certifying agent meet the requirements of this part; or

(2) The foreign government authority that accredited the foreign certifying agent acted under an equivalency agreement negotiated between the United States and the foreign government.”

The Agreement on Technical Barriers to Trade, in Article 2.7, states: “Member shall give positive consideration to accepting as equivalent technical regulations of other Members, even if these regulations differ from their own, provided they are satisfied that these regulations adequately fulfill the objectives of their own regulations.”

In other words, equivalence means that an importing country has found that an exporting country's regulatory system (statutes, regulations, conformity assessment systems, and enforcement) meets the objectives of the importing country's regulatory system.

A determination of equivalence is requested by the exporting government and the burden of demonstrating equivalence rests with the exporting government. An equivalence determination is a government function. However, because the importing country is looking to foreign regulatory authorities to ensure that specific technical requirements are being met, the factual basis for an equivalence determination should be publicly available and clearly understood. Preserving consumer confidence depends in large measure on the trust consumers have in the regulatory safeguards that exist.

To solicit stakeholder (including consumer) input, the USDA uses “notice and comment” rulemaking before the Department finalizes its determination on an equivalence request from a foreign government. It works like this:

USDA publishes a proposed rule in the Federal Register before reaching a final determination on a request for equivalence. The proposed rule states that USDA is proposing to add a foreign government to a list of governments authorized to export regulated products to the United States. The proposed rule will explain that the document review and the on-site review(s) of the foreign government's technical requirements and

conformity assessment system demonstrate that they are equivalent to relevant provisions in USDA statutes and implementing regulations. The public then comments on USDA's proposed determination.

As the USDA considers equivalence requests concerning organic regulations from member states of the European Union, the public should have the opportunity to provide input, through the National Organic Standards Board, on the fundamental objectives which are to be used to establish equivalence and the criteria used to make equivalency determinations.

II. Objectives of the US Organic Rule:

As stated in Section 2102 (7 USC 6501) of the Organic Foods Production Act of 1990, the purpose of the Act is:

“(1) to establish national standards governing the marketing of certain agricultural products as organically produced products;
(2) to assure consumers that organically produced products meet a consistent standard; and
(3) to facilitate interstate commerce in fresh and processed food that is organically produced.”

Neither OFPA nor the NOP Final Rule contain further statements of objectives or principles by which to evaluate the technical requirements of a foreign government. (Because the certification requirements in the Final Rule are based on ISO Guide 65 and the accreditation system is based on ISO Guide 61, ISO Guides 65 and 61 can be used to evaluate the conformity assessment system of a foreign government.)

On October 17, 2001, the National Organic Standards Board unanimously adopted Principles of Organic Production and Handling, consistent with the requirements of the Organic Foods Production Act and the Final Rule. In summary, the NOSB Principles state:

“Organic agriculture is an ecological production management system that promotes and enhances biodiversity, biological cycles, and soil biological activity. It emphasizes the use of management practices in preference to the use of off-farm inputs, taking into account that regional conditions require locally adapted systems. These goals are met, where possible, through the use of cultural, biological, and mechanical methods, as opposed to using synthetic materials to fulfill specific functions within the system.

An organic production system is designed to: optimize soil biological activity; maintain long-term fertility; minimize soil erosion; maintain or enhance the genetic and biological diversity of the production system and its surroundings; utilize production methods and breeds or varieties that are well adapted to the region; recycle materials of plant and animal origin in order to return nutrients to the land, thus minimizing the use of non-renewable resources; minimize pollution of soil, water, and air; and become established on an existing farm or field through a period of conversion (transition), during which no prohibited materials are applied and an organic plan is implemented.

The basis for organic livestock production is the development of a harmonious relationship between land, plants, and livestock, and respect for the physiological and behavioral needs of livestock. This is achieved by: providing good quality organically grown feed; maintaining appropriate stocking rates; designing husbandry systems adapted to the species' needs; promoting animal health and welfare while minimizing stress; and avoiding the routine use of chemical allopathic veterinary drugs, including antibiotics.

Organic handling practices are based on the following principles: organic processors and handlers implement organic good manufacturing and handling practices in order to maintain the integrity and quality of organic products through all stages of processing, handling, transport, and storage; organic products are not commingled with non-organic products, except when combining organic and non-organic ingredients in

finished products which contain less than 100% organic ingredients; organic products and packaging materials used for organic products do not come in contact with prohibited materials; proper records, including accurate audit trails, are kept to verify that the integrity of organic products is maintained; and organic processors and handlers use practices that minimize environmental degradation and consumption of non-renewable resources.

Organic standards require that each certified operator must complete, and submit for approval by a certifying agent, an organic plan detailing the management of the organic crop, livestock, wild harvest, processing, or handling system. The organic plan outlines the management practices and inputs that will be used by the operation to comply with organic standards.

Organic certification is a regulatory system which allows consumers to identify and reward operators who meet organic standards. It allows consumers to be confident that organic products are produced according to approved management plans in accordance with organic standards. Certification requires informed effort on the part of producers and handlers, and careful vigilance with consistent, transparent decision making on the part of certifying agents.

Genetic engineering (recombinant DNA technology) is a synthetic process designed to control nature at the molecular level, with the potential for unforeseen consequences. As such, it is not compatible with the principles of organic agriculture (either production or handling). Genetically engineered/modified organisms (GEO/GMO's) and products produced by or through the use of genetic engineering are prohibited.

Although organic standards prohibit the use of certain materials such as synthetic fertilizers, pesticides, and genetically engineered organisms, they cannot ensure that organic products are completely free of residues due to background levels in the environment.”

III. Recommended Criteria for Establishing Equivalency:

The NOSB International Committee recommends that the following criteria be used by the USDA when assessing technical regulations to determine if they are equivalent to US requirements:

- 1) Is the regulation consistent with US objectives, as stated in the summarized NOSB Principles of Organic Production and Handling?
- 2) Would recognition of the regulation as equivalent have any negative impacts on domestic producers?
- 3) Would recognition of the regulation as equivalent have any negative impacts on domestic handlers?
- 4) Does the foreign regulation meet the expectations of domestic consumers?
- 5) Does the foreign regulation contain environmental management requirements unique to the exporting country, which are not relevant in the United States?

IV. Primary Differences Between the EU and US Organic Regulations:

The following is a summary of the primary differences between the EU Regulation 2092/91 ('EU') and the National Organic Program Rule 7 CFR Part 205 ('US'), based on a comparative analysis conducted for the International Federation of Organic Agriculture Movements. The summary is divided into "Areas where the EU is less stringent than the US" and "Areas where the US is less stringent than the EU".

The summary does not cover requirements for certification or accreditation. The EU requirements for certification and accreditation are found in Annex III and include the requirements of ISO/IEC Guide 65 by reference. The US requirements for certification and accreditation are contained within the Rule as published, and are modeled after ISO Guides 65 and 61.

The NOSB International Committee provides the summary of primary differences as a guidance document to the USDA in order to facilitate the equivalency determination process. In order to determine if the EU regulation is equivalent to the US Final Rule, the primary differences listed below will need to be assessed using the criteria stated above.

A. Areas where the EU is less stringent than the US:

Crops

Conversion period. US requires 3 years with no prohibited materials prior to first organic harvest. EU requires 2 years of organic management prior to sowing and allows inspection bodies, with approval of competent authorities, to reduce the period further.

Sewage sludge. US prohibits sewage sludge; EU does not.

Buffer zones. US requires maintenance of buffer zones to prevent unintended application of prohibited materials. EU does not require buffer zones.

Manure. US sets restrictions on the time between application of raw manure and the harvest of crops for human consumption; this is not addressed by EU.

Treated lumber. US specifically prohibits use of lumber treated with arsenate or other prohibited materials; EU does not.

Residue levels. EU does not establish maximum residue levels specific for organic products, whereas US sets specific maximum residue levels for organic products.

Livestock

Period of organic management. EU only requires 12 months of organic management for equines and bovines, 6 months for small ruminants, 4 months for pigs, 10 weeks for meat poultry, and 6 weeks for egg-laying poultry. US requires organic management from last third of gestation for all slaughter species; organic management from second day for all poultry; and one year of organic management for dairy, except for a one-time conversion allowance for new herds.

Sources of stock. EU allows non-organic sources of slaughter stock. US does not allow non-organic sources of slaughter stock, except for day-old poultry. EU allows up to 40% non-organic stock, under certain conditions. US does not set allowed levels of non-organic stock, since stock must be under continuous organic management from the last third of gestation.

Conversion period. EU allows reduced conversion periods when there is simultaneous conversion of livestock and land. US sets requirements for conversion of land separately from requirements for organic management of animals. The conversion period for land cannot be reduced, nor can the requirements for organic management of animals.

Split operations. EU allows livestock to be moved from organic to non-organic production units. US prohibits this practice.

Feeds and pasture. US requires 100% organic feed. EU allows up to 60% ‘in-conversion feed’ and up to 25% conventional feed in a daily ration.

Parasiticides. US prohibits parasiticides for slaughter stock and sets specific restrictions for their use on dairy and breeder stock. EU does not prohibit parasiticides for slaughter stock or set other restrictions on their use.

Antibiotics. US prohibits the use of antibiotics. EU allows the use of antibiotics, provided that certain restrictions are followed.

Handling

Sewage sludge. US prohibits use of agricultural ingredients grown using municipal sewage sludge; EU does not.

Pest management. US contains extensive requirements for facility pest management; EU does not contain any comparable requirements. US sets requirements for measures to be taken following the application of non-approved pest control substances; EU does not.

Packaging. US specifically prohibits the use of packaging that has come in contact with synthetic fungicides, fumigants, or other prohibited materials; EU does not.

Prohibited substances. US requires certified operators to notify certifiers immediately when prohibited substances are applied; EU does not address this.

Residue levels. US sets maximum tolerance levels for prohibited substances. EU does not establish maximum residue levels specific for organic products.

Labelling

Use of term “organic”. US specifies that the term ‘organic’ may not be used modify a non-organic ingredient in a product name. This is not addressed by EU.

Calculation of % organic. Both EU and US require at least 95% organic ingredients in ‘organic’ products. However, under US, at least 95% of the *total* ingredients must be organic; under EU, at least 95% of the ingredients of *agricultural origin* must be organic. That is, non-agricultural ingredients are not included in the calculation under EU, whereas they are included in the calculation under US. The EU method of calculation can result in products with less than 95% of the total ingredients being labelled ‘organic’. Similarly, both EU and US require at least 70% organic ingredients in ‘made with organic ingredient’ products. However, under US, at least 70% of the *total* ingredients must be organic; under EU, at least 70 % of the ingredients of *agricultural origin* must be organic. Non-agricultural ingredients are not included in the calculation under EU, whereas they are included under US. The EU method of calculation can result in products with less than 70% of the total ingredients being labelled ‘made with organic ingredients’.

Limits on listing organic ingredients. US sets a limit of listing no more than three organic ingredients or food groups in the ‘made with organic ingredients’ label category. EU sets no such limit.

Listing allowed and prohibited inputs

Criteria. EU has less specific and therefore less restrictive evaluation criteria for crop and livestock inputs than does US. EU has no additional evaluation criteria for processing inputs, whereas US does include additional criteria for evaluating processing materials for use in organic products.

Crop inputs

Sodium chloride. EU lists sodium chloride as an acceptable fertiliser. US generally prohibits minerals of high solubility. There are a few exceptions listed with restrictions, but sodium chloride is not among the exceptions.

Inert ingredients. US restricts the types of inert ingredients in pesticides used in crop production; EU does not address inert ingredients.

Livestock inputs

Fish-based feeds. EU allows the use of fish, other marine animals, and their products and by-products as feeds. Fish and fish products are not considered to be from organic sources and on that basis are prohibited as animal feeds by US. (However, on 3/1/02, the NOP posted an answer to a “Frequently Asked Question” which indicates that fish products can be used for livestock feed.)

Processing inputs

Summary of differences. The following processing inputs are allowed by EU but prohibited by US: activated carbon, agar, argon, carrageenan, casein, egg white albumen, ethanol solvent, gelatine, karaga gum, tragacanth gum, hazelnut shells, isinglass, malic acid, potassium alginate, rice meal, sodium tartrate, talc, and tartaric acid.

Volatile solvents. US specifically prohibits synthetic volatile solvents in products labelled ‘organic’ and ‘100% organic’. EU does not specifically prohibit synthetic volatile solvents, but none are approved on the list of allowed processing inputs.

B. Areas Where the US is Less Stringent than the EU:

Crops

Conversion period. EU requires full implementation of organic practices during the entire conversion period. US does not require full implementation of organic practices during conversion, but requires 3 years with no prohibited inputs.

Storage of prohibited materials. EU prohibits storage of prohibited materials on organic farms; US does not.

Organic plans. EU requires applicants to sign ‘undertakings’ denoting agreement to follow the regulation and abide by enforcement measures. US does not require applicants and certified operators to sign undertakings or affidavits.

Manure. EU sets specific limits on the quantity of manure applied annually; US does not. EU sets specific requirements for the capacity of manure storage facilities; US does not. EU requires consideration of the source of manure allowing manure from organic production units and regulating the amount of manure from conventional sources. EU prohibits manure from ‘extensive husbandry’ or ‘factory farms’. US does not address manure source, other than to require that the nutrient management system not contaminate crops, soil, or water with plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances.

Propagation materials. EU will require organic propagation materials after December 31, 2003. US will continue to allow use of non-organic, untreated seeds when organic seeds are not commercially available.

Livestock

Stocking rates. EU contains detailed and prescriptive stocking rates in Annex VII and livestock housing specifications in Annex VIII. US does not specify outdoor stocking rates or indoor housing densities.

Handling

No items noted.

Labelling

Requiring % organic on label. EU requires that the organic percentage of the total agricultural ingredients be indicated on the label; US does not.

Crop inputs

Antibiotics. US allows the use of specific antibiotics to control plant diseases; EU does not.

Sodium nitrate. US allows the use of sodium nitrate for up to 20% of the crop's total nitrogen requirement. EU prohibits use of sodium nitrate.

Livestock inputs

No items noted.

Processing inputs

Summary of differences. The following processing inputs are allowed by US but prohibited by EU: hydrogen peroxide, ozone, potassium acid tartrate, potassium citrate, potassium iodide (nonsynthetic), and sodium citrate.