IFOAM EU GROUP

International Federation of Organic Agriculture Movements – EU Regional Group

President: Christopher Stopes

Director: Marco Schlüter

European Office
Rue du Commerce 124
1000 Brussels
Belgium

Phone: +32-2-280 1223
Fax: +32-2-735 7381
Email: info@ifoam-eu.org

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Mr João Onofre,
Head of unit, H3
DG Agriculture and Rural Development
European Commission
Brussels

Dear Mr Onofre,

Following our letter of 25th July 2012 on verification of livestock records of the operator and our letter of 19th September 2012 raising further concerns regarding the equivalence agreement between EU and US, IFOAM EU Group wishes to outline the way in which the production of antibiotic free livestock products may be achieved, thus enabling the exception to the agreement for "*agricultural products derived from animals treated with antibiotics cannot be marketed as organic in the United States*" to be overcome in the EU, both at the level of farm production and processing.

Furthermore IFOAM EU Group wishes to provide our interpretation on how the conversion period for animals that will produce products intended to be exported to US market can be applied on EU livestock farms.

1) Separation between AB-free animals and treated animals and their products

Identification of antibiotic (AB)-free animals and animals treated with AB at farm and processing level is feasible and has been applied in operations previously certified according to the USDA-NOP, consequently separation of livestock products at farm and processing level is achievable. Parallel production in livestock operations is allowed under US rules. Separation can be either physical or through the use of microchip or visible, physical marking systems that unequivocally identify the animals that have been treated with AB and those that are AB free, this allows for separation of AB-free livestock products for marketing. Control bodies (CB) currently verify the livestock records of the operator, including regarding veterinary treatment and the use of antibiotics, as specified in Articles 76 and 77 of Commission Regulation (EC) No 889/2008 and verify compliance with the production rules regarding the use of antibiotics as specified in Articles 23(2) and 24(2), 24(3), 24(4) and 24(5) of Commission Regulation (EC) No 889/2008.

Animals treated with AB are already closely controlled according to the EU organic regulations since, according to Article 24(5) of Commission Regulation (EC) No 889/2008, the withdrawal period between the last administration of an allopathic veterinary medicinal (including AB) and the production of organic products from such

animals must be twice the legal withdrawal period for conventional livestock farms or, where there is no withdrawal period legally specified, at least 48 hours.

At processing level the separation is and it would be, by time or by space, according to the different categories of products:

1) Organic (EU),

2) Organic (EU) compliant with the EU/US equivalence (coming from AB-free animals),

3) Conventional (if present).

Before the equivalence agreement came into force, there was a separation between EU certified products and NOP-certified products. It is clear that separation of products coming from AB-free animals and other products can be done and European CBs can easily carry out the check of traceability for AB-free animal products intended for sale in the US market.

The critical control points will vary from farm to farm and the CB will assess the controls that each farm has in place to ensure that they are effective. CBs will be assessed by competent authorities against the criteria used to define that products have been produced without the use of Abs, and what internal control systems are in place to verify and certify eligible products. These procedures will be consistent with the systems of certification and control that are already in place. Operators (at production and processing level) must be able to demonstrate how AB-free animals are identified and how the products of AB-free animals are kept separate in the supply chain.

The processing and storage operations are carried out according to articles 26 and 35 of Commission Regulation (EC) No 889/2008 and the operation records can be checked by the CBs.

According to the appendix 1 point 1 of the letter sent on 15th February 2012 by the USDA to the Commissioner Mr Dacian Cioloş, one of the exceptions for the equivalence determination is that "Agricultural products derived from animals treated with antibiotics cannot be marketed as organic in the United States". According the abovementioned procedure, the exception is completely fulfilled.

2) Conversion period in dairy livestock production

In a guidance statement of 13th April 2004 , the NOP program manager clarified the status of dairy animals treated with antibiotics stating that:

"Under section 205.238 (c)(1) of the NOP regulations, a dairy animal treated with antibiotics cannot be sold, labeled, or represented as organic. Milk or milk products derived from such an animal cannot be sold, labeled, or represented as organic.

Under section 205.236(a)(2), however, the regulations do not prevent a treated dairy animal from being used to produce organic milk or milk products, as long as the animal has been under continuous organic management for a minimum of one year prior to the milk or milk products being sold, labeled, or represented as organic. Also, the NOP regulations, at section 205.236(a)(3) do not prevent such an animal from being used as breeder stock. Livestock used as breeder stock may be brought from a nonorganic operation onto an organic operation at any time. If such breeder stock are gestating and the offspring are to be raised as organic livestock, however, the breeder stock must be brought onto the operation no later than the last third of gestation."
(http://www.ota.com/pics/documents/AntibioticGuidance041304.pdf)

Notwithstanding that the articles mentioned in the statement have been subsequently amended, the content is still valid and the interpretation would be that the animals treated with AB and any products produced following slaughter of such animals (eg meat) can never be sold, labelled or represented as organic. However, if such animals are removed from the herd and managed continuously for 12 months according to the NOP rules, their milk can be sold, labelled or represented as organic. Furthermore breeder stock treated with antibiotics may still give birth to organic offspring if they are brought onto the operation no later than the last third of gestation.

Conclusions

Through the procedures outlined above, IFOAM EU Group wishes to clarify a key aspect of livestock production that will enable trade of AB-free products between EU and US. The EU organic regulations already detail all the precautionary measures to prevent mixing between different types of products, both at the level of livestock production on-farm and at the processing level. European CBs already have the expertise to operate according the abovementioned procedures, and several European CBs have already been (and remain), accredited by the USDA to carry out control and certification according the NOP standards.

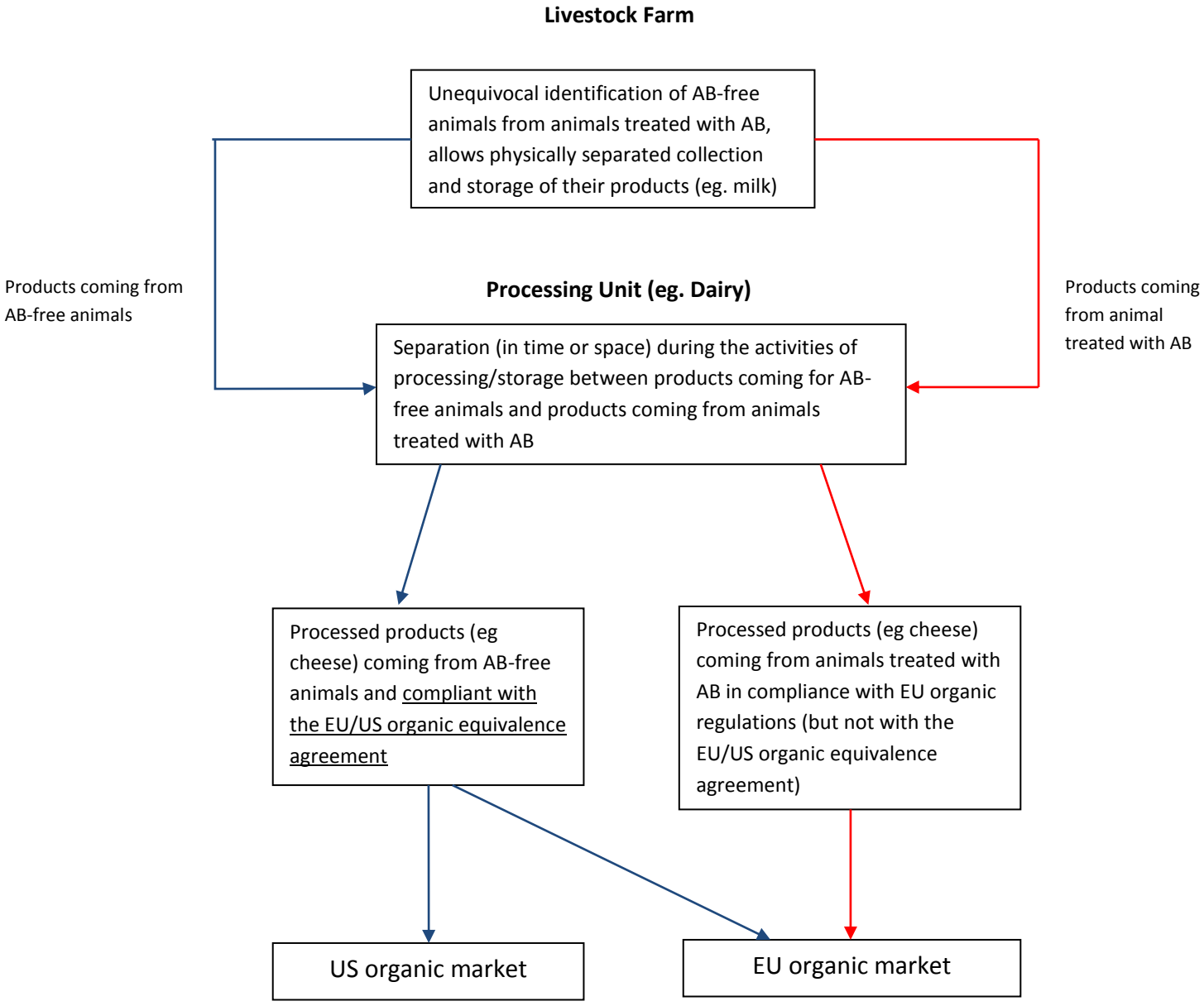
Annex I: Product Flow Chart outlining the procedure for AB-free livestock production and processing

Annex II: Reference articles of Commission Regulation (EC) No 889/2008

With thanks and best wishes,

Marco Schlüter
IFOAM EU Group Director

Annex I


Livestock Farm
Unequivocal identification of AB-free animals from animals treated with AB, allows physically separated collection and storage of their products (eg. milk)
Products coming from AB-free animals
Products coming from animal treated with AB
Processing Unit (eg. Dairy)
Separation (in time or space) during the activities of processing/storage between products coming for AB-free animals and products coming from animals treated with AB
Processed products (eg cheese) coming from AB-free animals and compliant with the EU/US organic equivalence agreement
Processed products (eg cheese) coming from animals treated with AB in compliance with EU organic regulations (but not with the EU/US organic equivalence agreement)
US organic market
EU organic market

Annex II

Reference articles of Commission Regulation (EC) No 889/2008:

Article 23(2) - Disease prevention

2. The use of substances to promote growth or production (including antibiotics, coccidiostatics and other artificial aids for growth promotion purposes) and the use of hormones or similar substances to control reproduction or for other purposes (e.g. induction or synchronisation of oestrus), is prohibited.

Article 24 (2)(3)(4)(5) - Veterinary treatment

2. Phytotherapeutic, homeopathic products, trace elements and products listed in Annex V, part 3 and in Annex VI, part 1.1. shall be used in preference to chemically-synthesized allopathic veterinary treatment or antibiotics, provided that their therapeutic effect is effective for the species of animal, and the condition for which the treatment is intended.
3. If the use of measures referred to in paragraph 1 and 2 is not effective in combating illness or injury, and if treatment is essential to avoid suffering or distress of the animal, chemically synthesised allopathic veterinary medicinal products or antibiotics may be used under the responsibility of a veterinarian.
4. With the exception of vaccinations, treatments for parasites and compulsory eradication schemes where an animal or group of animals receive more than three courses of treatments with chemically-synthesised allopathic veterinary medicinal products or antibiotics within 12 months, or more than one course of
treatment if their productive lifecycle is less than one year, the livestock concerned, or produce derived from them, may not be sold as organic products, and the livestock shall undergo the conversion periods laid down in Article 38(1). Records of documented evidence of the occurrence of such circumstances shall be kept for the control body or control authority.
5. The withdrawal period between the last administration of an allopathic veterinary medicinal product to an animal under normal conditions of use, and the production of organically produced foodstuffs from such animals, is to be twice the legal withdrawal period as referred to in Article 11 of Directive 2001/82/EC or, in a case in which this period is not specified, 48 hours.

Article 26 (2)(3)(4)(5) - Rules for the production of processed feed and food

2. Operators producing processed feed or food shall establish and update appropriate procedures based on a systematic identification of critical processing steps.
3. The application of the procedures referred to in paragraph 2 shall guarantee at all times that the produced processed products comply with the organic production rules.
4. Operators shall comply with and implement the procedures referred to in paragraph 2. In particular, operators shall:
(a) take precautionary measures to avoid the risk of contamination by unauthorised substances or products;
(b) implement suitable cleaning measures, monitor their effectiveness and record these operations;
(c) guarantee that non-organic products are not placed on the market with an indication referring to the organic production method.
5. Further to the provisions laid down in paragraphs 2 and 4, when non-organic products are also prepared or stored in the preparation unit concerned, the operator shall:
(a) carry out the operations continuously until the complete run has been dealt with, separated by place or time from similar operations performed on non-organic products;
(b) store organic products, before and after the operations, separate by place or time from non-organic products;
(c) inform the control authority or control body thereof and keep available an updated register of all operations and quantities processed;
(d) take the necessary measures to ensure identification of lots and to avoid mixtures or exchanges with non-organic products;
(e) carry out operations on organic products only after suitable cleaning of the production equipment.

Article 35 - Storage of products

1. For the storage of products, areas shall be managed in such a way as to ensure identification of lots and to avoid any mixing with or contamination by products and/or substances not in compliance with the organic production rules. Organic products shall be clearly identifiable at all times.
2. In case of organic plant and livestock production units, storage of input products other than those authorised under this Regulation is prohibited in the production unit.

3. The storage of allopathic veterinary medicinal products and antibiotics is permitted on holdings provided that they have been prescribed by a veterinarian in connection with treatment as referred to in Article 14(1)(e)(ii) of Regulation (EC) No 834/2007, that they are stored in a supervised location and that they
are entered in the livestock record as referred to in Article 76 of this Regulation.
4. In case where operators handle both non-organic products and organic products and the latter are stored in storage facilities in which also other agricultural products or foodstuffs are stored:
(a) the organic products shall be kept separate from the other agricultural products and/or foodstuffs;
(b) every measure shall be taken to ensure identification of consignments and to avoid mixtures or exchanges with non-organic products;
(c) suitable cleaning measures, the effectiveness of which has been checked, have been carried out before the storage of organic products; operators shall record these operations.

Article 76 - Livestock records

Livestock records shall be compiled in the form of a register and kept available to the control authorities or bodies at all times at the premises of the holding. Such records shall provide a full description of the herd or flock management system comprising at least the following information:
(a) as regards animals arriving at the holding: origin and date of arrival, conversion period, identification mark and veterinary record;
(b) as regards livestock leaving the holding: age, number of heads, weight in case of slaughter, identification mark and destination;
(c) details of any animals lost and reasons thereof;
(d) as regards feed: type, including feed supplements, proportions of various ingredients of rations and periods of access to free-range areas, periods of transhumance where restrictions apply;
(e) as regards disease prevention and treatment and veterinary care: date of treatment, details of the diagnosis, the posology; type of treatment product, the indication of the active pharmacological substances involved method of treatment and veterinary prescription for veterinary care with reasons and withdrawal periods applying before livestock products can be marketed labelled as organic.

Article 77 - Control measures on veterinary medicinal products for livestock

Whenever veterinary medicinal products are used the information according to Article 76(e) is to be declared to the control authority or body before the livestock or livestock products are marketed as organically produced. Livestock treated shall be clearly identified, individually in the case of large animals; individually, or by batch, or by hive, in the case of poultry, small animals and bees.