FY 2010 Commissioned project for improvement of reliability of the Organic Japan Agricultural Standards (JAS) system and related matters (Ministry of Agriculture, Forestry and Fisheries)

# Site Inspection Handbook

Methods of site inspections for the Organic Japan

Agricultural Standards (JAS) certification for inspectors

(Questions and answers on inspection and

determination of organic foods)

(Preliminary Translation)

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#### Introduction

This handbook is the expansion of "Sub-textbook on skill improvement of inspectors and judges for Japan Agricultural Standards (JAS) certification (Non-Profit Organization Japan Organic Inspectors Association)" published in 2003. The handbook summarizes the important points on inspection work performed by organic inspectors in a question and answer format.

In inspections of production process managers of organic plants and organic processed foods, basically, the compliance with the technical criteria for certification is confirmed. There are, however, various methods for confirmation of compliance. There are no definite methods. Depending on registered certifying organizations, inspection manual and/or rules are prepared in order to complement the rules for certification work and specific confirmation methods are defined. Inspectors and judges are also required to use different methods of confirmation. Actually, inspectors have to perform the work in compliance with an inspection manual of a registered certifying organization.

In Chapter I of this handbook, general inspection procedures are detailed based on the International Organization for Standardization (ISO) Guide 65, which applied to organic certification services. Basic inspection procedures required for every registered certifying organization are described in Chapters II and III. Each section is presented in a user-friendly question and answer format according to the technical criteria for certification and the JAS. Organic plants and organic processed foods are described in Chapters II and III, respectively.

Standards, criteria, and questions and answers applied in this handbook

This handbook was prepared based on the following standards and criteria valid as of March 2011.

- Technical criteria for certification for production process managers of organic plants: Notice No. 186, February 22, 2006
- Japanese Agricultural Standards of organic plants: Notice No. 1180, August 27, 2009
- Technical criteria for certification for production process managers of organic processed foods: Notice No. 186, February 22, 2006
- Japanese Agricultural Standards of organic processed foods: Notice No. 1464, October 27, 2006
- Questions and Answers on the Japanese Agricultural Standards for Organic Plants and Organic Processed foods (Labeling and Standards Division, Food Safety and Consumer Affairs Bureau,

Ministry of Agriculture, Forestry and Fisheries): July 2010 (hereinafter referred to as Q&A in this handbook)

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# I. Inspection procedures based on the International Organization for Standardization (hereinafter referred to as ISO) Guide 65

# (Q1) Relationship between the Organic Japan Agricultural Standards (hereinafter referred to as JAS) Certification and ISO Guide 65

What is the relationship between the Organic JAS Certification system and ISO Guide 65?

(A)

The details of certification and conformation work by registered certifying organizations are set under Article 46 of the Enforcement Regulations for the Law Concerning Standardization and Proper Labeling of Agricultural and Forestry Products (hereinafter referred to as "the Ministerial Order"). For, example, item (i) (e) of Article 46 specifies that "the certification operation shall be the method which complies with standards concerning product certification organizations defined by the International Organization for Standardization and..." This is the corresponding part that indicates that the operations of registered certifying organizations have to be complied with ISO Guide 65.

As mentioned above, ISO Guide 65 gives the ISO requirements that product certifying organizations have to comply with.

# (Q2) Roles of inspectors and judges

What are the roles of inspectors and judges?

(A)

- Inspectors check the applicant information through an application and site inspections, and then report the facts and evaluate its compliance.
- Judges finally evaluate whether or not the applicant is compliant, and make a decision of certification.

Inspectors may point out incompliance with criteria during inspection, but may not directly mention the decision of certification to an applicant.

Judges evaluate whether or not every item is compliant based on documents submitted by the applicant and reports by inspectors. Judges evaluate whether the applicant can manage the production processes in accordance with the acts and whether or not the products scheduled to be

graded are complied with the JAS and finally make decisions of certification.

#### (Q3) Work of inspectors

How does ISO Guide 65 provide the work of inspectors?

(A)

ISO Guide 65 does not provide the details of work of organic inspectors. It states that organic inspectors should perform their work with reference to other standards, the ISO 19011 Guidelines for Auditing. ISO 19011 corresponds to the guidelines for inspections in the Organic JAS system. It is also used for auditing a quality management system (ISO 9001) and an environmental management system (ISO 14001), and an internal audit of a business entity.

# (Q4) Don'ts of inspectors and judges

What are the don'ts (prohibited matters) of inspectors and judges?

(A)

#### 1. Confidentiality

Inspectors have to protect the confidentiality of information obtained from inspections. For example, inspectors must not reveal information about a producer, who the inspector had inspected, without asking the producer during an inspection of another producer or on a public occasion (e.g., "Producer XXX used fertilizer YYY").

#### 2. Ban on judgment

Inspectors must not evaluate or judge production process managers who they inspected. Therefore, inspectors must not say that "you can (or cannot) be given certification."

# 3. Ban on inspection and judgment of production process managers by an interest

Stakeholders of production process managers must not perform inspections or make judgments. Stakeholders include relatives of such production process managers, and inspectors and judges who are distributors buying and selling plants of such production process manager, and who had conducted a consultation for an applicant entity. All stakeholders have to decline inspection and judgment work when requested by a certifying organization. Some registered certifying organizations do not appoint inspectors who live the same city or the same inspectors for several consecutive years.

#### 4. Ban on unfair reports

Inspectors have to perform an evaluation based on the evidences obtained from inspections, but must not make judgments by their own preconceptions and assumptions. Inspectors must not judge based on the thought out of past experiences, such as "this is impossible." They have to evaluate based on the facts they have actually confirmed. Inspectors must not denigrate the person who they inspected even if he or she gave a bad impression. When non-compliance is suspected, inspectors have to strictly refrain from judgments without asking questions in the inspection site. In that case, inspectors have to fully question the applicant about the circumstances in the suite prior to evaluation.

# 5. Ban on consulting

The role of inspectors is to confirm compliance with standards and/or criteria. Inspectors are not technical guidance officers. For example, inspectors must not

- Recommend specific fertilizers, agricultural chemicals, and others in the inspection site;
- Give guidance for agricultural management based on their own past experiences and knowledge;
- Recommend a specific inspection institute for soil analysis;
- Receive a payment other than inspection fee after the inspection by, for example, signing an advisory contract with such production process managers after the inspection; or
- Show or prepare a sample of rules and/or regulations.

# 6. Ban on receiving entertainment such as gifts, and wining and dining

Needless to say, <u>receiving entertainment such as gifts</u>, and <u>wining and dining</u> is banned. As for payment of lunch and other related expenses during the inspection, inspectors must comply with rules each registered certifying organization established.

#### 7. Ban on activities beyond the scope of inspection work

Other than listed above, inspectors have to be careful of their acts and behaviors, because a casual talk by an inspector about his or her job related advertisements might put an applicant under pressure.

# (Q5) Inspection procedures

What procedures are required for inspections?

(A)

Item 1 (a) of Article 46 of the Ministerial Order provides that the compliance with the technical criteria for certification has to be confirmed by documentary examinations and site inspections." These procedures are the same as those set under ISO Guide 65. Based on the Ministerial Order and

ISO Guide 65, inspectors, actually, have to follow the inspection procedures under the operating rules set by each registered certifying organization. Generally, inspection work is performed in the following order:

- 1. Acceptance of an inspection;
- 2. Documentary examination;
- 3. Site inspection; and
- 4. Preparation of inspection reports.

The procedures mentioned above are not necessarily performed by only one inspector. In some registered certifying organizations, the secretariat does the planning and conducts documentary examinations, which are preparation of inspections.

#### (Q6) Scope of processing steps that production process managers are allowed to carry on

Under what circumstances are production process managers of organic plants allowed to carry out the processing within the limits of the certification?

(A)

Production process managers of organic plants may grade "organic plants." If end products that are produced as a result of processing are plant products, production process managers may grade the plant products.

If end products are "organic processed foods," production process managers have to be certified as production process managers of organic processed foods, no matter how small the producing equipment is. If documentary examinations reveal that processed foods are listed as a production item in the document, it is indicated that production process managers of organic plants may not grade the processed foods.

For instance, the following is indicated based on the Q Nos. 48 to 50.

- Polished rice is not a processed food but is considered as an organic plant product. Therefore, production process managers of organic plants may grade the polished rice that they produced.
- Crude tea (aracha) of green tea is basically regarded as a processed food. Tea leaves are, however, often immediately processed to prevent them from being discolored by an enzyme. When the tea leaves (aracha) are processed in their own facility, certified production process managers of organic plants may grade them, except the case when producers sell their tea to consumers.

As for the details of plant products and processed foods, see Q No. 48. The following table lists the products that production process managers of organic plants may grade, that is, they may include the products in the scope of application for certification.

Examples of end products or processing	Graded by production process managers
processes	
Rice polishing by a rice polishing equipment in	Yes
own facility	
Cracking and halving of soy beans	Yes
Crude tea of own produced green tea, except in	Yes
the case of selling to consumers	
Production and processing tea	No
Cut daikon (Japanese radish)	Yes
Kiriboshi daikon (dried Japanese radish strips)	No
Blanched frozen vegetables	No
Crude tea of black tea or oolong tea	No

Besides the above, for example, dried shiitake mushrooms are regarded as a processed food, and therefore, production process managers of organic plants may not grade them. When a food is difficult to be defined as an agricultural product or a processed food, leave the decision up to the registered certifying organizations, and documentary examinations will be started once the decision is made.

# (Q7) Procedures of documentary examinations

What is done in documentary examinations?

# (A)

Based on the documents submitted by an applicant entity, the compliance of the operation of the entity with the technical criteria for certification is evaluated, and whether or not plants and processed foods of the entity are produced complying with Organic JAS is assessed.

Documents submitted by an applicant entity are an application form and supporting documents specified by registered certifying organizations. The supporting documents include field drawings, drawings of facilities, internal rules, grading rules, and a list of people in charge (resumes) for plants, and drawings of facilities, production process chart, internal rules, grading rules, and a list of people in charge (resumes) for processed foods. The evaluation is performed based on those documents.

In an annual survey, the previous year's reports and matters to be improved are sent by registered certifying organizations to inspectors as references.

#### (Q8) Preparation of site inspections

What points should be considered in the preparation of site inspections?

(A)

#### 1. Planning of inspections

In planning inspections, visited time (e.g., appointments), beginning and ending time of the inspections, contents of site inspections (including visiting site), and documents and reports required from an applicant entity are notified to the entity. It is important to plan an inspection as far in advance as possible.

# 2. Picking up the important check points

In order to conduct efficient site inspections, it is useful for inspectors to sum up important check points based on the results of documentary examinations prior to site inspections. In fact, different problems other than the important check points might be observed on the site, and therefore, inspectors are required to be flexible under any circumstances.

# (Q9) Procedures of site inspections

What are the procedures of site inspections?

(A)

Generally, site inspections are performed in the following order:

- 1. Conducting of an initial meeting;
- 2. Interviews, site visits, and confirmation of documents and records; and
- 3. Preparation of reports of the results of inspections and conducting of a final meeting.

As for step 2, inspectors may decide by themselves the order of interviews, site visits, and confirmation of documents and records in order to perform efficient inspections. For example, in order to check the operational status of a facility, which is operated only in the morning, visit the facility during the operational hours. Further, in the first visit to a facility, it is efficient to inspect the production site first to understand the actual production process.

# (Q10) How to conduct an initial meeting?

What should be explained in an initial meeting?

(A)

The following items are discussed with a business entity in an initial meeting. The initial meeting should be short and simple to discuss the necessary things. Some of the following sometimes can be explained in the final meeting.

#### 1. Self-introduction

Introduce each other and confirm the names of people in charge of the entity to be inspected, who will participate in inspections.

#### 2. Confirmation of the purpose and scope of inspections, and the criteria

The following is confirmed.

(Example)

Purpose: Inspection for certification (or annual survey)

Criteria: Technical criteria for certification of organic plants (and evaluation of compliance with the criteria)

Scope of inspections: Confirmation of field, material storage, post-harvest facility, and records (confirm whether those areas can be inspected prior to the visit)

#### 3. Schedule of inspection and other check points

Starting time, scheduled closing time, order of inspection (interviews, site visits, conformation of records and documents), and rules of the entity to be inspected (e.g., confirm carry-on writing material in the facility, use white coats and masks, remove accessories during inspection to prevent foreign matters). Inspectors have to follow the instructions of people in charge of the facility for safety of inspection work. Confirm some precautions like those mentioned above.

#### 4. Implementation methods and procedures of inspections

The following two have to be known to the entity to be inspected.

- The inspection is a sampling audit. (An inspection is usually conducted in about one day, and therefore, the entire entity cannot be checked, depending on size of entity.)
- There are elements of uncertainty. (Because of a sampling inspection, it is possible to find non-compliance that was not found in the previous year. Therefore, non-compliance is sometimes pointed out, even if the entity to be inspected thinks that no such indication was found in the previous year.)

#### 5. Confirmation of matters relating to confidentiality

Inspectors inform that they have signed a nondisclosure contract with registered certifying organizations, and maintain confidentiality.

#### 6. Objections to the implementation or results of inspections

Inspectors inform in advance that an applicant entity may express objections about the results of the inspection to the inspectors.

# (Q11) Sampling inspection methods

What is the actual scope of a sampling inspection?

(A)

Generally speaking, it is impossible to check in a one-day inspection all activities, done by production process managers for one year, which are subject to inspection, and therefore, a sampling inspection is performed.

In order to determine whether production complies with JAS, as a rule, all fields are visited, because the immediate environment of the fields may change every year. However, it is impossible to check all documents such as shipping forms, because there must be several hundred slips if the business entity makes shipments to its customers every day. It is preferable to check all such documents and records, but if unable to do so, some samples will be taken from them for inspection. It is important to write down names and created dates of sampled documents. It's advisable that registered certifying organizations set certain standards concerting the what, how, and how many samples, to eliminate the variability of checking method of reports by sampling among inspectors.

# (Q12) Important points on interviews

What should be paid attention to during interviews?

(A)

#### 1. <u>Interview the appropriate people engaged in the activities that are going to be checked</u>

For instance, when a person in charge in the planning department who is not involved in the actual production applies for the certification, interview a person in charge in the production department to obtain accurate information on the production processes.

#### 2. Try to let interviewees relax

Interviewees might feel pressure to undergo inspection, and therefore, inspectors should try to let the interviewees relax to efficiently obtain information through good communication. Inspectors always have to keep in mind that they express their gratitude for interviewees.

#### 3. Avoid leading questions

Inspectors try not to ask yes-or-no questions but questions that yield specific answers. Make sure that the obtained answers are written down in order to well organize the information after the inspection or during the preparation of reports.

# (Q13) How to conduct a final meeting

What should be done in a final meeting?

(A)

#### 1. Agreement on the evaluation

Inspectors classify the findings from the inspection into four categories: non-compliance, not non-compliance but recommended improvement, other points noticed, and good points. Inspectors and the business entity check together if the results are factually correct or not.

#### 2. Possibility of improvement

When the business entity requires improvement, the deadline and the contact name (an inspector or a registered certifying organization), to which the entity will report the complete improvement, are determined. When the business entity has disagreement on the issues pointed out by inspectors, both make an effort to solve the disagreement. A result of disagreement has to be recorded in the inspection reports and reported to registered certifying organizations.

The following are important points in a final meeting.

- The results of non-compliance have to be classified as either critical non-compliance or minor non-compliance. It is critical when products, which do not comply with Organic JAS, are going to be shipped (or have already shipped), and urgent measures are required. In the case of minor non-compliance, such as a transcription error, which did not strictly observe with the rules but other records prove that the production process was complied with Organic JAS, the business entity may be given time to consider preventive measures. It is important to provide an understandable explanation of the state of non-compliance, such as which parts of the technical criteria for certification (or JAS) are not complied.
- If there are risks in the management points of the business entity, which are not regarded as

non-compliance, it may be recommended to improve its operations. In this case, the business entity has to be informed that it is not non-compliance and that the recommendation has no binding force. Even if registered certifying organizations establish operational rules, the operational rules are published in a manner that business entities can know about.

- The results indicated by inspectors are not always the same as the final determination by registered certifying organizations. It has to be informed to the business entity that the final determination might be different from the agreement reached in the final meeting.
- Inspectors should conduct a final meeting with not only the director but as many people in charge as possible in order to share the results.

# (Q14) How to prepare inspection reports

What should be included in inspection reports?

(A)

Inspection reports include the information checked in documentary examinations and site inspections, and the results of the evaluation in a written form or a checklist. Any forms have to describe compliance with JAS and technical criteria for certification. The standards or criteria, which are based for the evaluation of compliance or non-compliance, have to be described. Inspection reports have to include compliance with all matters, including results of re-evaluation (i.e., results obtained from the check of the improvement by the applicant who was indicated non-compliance).

Inspectors have to prepare reports that have to include understandable information for judges, because judges make decisions only based on the reports and accompanying information. Inspectors check the facts in documentary examinations and site inspections. The improvement from the previous year of business entities, if any, should be included in inspection reports.

# (Q15) Role of judges

How do judges evaluate reports and make final decisions?

(A)

Judges evaluate compliance with each section of the standards based on the documents submitted by an applicant and inspection reports and accompanying information. They check the basis of the compliance evaluation described in inspection reports, and whether or not the basis is appropriate. When all necessary items are complied with (or will be complied with in the future management), the certification is determined. Without identifying improvement of non-compliance, the certification may not be issued. Specific parts of articles, criteria, and others, which are not complied, have to be

clarified for judgments. Judges do not have to make decisions based on their own subjective views and expectations, but on criteria. Judges have to evaluate inspections for certification completely based on published standards.

#### II. Inspections of organic plants

1. Items concerning technical criteria for certification

Facilities for production and storage

- 1. Facilities for production
- (1) Fields or collection areas are complied with the section on fields and collection areas of Article 4 of Organic JAS (skip).
- (2) Places for raising seedlings are complied with the section on fields and collection areas or the section on management of raising seedlings of Article 4 of Organic JAS.

#### 2. Facilities for storage

Facilities for storage have size, illumination, and structures enough to manage products in accordance with the section on the management of harvest, transportation, selection, processing, cleaning, storage, packaging, and other processes described in the table in Article 4 of Organic JAS.

#### (Q16) Places to be confirmed in site inspections

What facilities and places have to be confirmed in site inspections?

(A)

Facilities for production (fields and raising seedling facilities) and facilities for storage, which are specified in the technical criteria for certification mentioned above, are confirmed as to whether they comply with JAS. Therefore, not only production fields but all facilities where post-harvest plants pass through have to be confirmed. For example, when a rice producer processes rice at home, the home has to be confirmed.

In order to confirm whether a production process complies with JAS, not only production fields but also compost sites, material yards, and other relates places have to be confirmed.

As for mushrooms, the following places have to be confirmed: inoculation sites, temporary log lying and log lying places (houses), dip tanks, sites of occurrence, and sites for selection and storage for wood log cultivation, storage sites of raw materials, sites for medium preparation, and places for

sterilization, inoculation, cultivation, occurrence, selection, and storage for fungal bed cultivation.

All related facilities have to be confirmed with regard to the compliance with the standards in every annual survey, even if a business entity has already been certified.

# (Q17) Confirmation of fields

In order to confirm that the location and area of applicant fields correspond to those described in an application, what should inspectors confirm and what kind of information should it be based on?

(A)

Generally, inspectors confirm that "the location and area of target fields correspond to those described in an application" by checking them against the application and drawings.

First, confirm whether drawings of all fields have been submitted and then that each drawing includes the area of the field.

There are various confirmation methods. When a registered certifying organization assigns a specific method, follow the method. At least the following has to be confirmed in site inspections.

- Visually confirm that the actual shape of the field corresponds to that in the drawing, and that the environment surrounding the field corresponds to that in the drawing (when the location is different, another field might be checked).
- Visually confirm that the area of the field corresponds to the area written in the application (if the area is not correct, another field may be checked or it is checked whether this is due to an error in units of area, such as square meter and Tan (a Japanese unit of area). When the area is not the same as that mentioned in the application, the reason of the description has to be confirmed. Reasons include that the area was actually measured by an applicant and that the area in the application was a transcription from the official document such as a plot drawing and a land register.
- Direction has to be confirmed using a compass, avoiding an ambiguous indication in the final decision (e.g., "In the adjoining site on the east side,..." It is easier to indicate the results using directional terms).
- The confirmation is performed according to the procedures of each registered certifying organization. Some registered certifying organizations require inspectors to measure fields that were certified in the first year or that were additionally applied for certification.
- In an annual survey, especially modifications of the field numbers and the areas have to be confirmed. (Some modifications are due to integration, partition, and abolishment.)

# (Q18) Confirmation of facilities

In order to confirm that the "facilities for storage have size, illumination, and structures enough to manage products in accordance with the section on the management of harvest, transportation, selection, processing, cleaning, storage, packaging and other processes described in the table in Article 4 of Organic JAS," what kind of information is collected?

(A)

As for the abovementioned processes, Article 4 of Organic JAS provides four rules: 1) Prevention of mixing of non-organic plants, 2) restrictions on the use of pest control materials and materials for preparation, 3) restrictions on irradiation, and 4) prevention of drug contamination. It has to be confirmed that facilities have size and structure enough to observe the above four rules (as for 1) and 4), see the Q No. 42 and 43, respectively).

For example, in inspections of storage facilities, the size for the production volume of an applicant, the appropriate illumination to discriminate products, and the sufficient space to store separately organic and non-organic plants are estimated and evaluated.

How to implement management or understanding of production processes

- 1. Let production process chief managers implement the following:
- 1) Planning and promotion of the plan for management or understanding of production processes;
- 2) Planning and promotion of the plan for management or understanding of subcontract management, if applicable; and
- 3) Measures or guidance in case problems occur in production processes.

# (Q19) Confirmation of production plans

As for "Planning and promotion of the plan by a person in charge of management or understanding of production processes," what kind of specific information do inspectors collect?

(A)

There are various kinds of information, depending on the responsibility levels of production process managers, such as the following:

- Is there an annual planting plan (or planting plans based on crop types)?
- Is the planting plan made (or approved) by production process chief managers (or people in charge of production process management)?

- Is there a checking system for production management state (e.g., frequency of rounds of fields)? Is the check performed by people in charge of production process management?
- -If there is a group of people in charge of production process management, are workshops or training sessions conducted for the group?

When a chief manager of production process management seems to be nominal (e.g., an honorary post and an unauthorized young employee), inspectors have to confirm through interviews whether or not the person is qualified for the post. In an annual survey, management conditions and records concerning workshops are confirmed.

# (Q20) Confirmation of measures against problems and other events occurring in production processes

As for the item "Measures or guidance in case problems occur in production processes," what kind of specific information should inspectors collect?

(A)

Specific examples of "problems occurring in production processes" include

- Because the growth conditions were different from the expectation, materials defined in an appendix were used to prevent the damage from spreading.
- Banned substances were forced to be used in a field (or they had been used). Or, organic certification of a field had to be revoked because the field got contaminated from banned substances used in an adjoining field.
- Shipment of crops in a poor growing location were cancelled.
- After harvesting, organic and non-organic crops were mixed.

Inspectors have to confirm in writing or in interviews as to how people in charge of production process management deal with the problems mentioned above. These kinds of problems and measures are not required to be written in the rules of a business entity, and therefore, some entities might not have documents describing them. In that case, inspectors should conduct interviews to evaluate that the business entity can take appropriate measures for the problems. When a registered certifying organization recommends that reviews and notices of rules are states in the rules, inspectors tell the business entity to do so. Inspectors may not give suggestions for judgments beyond the technical criteria.

An annual survey confirms whether those kinds of problems occurred, and how did they cope with them, and the measures against them are confirmed.

How to implement management or understanding of production processes

2. As for the following items, specific and systematic internal rules have to be established. (Skip the rest.)

# (Q21) Confirmation of internal rules

What is the basis for making the decision as to whether or not the internal rules submitted by an applicant entity are "specific and systematic"?

(A)

The following are examples of specific rules:

- Documents of rules or appendices have to contain specific names and other details of materials and substances to be used.
- When more than one crop is cultivated and different cultivation methods are used (e.g., rice and vegetables and vegetables and fruits), each method has to be described in documents of rules or appendices.

The following are examples of non-specific rules:

- The words in the technical criteria for certification or JAS are copied in documents of rules or appendices.
- Documents of rules or appendices contain exact copies of rules set by a certifying organization or rules written in commercial materials. (When an applicant entity borrows these rules because it is not able to develop the concepts of rules, it will be confirmed whether the borrowed rules fit the operation and whether the applicant understands the rule.)

Being "systematic" means that the six items to be described as internal rules are easy to find in the document. If there are appendices and/or recording forms, they should be arranged to show clearly the six items to be described. (E.g., materials, substances and machinery to be used are listed, and a recording form of production management is established, and therefore, contents of the record are clear to understand.)

Items of internal rules

- (2) Items concerning fertilization management, control of noxious animals and plants, general management, and management of raising seedlings
- (3) Items concerning machinery and equipment used in production

#### (Q22) Confirmation of prevention of banned substances

In order to confirm that a producer, who also cultivates non-organic plants, does not use or bring substances listed in Appendices 1 and 2 in those fields that are meant for organic certification, what kind of information should be collected?

(A)

When one producer produces both organic and non-organic plants, there is a risk that substances banned for use in organic production (banned substances) are used or brought in organic fields. Therefore, measures have to be taken to prevent banned substances from accidentally being used or brought in organic fields. Following are some of the examples:

- Does the producer know that the banned substance cannot be used in organic fields?
- By whom and how are the substances to be used managed? (Does the manager confirm that?)
- When machinery such as spraying equipment is used in both organic and non-organic fields, it is necessary to confirm that measures are taken to prevent banned substances remaining in the machine from being brought into organic fields or crop.
- When oil gets leaked, even if the machine is fully cleaned, there is a risk that the machine oil may accidentally get into organic fields. Various risks of entry of banned substances have to be checked.

Specific examples of checking risks: Checking the state of control of banned substances in storage of substances; and confirming consistency between the producer's explanation and the results from checking purchasing forms of substances and the used amount described in a stock management table.

When there is a group of production process managers, it should be confirmed that a management system of banned substances is provided and then that the management is done according to the system.

How to implement management or understanding of production processes

3. Appropriate management or understanding of production processes has to be implemented according to internal rules and records of the management or understanding, and documents including evidence of the records have to be retained for more than a year from the shipment date of

graded organic plants.

#### (Q23) Confirmation of management or state of understanding of production processes

How do inspectors confirm that management or understanding of production processes "is appropriately implemented" according to internal rules?

(A)

First of all, inspectors have to confirm whether production process managers recognize that "they must manage or understand production processes based on the internal rules they made themselves." Examples for confirmation:

- Confirm whether cultivation methods and work described in the rules correspond to the actual conditions. If the description is abstract, ask them about the specific meaning of each item.
- As for a group of producers, each producer does not sometimes sufficiently understand the rules which he or she should follow. Confirm what points each producer focuses on in production management and whether there is a discrepancy among the contents described in the rules.
- Confirm whether the documents listed in the rules are actually stored.

Rules submitted at the time of application for certification should reflect cultivation management during the last couple of years (the period is different depending on perennial crops or others; one year is for plants under conversion). There should be documents including about the operation of production. Superficial rules only to obtain certification (e.g., rules made in reference to other production process managers or some reference documents) or rules in which all internal rules are integrated in a group of producers often do not correspond to the previous management. Inspectors confirm consistency with internal rules through documents, interviews of an applicant, and observation of facilities.

#### (Q24) Confirmation of evidence documents on production processes (records)

What are "evidence documents of such records"?

(A)

A specific document cannot be specified because documents are different depending on the management methods of production process managers. For instance, when production process managers of a large production group prepare a summary table of records of management, which is a transcription of the journals of each producer, the table is regarded as a document of management records and the journals are the evidence documents of those records.

However, a journal of an independent producer, in itself, is sometimes the records of the management. Evidence documents include information and purchasing forms of substance such as fertilizers and agricultural chemicals, organic certifications of seedlings, purchasing forms, shipping slips, and contract documents. In inspections, confirm which documents production process managers use as "records of management or understanding" of production processes and "evidence documents of those records"; that is to say, confirm the documents which they retain over three years.

Then, judge whether or not the documents provide enough evidence that production management methods of an applicant comply with the JAS.

How to implement management or understanding of production processes

4. An appropriate review of internal rules is regularly performed, and internal rules are fully disseminated to employees.

#### (Q25) Confirmation of a review of internal rules

How is it judged that "a review of internal rules is regularly performed" in inspections?

(A)

A review of internal rules of a business entity is not necessary in the first site inspection, because the rules have been just prepared. In this case, confirm that rules on a regular review of internal rules are established. A review of internal rules is not a requirement to be listed in the rules, and when it is not documented, confirm it by interviews. (When registered certifying organizations recommend that reviews and notices of rules be stated in the rules, inspectors may tell the business entity to do so. Inspectors may not give suggestions for judgments beyond the technical criteria.)

In an annual survey, confirm that a review is performed according to the rules, and if a change of rules is required by the review, that the rules are updated.

How to grade

2. As for the following items, specific and systematic rules on grading (hereinafter referred to as grading rules) have to be established. (Skip the rest.)

# (Q26) Confirmation of grading rules

How is it determined that grading rules are "specific and systematic"?

(A)

Because grading has not been performed at the time of inspections, grading rules cannot be confirmed. However, grading rules can be estimated if they specify that grading is performed by whom, when, where, and by what records. It is important that inspectors can imagine a specific situation of grading by reading grading rules.

Non-specific grading rules include the following:

- Grading rules in which words of the notice on inspection methods of the technical criteria for certification and production processes (\*) are copied.
- Grading rules in which rules suggested by certifying organizations or in commercial materials are copied.
- (\*): Notice No. 210 of the Ministry of Agriculture, Forestry and Fisheries of Japan, February 28, 2006

The rules in which no recording methods are defined are not regarded as specific.

The rules in which five items to be described in grading rules are clearly described are systematic. Also, if the rules define no methods to record the results of inspection of production processes for grading, they are not regarded as systematic.

Inspection methods of production processes

Inspections of production processes of organic plants have to be performed by lot, which such certified production process managers have admitted to be produced by the same production methods (hereinafter referred to as the production lot), according to the following: (Skip the rest.)

# (Q27) Confirmation of grading each production lot

What are the important points for confirming that grading is performed "by production lot by the same production methods"?

(A)

Under grading rules, a unit which is to be employed in grading is confirmed.

For example, in grading of fruits, which are shipped immediately after harvest, a unit of production lot may be a daily harvest. In the case of rice, which is harvested and processed over several days, a unit of production is often a series of processes. The term "lot" is generally used, and the unit of lot

is determined by an applicant. Inspectors confirm such lots depending on the situation of applicants. Applicants may manage their all rice harvested in the year as one lot. When plants harvested by several producers are grouped into one lot by harvest date, special inspection methods of production processes are required for confirming whether non-organic plant products enter in the lot.

# (Q28) Confirmation of time and methods of grading

What kind of information should be the basis in order to confirm that inspections of production processes are performed by appropriate methods at the right time?

(A)

It is important to check carefully the time and methods of grading in the confirmation of whether grading rules are specific.

Inspections of production processes do not always have to be performed by tracing back all processes just before shipment. Preliminary inspections on some parts are sometimes efficient.

For example, it must be an appropriate time to confirm the cultivation state when harvest is approaching and operation in fields has already finished. The completion of confirmation of cultivation state means that a part of inspections of production processes has been finished. Then, a harvest to shipment process is confirmed for every shipment and graded.

In the case of a group of producers, the inspection operation may be divided. For example, inspections of production processes are performed along with field observations, which makes the final confirmation step of the process easier.

Grading has to be performed before shipment. Post-harvest inspections of production processes are against the law.

In such divided inspections, confirm that the inspection items of production processes provided in the grading rules are in compliance with all the procedures of the JAS.

In an annual survey, confirm that inspections of production processes are performed according to rules. Actually, inspectors evaluate compliance by tracing records in site inspections. When those records reveal compliance with the JAS, it is recognized that all necessary items of the grading rules are included.

Items of grading rules

- (1) Inspections of production processes
- (2) Grade labeling
- (3) Shipment and disposal of lots after grading
- (4) Preparation and storage of records on grading
- (5) Requirements for appropriate confirmations of the actual state of implementation of grading by certifying organizations

# (Q29) Confirmation of items of grading rules

In order to confirm whether items of grading rules are appropriate or not, what kind of information should be collected?

(A)

For example, confirm the following:

- As for (1), specific names of records and documents used in inspection of production processes are listed.
- As for (2), how to indicate the Organic JAS mark (e.g., to print it on a cardboard carton, to put a seal of it, and print it on a bag), which is a specific description. It is preferable that preparation of a shipment and receiving book and a store management table, storage place, method of storage, and others are specified.
- As for (3), there are methods to confirm that no plants have been contaminated "from grading to shipment," when plants are stored for some time after grading and shipped. If non-compliance, such as contamination, is detected through confirmation, procedures of removing the Organic JAS mark and an organic label are described (e.g., disposal, diversion to general products).
- As for (4), it is preferable for understanding that recording methods, people who keep records, reporting place, duration of storage of records, and others are specific.
- Requirements in (5) include annual inspection of past grading, inspection required of registered certifying organizations by the Farm Ministry or the Food and Agricultural Materials Inspection Center (FAMIC), and irregular inspections. Response to a request for cooperation from registered certifying organizations is provided in the rules.

How to implement grading

3. Appropriate grading and labeling of grade are performed according to grading rules, and then it is confirmed that the appropriate labeling of grade is conducted.

# (Q30) Confirmation of future gradings that have not been conducted

What kind of information should be collected in order to confirm that the operation is appropriately performed and therefore the right labeling of grade is conducted?

(A)

At the time of evaluating compliance of this operation during inspections, grading has not been conducted. Therefore, at the time of inspections and judgments, it is judged whether "appropriate grading will be conducted" in the future.

Grading operation is confirmed through interviews or other methods in inspection for certification. It is judged how people in charge understand grading rules in the interviews.

In order to confirm this, grading practice (simulation of grading) may be required based on these rules. Such simulation of grading may reveal that records listed in the rules do not exist at that point (e.g., records are to be summarized after operation) and an amendment can be suggested. Simulation of grading also makes the rules more effective and, at the same time, makes people in charge deeply understand the grading methods. Simulation of grading also makes it easier for inspectors to evaluate the comprehension of people in charge and judge whether these people can conduct appropriate grading under revised rules

In an annual survey, compliance of implementation with grading rules is judged by confirmation of documents including records of inspections of production processes, management records on labeling of grade (management records of the JAS mark), shipment records, and disposal records of non-compliance products.

How to implement grading

5. Compliance of labeling of names with the methods provided in Article 5 of the Organic JAS has to be confirmed.

#### (Q31) Confirmation of future labeling that has not been conducted

What kind of inspections should be performed to confirm that appropriate labeling of names is surely performed?

(A)

As is the case in inspections and judgments in which it is judged that "appropriate grading will be conducted" in the future, information is collected in order to judge whether "labeling of names is

surely performed" after certification at the time of inspections and judgments.

People in charge are interviewed if they know the standards concerning labeling provided in Article

5 of the JAS and understand the contents. Article 5 includes the following.

Article 5 of the JAS: Labeling methods

One of the following has to be described:

- 1. "Organic plants"
- 2. "Organic cultivated plants"
- 3. "Organic plants XXX" or "XXX (Organic plants)"
- 4. "Organic cultivated plants XXX" or "XXX (Organic cultivated plants)"
- 5. "Organic cultivated XXX" or "XXX (Organic cultivated)"
- 6. "Organic XXX" or "XXX (Organic/yūki)"
- 7. "Organic XXX" or "XXX (Organic)"

Notice: "XXX" is replaced by the general name of such plants.

When labeling methods have been determined, confirm visually compliance of the indication on label, container, package, or invoice with the above.

However, labeling methods are sometimes determined in the first inspections. In this case, interview what kind of labeling will be scheduled and confirm compliance with the above (Article 5). Generally, label samples are submitted to be judged by registered certifying organizations after certification. Inspectors determine that post-certification confirmation is appropriate, which is mentioned in reports as a confirmation item at the time of judgment or after certification.

When there are no specific methods or when the schedule is changed, confirm that a target entity recognizes that it has to request confirmation from registered certifying organizations as soon as possible once the methods are decided (pre-printing is preferable).

A business entity has started organic shipment, and then compliance of the indication on label, container, package, or invoice is confirmed as visually as possible in an annual survey. As for products under conversion, confirm that labeling of "under conversion" is clearly indicated. Especially when organic plants are also (or will be) produced and shipped, confirm that different labels are used for organic plants and plants under conversion. As for "raw rice and polished rice," one should be careful to confirm them, because methods of labeling "names" are set according to individual quality labeling standards.

Qualification and the number of people in charge of grading

When such production process managers manage and understand several facilities for production and storage, the number of facilities and people in charge required for appropriate grading as to distribution... (Skip the rest.)

# (Q32) The number of people in charge of grading

How is it confirmed that the number of people in charge is appropriate?

(A)

Confirm operation size of production process managers, type of plants, post-harvest processes, and others.

Confirm whether such number is proper for grading by checking the grading rules based on the confirmed condition. Inspectors judge the number by themselves and ask production process managers about the reasons why they think that it is appropriate.

For example, when each producer separately harvests and ships crops on the same day, it is obviously impossible for only one person in charge of grading to conduct pre-harvest grading in terms of time. Also, when there are many packaging areas (e.g., every producer conducts packaging at home), it is physically impossible for only one person in charge of grading to grade. In those cases, a person in charge of grading probably cannot assume actual operation. Inspectors should make a comprehensive judgment of suitability of the number of people in charge of grading based on simulation of grading and others mentioned above.

When there are several people in charge of grading, a manager of grading is appointed. Therefore, operation of managers has to be confirmed.

#### 2. Items concerning Article 4 of the JAS

#### Field conditions

Measures have to be taken in fields to prevent banned substances from coming in and flowing from nearby areas and they correspond to one of the following. (Skip the rest.)

# (Q33) Prevention of coming in and flowing of banned substances from nearby areas of fields

What kind of information should be collected in order to confirm that applicant fields "have taken

measures to prevent banned substances from coming in and flowing from nearby areas"?

(A)

In documentary examinations, confirm that field drawings contain information of banned substances incoming from nearby areas (e.g., conventional farming methods are employed in adjacent areas) and the indication of a separation between adjacent areas.

In field confirmation, confirm whether some separations exist between fields and adjacent areas (e.g., footpaths between rice fields, paths, and water channels). Procedures to "prevent agricultural chemicals from coming in" include the following, which is described in Q&A No. 54:

- To have space between fields
- To separate fields by paths
- To install windshield nets
- To maintain buffer zones for cultivation of plants in boundary areas (When an applicant harvests in buffer zones, the crops have to be managed distinctively from organic crops.)

Observation of weed conditions in the nearby fields offers important clues for considering the possibility of incoming banned substances, such as herbicides. After a risk assessment of the possibility of contamination from nearby areas of fields, confirm whether there are some preventive measures for contamination as mentioned above. Thereafter, assess whether those preventive measures are effective. In a risk assessment, methods of application of substances in nearby fields have to be considered. For instance, influence is different between a spray vehicle and a manual pressure sprayer used in orchards.

Moreover, interview whether an applicant producer has good relationships with the nearby producers to gain their cooperation. (A written agreement would be reliable, however, it may sometimes not be obtained. Some registered certifying organizations set rules in which a distinct indication should be provided depending on if there is a written agreement. Provide an indication in accordance with the rules set by the registered certifying organizations.)

When aero application is conducted in nearby fields, confirm whether some preventive procedures for coming in of banned substances have been taken. The following, which Q&A No. 56 mentions, is confirmed:

- Whether appropriate buffer zones are maintained under some conditions, including landforms and direction of the wind?
- How is the aero application being conducted?

As for those cases, the registered certifying organizations sometimes set their own standards and policies. Therefore, based on such standards and policies, necessary information should be collected and evaluated in inspections and judgments. (For example, standards provide that distances of XXX and YYY meters are required for a manned helicopter and a radio-controlled helicopter, respectively.)

# (Q34) Possibility of contamination from conventional rice fields surrounding target fields

What do inspectors confirm to judge the possibility of contamination from conventional rice fields?

(A)

The Q&A No. 57 mentions the following:

- When (1) water directly from rivers, (2) well water, and/or (3) water directly from marshes are used, preventive procedures for flowing of banned substances are not required;
- When water running through conventional cultivation fields is used for farming, preventive procedures against flowing of banned substances into organic cultivation fields are needed. For example, water is temporarily reserved in a clarification rice field(\*) prior to flowing into the organic cultivation fields.

Therefore, based on maps of water system, interviews during inspections, site observations, and others, the following is confirmed:

- What is a water source?

When water directly from rivers, well water, and/or water directly from marshes are used, as mentioned above, further confirmation is not required (except when contaminated substances obviously enter). When water from a water channel into which domestic wastewater flows is used, it is required to carefully confirm whether banned substances enter or not.

- Are water for farming and wastewater separated?

When there is no problem of water source and water for farming and wastewater are separated, there is basically no contamination. Because herbicides are sometimes, however, applied near water for farming, water has to be observed in site inspection.

- When water for farming and wastewater are not separated and water running through conventional cultivation fields is used, banned substance may enter. In this case, it is confirmed whether preventive procedures are taken and effective.
- A clarification rice field is described as an example of necessary procedures in Q&A No. 57. It is, however, only an example, and there seem to be other preventive procedures.

(\*) A clarification rice field is a buffer field. Generally, there are successive organic rice fields and the first rice field which the water from non-organic rice field enters into is used as a buffer field. Harvest from the buffer field is not regarded as organic.

#### Conditions of field and others

Over three years before the first harvest for crops which are harvested from perennial plants and over two years before planting or sowing for other crops... (Skip the rest.)

# (Q35) Confirmation of histories of new applicant fields

In order to judge whether a field complies with the criteria of "being organically cultivated over three years before harvest," what do inspectors confirm?

(A)

Confirm whether the applicant field has complied with the JAS by documentary examinations. The documents with cultivation state during the past three years should have been submitted

In field observation, confirm whether there is some evidence which reveals obvious use of banned substances.

At an annual survey, certified fields have already confirmed to be used for organic cultivation for the last three years, and therefore documents after inspection for certification are confirmed. However, at an annual survey, new fields are applied for certification and/or producers are added in a production group, which are confirmed as is the case in inspections.

As for the purchasing history and storage condition of substances used, documents such as packing slips, storage condition in a storehouse, and purpose of use of banned substances may be confirmed.

As for fields under conversion, the same items as the above are confirmed for a certain part during the conversion period.

#### Conditions of field and others

More than one year before sowing or planting for fields that are developed or are not used for cultivation, banned substances have not been used over two years, and production of plants is started... (Skip the rest.)

# (Q36) Confirmation of histories of developed fields

As for "banned substances that have not been used in reclaimed fields," how should inspectors collect information?

(A)

As for developed fields, inspectors confirm whether an applicant knows the owner of the fields before their development and the previous management state.

When an applicant owns fields, records of the applicant (journals of every work, etc.) are confirmed (e.g., the applicant does not do cultivation work, but does management work, such as patrol).

When the fields were owned by another person other than the applicant, it is confirmed whether the previous owner can prove that the substances banned by the JAS were not used. Inspectors may obtain a document stating that described banned substances were not used (pledge card) from the previous owner.

#### Cultivation management in fields

Only fertilizers and soil improvement substances listed in Appendix 1 are used when the production capacity of farm fields derived from soil properties cannot be improved or maintained by only using the function of organisms which live or grow in such fields and/or the surrounding areas.

# (Q37) Confirmation of the case for using external fertilizers

When fertilizers are externally purchased for use, how should inspections be performed to confirm whether a case has complied with the criterion "production capacity of farm fields cannot be improved or maintained by using residues in fields or self-sufficient manure in nearby areas"?

(A)

Q&A No. 69 stated that the case in which the production capacity of farm fields cannot be improved or maintained means that "such plants cannot grow normally because of insufficient nutrients."

When externally purchased fertilizers are usually used, the reasons for usage are sometimes not listed in internal rules. Applicants will be interviewed how they estimate "insufficient nutrients of plants," when there are no specific descriptions in the rules.

The basis of estimates include the following:

- At planning of fertilization, measurements of fertility from manure reveal insufficient nutrients for

the growth of crops.

- Soil analyses show lack of specific nutrients.
- An observation journal of the growth state of plants shows that plant nutrient is more deficient than the average year.
- Amount of fertilizers required for such plants can be derived from past practices. Externally purchased substances have been traditionally applied as fertilizers.

# (Q38) Confirmation of compliance with Appendix 1 on fertilizers

What kind of information should inspectors collect for judging of compliance with Appendix 1?

(A) In Appendix 1, most substances are listed with conditions in the section on criteria. These conditions mean that it is often difficult to determine by confirmation whether those substances are appropriate by checking a guarantee of fertilizer.

Therefore, in order to prove that substances are meeting such conditions, production process managers may request a fertilizer company to issue a written proof with names of raw material and production methods.

When farmers produce fertilizers by themselves or they obtain manure from nearby livestock farmers, the production methods have to be described in a document.

In inspections, confirm the following: how production process managers confirm that substances meet the criteria, the confirmation methods are appropriate, and the determination that whether the substances that can be practically used are appropriate (e.g., inappropriate substances are determined as appropriate.)

Also, when it is required to check with registered certifying organizations about adequateness prior to use (or registered certifying organizations obligate to do so), details of fertilizers are sometimes not required to be confirmed by confirming that substances certified by registered certifying organizations are used.

Seeds, seedlings, and others used in fields

- 1. Seeds, seedlings, and others have to comply with the criteria in the section of fields or collection areas (skip) in the table.
- 2. Seeds, seedlings, and others mentioned above in section 1 are not difficult to obtain. (Skip the rest.)

#### (Q39) Confirmation of seeds, seedlings, and others used in fields

In order to confirm whether seeds, seedlings, and others are organic ones, which comply with the criteria of "seeds, seedlings, and others used in fields," what kind of information should be collected?

(A)

Contents of confirmation are dependent on purchased or home-produced organic seeds and seedlings.

The contents of confirmation include the following:

- Confirm that seeds and seedlings are ones derived from organic plants by checking supplier, slips, label, information sheet, pamphlet, and others of the seeds and seedlings. However, currently it is difficult to purchase organic seeds, and producers have little choice but to obtain them from fellows or in sales exhibitions by related bodies. Therefore some kind of documents, labels, and others about the seeds and seedlings might be obtained.
- Confirm cultivation methods and collecting methods for home-produced seeds.

Also, it has to be confirmed whether producers do some treatments such as seed disinfection and that such treatment methods are appropriate.

# (Q40) Confirmation of cases when non-organic seeds and seedlings are used

When organic seeds and seedlings are not used, what kind of information should be collected in order to confirm that "they are difficult to be obtained"?

(A)

Q&A No. 67 described the following:

- When volumes of sales of seeds, seedlings, and others are significantly small or when their prices are very high, and therefore organic seeds and seedlings are not used, the reasons of "the case when they are difficult to be obtained in the usual manner" are confirmed. For example, interview about (1) whether routes for purchasing, transfer, or exchange were searched; (2) how much they were if available, and other related things.

Under the current general situation in Japan, it is difficult to obtain, especially to purchase commercially, organic seeds and seedlings. They just have to be home-produced, or supplied among

an organic production group.

Production of seeds requires advanced techniques. Some breeds are unsuitable for home production (e.g., F1). All non-home-produced seeds are not always determined to be unsuitable.

Control of noxious animals and plants in fields

Only agricultural chemicals listed in Appendix 2 may be used in the cases when there is immediate and significant danger to crops as well as when noxious animals and plants in fields cannot be effectively controlled by cultural, physical, and biological control procedures, or their combination.

## (Q41) Confirmation of compliance with Appendix 2 on agricultural chemicals

Agricultural chemicals in Appendix 2 are approved for use "when there is immediate and significant danger to crops." When an applicant uses (or used) the agricultural chemicals listed in Appendix 2, what kind of information should be collected to judge compliance?

(A)

Q&A No. 78 described the following:

- It is the case when noxious animals and plants appear in nearby or target fields or when their appearance is expected with high probability based on previous experiences and it is predicted that such crops suffer enormous damage if noxious animals and plants are left.

That is to say, though there is no "immediate and significant danger to crops," use of the agricultural chemicals in Appendix 2 is included in a cultivation plan from the beginning, which does not comply with the requirements.

Inspectors confirm what standards producers use for making decisions (basis of the determination of usage of agricultural chemicals) through interviewing production process managers about the conditions when agricultural pests appear and the further condition if the pests are left. As for a production group, inspectors confirm a person making judgments and methods of reporting and confirmation.

In the case of "appearance is expected with high probability based on previous experiences," preventive control may be employed. Preventive control, however, has to be performed after conducting all cultural, physical, and biological control procedures. In inspections, whether a judgment is made is based on the effects from all of those procedures.

Even if crops finally require the agricultural chemicals in Appendix 2, the reasons for preventive use have to be clear.

Management of harvest, transportation, selection, processing, cleaning, storage, packaging, and other processes

2. Management without non-organic plants has to be performed in harvest, transportation, selection, processing, cleaning, storage, packaging, and other processes.

# (Q42) Confirmation of preventive procedures for entering of non-organic plants in post-harvest processes

What kind of information should be collected, in order to confirm that management without non-organic plants is performed in the above-mentioned processes?

(A)

There are various post-harvest processes depending on types of crops and producers. Therefore, inspectors confirm what kind of post-harvest processes crops pass through by checking submitted documents and interviews, and then confirm the possibility of entering of non-organic plants into organic plants.

Possible risks include the following: (1) non-organic plants may enter through the machinery used at harvest and processing process; (2) non-organic plants may be mixed up during transportation from a harvest site to workplaces for shipment; (3) non-organic plants may enter by improper handling of containers when brought into workplaces; (4) work at workplaces may not be physically and temporally separated; (5) procedure for preventing non-organic plants from entering in temporary storage or storage may not be taken; and (6) substances for processing listed in Appendix 3 may be used.

Generally, the following should be confirmed:

- Clear separation of crops during transportation
- Management of prevention of entering by using labels, special boxes for organic plants, and others
- Conveyor and selection lines for organic plant are exclusively used (if not, how are they managed?)
- Working time is separated, such as time for harvest and so on
- Crops harvested in buffer zones are differentiated from organic plants
- Processing process is an exclusive process (if not, how are they managed?)
- Each of organic and non-organic plants is given an individual storage place

- Storage facilities are separated for prevention of mixing lots of organic plant with lots of non-organic plant
- Lots are distinguished by marks, such as tags and labels
- When storage and transportation are outsourced, a written agreement on prevention of entering of non-organic plants and agent contamination (See next section) is prepared (or meetings and/or instructions are provided).

Management of harvest, transportation, selection, processing, cleaning, storage, packaging, and other processes

4. Organic plants are managed not to be contaminated with agricultural chemicals, cleaning agents, disinfectants, and other agents.

# (Q43) Prevention of contamination by agricultural chemicals, cleaning agents, disinfectants, and other agents

What kind of information should be collected in order to confirm that produced organic plants are managed so as not to be contaminated by agricultural chemicals, cleaning agents, disinfectants, and other agents?

(A)

As with the previous section, inspectors confirm in which processes agents are used and what kind of procedures are taken to prevent contamination by such agents.

Possible risks include the following: (1) Contamination by agents in a truck during transportation; (2) use of agents, which might be a source of contamination, at workplaces and places of storage and preservation; (3) contamination through machinery used, such as during processing; and (4) something which becomes a source of contamination enters into water in the cleaning processes.

Generally, the following should be confirmed:

- Prevention of insects and rodents in each process and whether or not agents were used
- Cutting equipment used during processing is exclusive to such processes and cleaned
- Methods of cleaning
- Packaging materials used

#### III. Production process managers of organic processed food

## 1. Items concerning technical criteria for certification

Facilities for production and storage

Facilities for production, processing, packaging, storage, and other processes have enough size, illumination, and structures to manage processes in accordance with (skip) the criteria in the section on the management of production, processing, packaging, storage, and other processes described in the table in (skip) Article 4 (skip) of the JAS on organic processed food.

## (Q 44) Facilities to be confirmed in processing factory

What facilities should be confirmed in inspections?

(A)

As provided in the above technical criteria for certification, inspectors have to visit and confirm all the facilities for production, processing, packaging, storage, and other processes of organic processed foods and other facilities relating to the production of organic processed foods.

By checking an application and related information submitted before inspections, inspectors make an inspection plan. For example, inspectors determine whether a commissioned warehouse listed on an application should be visited in this inspection, and confirm with registered certifying organizations of the facilities to be visited.

In an annual survey, inspectors have to confirm whether all related facilities comply with the criteria.

#### (Q45) Confirmation of size, illumination, and structures of facilities

What kinds of facilities are not enough to manage processes?

(A)

#### 1. Size

For example, a storage facility which is too narrow to store organic and non-organic raw materials and half-finished products separately.

#### 2. <u>Illumination</u>

For example, a facility which has poor illumination and where residues of previous production cannot be confirmed after cleaning for switching. As for illumination, a guideline of 50 lux can be used as a reference. This value is the standard of illumination at a food production site set by a

municipal corporation based on the Food Sanitation Act.

#### 3. Structures

For example, a production line producing both organic and non-organic foods, where cleaning process cannot be performed or cleaned by extrusion cleaning (cleaning with same ingredient). Such a production line cannot ensure prevention of entering of non-organic products.

How to implement management or understanding of production processes

- 1. Let production process chief managers implement the following:
- (1) Planning and promotion of the plan for management or understanding of production processes
- (2) Planning and promotion of the plan for management or understanding of subcontract management, if applicable
- (3) Measures or guidance in case of problems occurred in production processes

### (Q46) Confirmation of production plans

As for "Planning and promotion of the plan by people in charge of management or understanding of production processes," what kind of specific information do inspectors collect?

(A)

There are various kinds of information, depending on responsibility levels of production process managers, such as the following:

- Is there a system for planning of annual production? (When a producer cannot plan annual production because of its make-to-order system, do production process managers have their responsibilities in specific planning in a factory after receiving orders?)
- Was the plan made (or approved) by a production process chief manager (a person in charge of production process management)?
- Is there a system for checking of management status? Do production process managers perform the check?

In an annual survey, the actual management state is confirmed.

## (Q47) Confirmation of measures against problems and others that occurred in production processes

As for the item "Measures or guidance in case of problems that occurred in production processes," what kind of specific information should inspectors collect?

(A)

Specific examples of "problems that occurred in production processes" include the following:

- Non-organic products accidentally enter into the production processes.
- Organic production is started without cleaning for switching.
- Confirmation of produced volume shows the impossible volume based on yields, and therefore entering of non-organic products is suspected.
- Drug fumigation is accidentally performed in a place with organic products.

Inspectors have to confirm in writing or interviews how a production process chief manager is involved in dealing with the problems mentioned above. Those kinds of problems and measures are not required to be written in the rules of a business entity, and therefore some entities might not have such documents. In that case, inspectors should conduct interviews to evaluate if the business entity can take appropriate measures for the problems.

An annual survey confirms whether those kinds of problems occurred and how did they cope with them, and the measures against them are confirmed.

How to implement management or understanding of production processes

2. As for the following items, specific and systematic internal rules have to be established. (Skip the rest.)

### (Q48) Confirmation of internal rules

What is the basis for making a decision on whether or not the internal rules submitted by an applicant entity are "specific and systematic"?

(A)

Confirmation is performed in the same manner of (Q21). See (Q21).

As for processed foods, the following are examples of specific rules:

- Documents of rules or appendices have to contain specific names and others of raw materials and products to be used.
- When products from more than one category are produced, a production method has to be described for each product. (Or a production process drawing has to be prepared for each product.)

Items of internal rules

- (3) Items concerning production, processing, packaging, storage, and other processes
- (4) Items concerning machinery and equipment used in production, processing, packaging, storage, and other processes

## (Q49) Confirmation of prevention of non-organic raw materials and banned substances

What kind of information should be collected in order to confirm if there is contamination by non-organic raw materials and/or agents in a factory producing organic and non-organic versions of the same items?

(A)

Most factories of processed foods often produce organic and non-organic versions of the same products.

Therefore, in such factories, there are possibilities that a non-organic version of the same raw materials and agents as those that are used during an organic production period is stored.

In this case, some measures have to be taken to prevent non-organic raw materials and/or banned substances from accidentally being used or entering. For example, the following have to be confirmed:

- Whether it is recognized that such raw materials and substances are not used during organic production?
- By whom and how are the raw materials managed?
- When machinery is used in both organic and non-organic production, do the residues of raw materials and/or banned substances on the machinery manage not to enter into or contaminate organic production?

A specific example of checking risks is to confirm that distinguishing methods in a storage place of raw materials and semi-finished products and the management state of an agent storage area correspond to the explanation of a producer.

How to implement management or understanding of production processes

3. Appropriate management or understanding of production processes has to be implemented according to internal rules and the records of the management or understanding, and documents including evidence of the records have to be retained for more than a year from the shipment date of graded organic processed foods.

## (Q50) Confirmation of management or state of understanding of production processes

How do inspectors confirm that management or understanding of production processes is "appropriately implemented" according to internal rules?

(A)

Confirmation is performed in the same manner of (Q23). See (Q23).

When a factory produces organic processed foods for the first time and a format of documents, which is submitted at the time of application for certification, is newly established for only organic production, more items tend to be listed in the applicant documents, compared with conventional records of processing in non-organic production. Then, whether the documents are actually possible to be written has to be evaluated based on interview and previous records of non-organic production.

Inspectors confirm consistency with internal rules by documents, interviews of applicants, and observation of facilities.

(Q51) Confirmation of evidence documents on production processes (records)

How should inspectors confirm appropriate records?

(A)

Records should be inspected based on the following:

## 1. Is there an adequate sufficient recording system?

It is confirmed that records demonstrate compliance with the Organic JAS (e.g., whether there are records of cleaning and washing before the start of production for prevention of entering of non-organic raw materials? Can the products be traced to their organic raw materials?) One of the effective methods for this confirmation is to confirm that it is possible to trace back from shipment of products (or grading records) to acceptance of raw materials.

#### 2. Consistency of quantity

Impossible yields may reflect some errors of records or entering of non-organic raw materials. Consistency between volumes of raw material used and volumes of shipped products has to be confirmed. It is generally called immutable weight control. This method is easy or difficult to use depending on product properties. It has to be done effectively, or it would be a waste of time. In an annual survey, volumes listed in past grading reports submitted by a business entity may be used.

How to implement management or understanding of production processes

4. An appropriate review of internal rules is regularly performed and the internal rules are fully disseminated to employees.

#### (Q52) Confirmation of a review of internal rules

How is it judged that "a review of internal rules is regularly performed" in inspections?

(A)

Confirmation is performed in the same manner of (Q25) in the section of organic plants. See (Q25).

How to grade

2. As for the following items, specific and systematic rules on grading (hereinafter referred to as grading rules) have to be established. (Skip the rest.)

## (Q53) Confirmation of grading rules

How is it determined that grading rules are "specific and systematic"?

(A)

Confirmation is performed in the same manner of (Q26) in the section of organic plants. See (Q26).

Inspection methods of production processes

Inspections of production processes of organic processed foods (skip) have to be performed by the production lot by certified production process managers, according to the following. (Skip the rest.)

## (Q54) Confirmation of grading each production lot

What are the important points for confirming that grading is performed "by production lot"?

(A)

Confirm the timing and units for grading provided in grading rules.

Unit of a lot is determined by an applicant. Inspectors perform confirmation depending on situations. When products are packaged, this one lot is regarded as one production lot, and compliance of production lot with the JAS is confirmed.

In the case of stepwise production, such as the cases of miso (fermented soybean paste) and soy sauce, production processes of semi-finished products in a tank are confirmed. The unit of measure is a tank. Then the successive processes are confirmed in the packaging process. Therefore, stepwise

grading is also possible. In the cases of miso and soy sauce, all ingredients are prepared and put in a large tank, which is one lot, for long fermentation and maturation. Then the products in the tank will be subdivided, filled in a container, and packaged.

#### (Q55) Confirmation of time and methods of grading

What kind of information should be the basis in order to confirm that inspections of production processes are performed by appropriate methods at the right time?

(A)

It is important to check carefully the time and methods of grading for confirming whether grading rules are specific.

Inspections of production processes do not always have to be performed by tracing back all processes just before shipment. As in the cases of miso and soy sauce described in the previous section, preliminary inspections on some parts are sometimes efficient.

Grading has to be performed before shipment. Post-harvest inspections of production processes are against the law. When shipment is carried out just after harvest in early morning or at night, it should be confirmed whether the person in charge of grading can conduct pre-shipment grading.

In an annual survey, confirm that inspections of production processes are performed according to the rules. Actually, inspectors evaluate compliance by tracing records in site inspections. When those records reveal compliance with the JAS, it is recognized that all necessary items of the grading rules are included.

Items of grading rules

- (1) Inspections of production processes
- (2) Grade labeling
- (3) Shipment and disposal of lots after grading
- (4) Preparation and storage of records on grading
- (5) Requirements for appropriate confirmations of the actual state of implementation of grading by certifying organizations

#### (Q56) Confirmation of items of grading rules

In order to confirm whether items of grading rules are appropriate or not, what kind of information should be collected?

(A)

Confirmation is performed in the same manner of (Q29) in the section of organic plants. See (Q29).

How to implement grading

3. Appropriate grading and labeling of grade are performed according to grading rules, and then it is confirmed that appropriate labeling of grade is conducted.

## (Q57) Confirmation of future grading that has not been conducted

What kind of information should be collected in order to confirm that the operation is appropriately performed and therefore the right labeling of grade is conducted?

(A)

At the time of judgment of certification, grading has not been conducted. Therefore, at the time of inspections and judgments, it is judged whether "appropriate grading will be conducted" in the future.

Confirmation is performed in the same manner of (Q30) in the section of organic plants. See (Q30).

How to implement grading

5. Compliance of labeling of names and names of raw materials with the methods provided in Article 5 of the JAS of organic processed foods has to be confirmed.

## (Q58) Confirmation of future labeling that has not been conducted

What kind of inspections should be performed to confirm that appropriate labeling of names and names of raw materials is surely performed?

(A)

Information is collected in order to judge whether "labeling of names and names of raw materials is surely performed" after certification at the time of inspections and judgments.

Specifically, confirmation is carried out in the same way as (Q 31) in the section of organic plants. See (Q 31). The labeling standards of organic processed foods are provided in Article 5 of the JAS as below.

Article 5 of the JAS: Labeling methods

Labeling of names and names of raw materials of organic processed foods in Article 5 shall be conducted according to the following:

Item	Standards
Labeling of	1. Either of the following has to be written:
Names	(1) "Organic XXX" or "XXX (Organic/yūki)"
	(2) "Organic XXX" or "XXX (Organic)"
	Notice: "XXX" is replaced by the general name of such processed foods. In the case
	that among the organic processed foods of agriculture and livestock, the general
	name to be replaced by "XXX" is the same as that of an organic agricultural
	processed food, do as required by the Minister of Agriculture, Forestry and
	Fisheries.
	2. Despite the standards of the above 1, foods processed with organic plants under
	conversion, or produced or processed organic plants under conversion shall be
	assigned a name from the above (1) or (2), with "under conversion" before or after
	of the name.
Labeling of	1. Among the raw materials used, organic plants (except organic plants under
names of raw	conversion), organic processed foods (except those made with organic plants under
materials	conversion), or organic livestock products shall be added with "Organic" and other
	indications in their general names.
	2. As for the processed foods in which organic plants under conversion or products
	with produced or processed organic plants under conversion are used, "under
	conversion" shall be added before or after the names of raw materials based on the
	standards 1.

Many organic labels might be used for processed foods, because business entities produce private brand products. Depending on the rules of the registered certifying organization, all labels are required to be confirmed at the first inspection, and new labels are confirmed to be appropriate in an annual survey (or whether the new labels are checked by the certifying organization in each case). It should be noted that individual quality labeling standards are laid down for some items of processed foods, for which the labeling methods of "name" and "name of raw materials" are specified.

## Qualification and the number of people in charge of grading

When such production process managers manage and understand several facilities for production and storage, the number of facilities and people in charge required for appropriate grading as to distribution... (Skip the rest.)

#### (Q59) The number of people in charge of grading

How is it confirmed that the number of people in charge is appropriate?

(A)

Confirm operation size of production process managers, type of processed foods, production processes, and others.

Confirm whether such number is proper for grading by checking the grading rules based on the confirmed condition. Inspectors judge the number by themselves and ask production process managers about the reasons why they think that it is appropriate.

For example, products produced every day, such as tofu and natto, have to be graded every day. Only one person in charge of grading is not enough to grade products because of his or her business trips or days off. More than one people in charge of grading would be required depending on situations.

When there are several people in charge of grading, a manager of grading is appointed. Therefore, operation of the managers has to be confirmed.

#### 2. Items concerning Article 4 of the JAS

Conditions of raw materials including processing aids

- 1. Of the following, products whose labels are put on their packages, containers, or invoices. Except organic processed foods, which are produced by an entity that produces or processes such foods and which are graded based on Articles 14 or 19-3 of the Law Concerning Standardization and Proper Labeling of Agricultural and Forestry Products (Law No. 175; 1950).
- (1) Organic plants
- (2) Organic processed foods
- (3) Organic livestock products

## (Q60) Confirmation of the JAS mark of organic raw materials

How is it confirmed that "products whose labels are put on their packages, containers, or invoices"?

(A)

This item indicates that organic raw materials used are labeled with the Organic JAS mark. Therefore, confirmations to be carried out include the following: whether the Organic JAS mark of

raw materials was confirmed at the time of acceptance and storage, or whether it is available to confirm that confirmed raw materials were used at production processes according to the records.

The completed confirmation mentioned above complies with the JAS. Actually, most business entities often seem to confirm by the certifications of production process managers or re-packers that an annual survey of raw materials to be used, as well as confirmation of the Organic JAS mark at acceptance were done. When it is specified in criteria and other standards that such entities establish such internal rules, confirm whether they follow the rules.

(Q61) Where self-produced organic plants are used as raw materials of organic processed foods How should the item after "However," be confirmed?

(A)

This proviso means that producers who produce agricultural plants use their raw materials to produce processed foods. In this case, the producers are not required to label the Organic JAS mark on their own products to use them in the next processing process. Labeling of the JAS mark (labeling of grade) is not needed; however, grading (inspection of plant production processes and judgment of the JAS compliance) is required. It is confirmed that the items mentioned above are confirmed and recorded. (Strictly speaking, this confirmation corresponds to information items in inspections of production process managers of organic plants, although it is preferable to also perform this confirmation in inspections of production process managers of organic processed foods because of production continuity.)

Conditions of raw materials including processing aids

- 2. Agricultural and livestock products other than 1, except the following:
- (1) Agricultural and livestock products that are of the same kind of organic plants and livestock products as the ones used as raw materials
- (2) Agricultural and livestock products treated with irradiation
- (3) Agricultural and livestock products produced using recombinant DNA technology
- 3. Marine products (Skip text in parentheses)
- 4. Processed products of agricultural, livestock, and marine products (Skip text in parentheses)

#### (Q62) Confirmation of non-organic raw materials

How are items provided on non-organic raw materials confirmed?

(A)

The use of organic and non-organic versions of the same raw materials are not permitted. As for the interpretation of the same raw materials, see Q&A No. 117.

As for raw materials treated with irradiation, confirmation is conducted according to Q&A No. 119.

As for production using recombinant DNA technology, in Japan today it would be sufficient to confirm only raw materials derived from the following:

(Target crops specified by the quality labeling standards concerning recombinant DNA)

1. Soybeans (including green soybeans and soybean sprouts); 2. Corn; 3. Potatoes; 4. Rapeseed; 5. Cottonseed; 6. Alfalfa; 7. Sugar beet

When agricultural products and processed foods derived from the above exist among non-organic raw materials, it has to be confirmed whether certifications proving no derivation from non-recombinant DNA have been obtained.

Conditions of raw materials including processing aids

- 5. Salt
- 6. Water
- 7. Food additives listed in Appendix 1 (Except what is produced using recombinant DNA technology. Same as below.)

#### (Q63) Confirmation of salt

How is it confirmed that salt complies with the standards?

(A)

As described in Q&A No. 121, the use of salt with a flavor enhancer, food additives, and various minerals is not permitted. Judge salt by checking written standards of salt.

## (Q64) Confirmation of water

How is it confirmed that water complies with the standards?

(A)

There are no specific rules provided by the JAS. Water to be used as a raw material is required to be drinkable under the Food Sanitation Act.

There would be no worry on the use of tap water. In the case of the use of well water, it is to be confirmed how the business entity confirms that the well water is drinkable and whether it has obtained and managed the results of water analyses if applicable.

## (Q65) Confirmation of compliance of food additives with Appendix 1

How is it confirmed that food additives comply with Appendix 1?

(A)

It is possible to confirm that food additives comply with Appendix 1 by the food additives' standards and others.

It should be noted that Appendix 1 includes food additives available for organic livestock processed foods but not for organic plant processed foods. It should be well considered whether a business entity interprets this incorrectly.

Some food additives are restricted in their use. The standards described in the right-hand column of Appendix 1 should be fully checked.

Mix ratio of raw materials

The ratio of weight of raw materials listed in standards 2, 3, 4, and 7 (except: processing aids) of the section of raw materials (including: processing aids) in the table in the weight of raw materials (except: salt, water, and processing aids) shall be 5% or less.

## (Q66) Confirmation of mix ratio of organic raw materials

What are the important points in the confirmation of mix ratio?

(A)

As for mix ratio, internal rules or their appendices including scheduled mix ratio have been submitted, and therefore mix ratio is confirmed by documentary examinations.

In site inspections, it is no problem that the organic ratio is 100%. When products are planned with the mix ratio set to at most 95% and the ratio of raw material to be used is variable by each lot, it could be impossible for each lot of such products to comply with the standards of 95% or more. In this case, confirm that management records such as journals are maintained to easily calculate organic ratio and that the results of mix ratio are validated at the time of grading (in inspections of production processes).

Production and processing methods

1. Production and processing have to be performed by the methods using physical and biological functions (except methods using organisms produced by recombinant DNA technology; same as below), and when food additives are used, they have to be limited to the minimum necessary.

## (Q67) Confirmation of use of food additives

How should inspection be performed to judge whether food additives are the minimum necessary?

(A)

First of all, a business entity is required to explain that the use of food additive is essential and the use amount is the minimum necessary. Numerical values of the limit of the minimum necessary by each product are not specified in the JAS, and, therefore, registered certifying organizations should finally judge this. Inspections have to collect information on this issue and repot it to registered certifying organizations.

Ban on entering of non-organic raw materials

2. Organic plants, organic processed foods, and organic livestock products to be used as raw materials have to be managed so as not to be entered with other agricultural and livestock products or their processed foods.

#### (Q68) Preventive measures of entering of non-organic raw materials

What kind of information should be collected to confirm whether the management measures have been conducted to prevent non-organic raw materials from entering?

(A)

It is thought that factories generally produce organic and non-organic versions of the same product. Such factories generally take preventive measures against entering of non-organic raw materials through time or space separation. Time separation includes that production is carried out at the first time of the day and no parallel production is conducted. Space separation includes that an exclusive organic production line or storage place is established. There are various measures among business entities. First, it is confirmed what kind of preventive measures such a business entity has taken by the internal rules and procedure appendices of a business entity.

In site inspections, inspectors confirm actual lines, check those points where there are risks of entry

due to machine structures, and conduct interviews to ensure that measures at the risk points are sufficient.

Prevention measures of rodents and insects in facilities

3. Control of noxious animals and plants has to be carried out by methods using physical and biological functions. However, when control using only physical and biological functions is little effective, only agents listed in Appendix 2 (except what is produced using recombinant DNA technology) may be used. In this case, entry into raw materials and products has to be prevented.

## (Q69) Physical control of noxious animals and plants

What kind of information inspectors should collect for judging whether that physical control is effective?

(A)

The use of substances listed in Appendix 2 without reason is not permitted, but it is permitted only when physical (or biological) control is little effective. Effective method for this judgment is monitoring. It is important that monitoring inspections are carried out and based on the results it is determined whether agents are used or not. When by a specialized company for prevention of rodents and insects offered advices based on the monitoring, the reports of monitoring results are confirmed.

With or without of irradiation

4. Irradiation may not have to be used for control of noxious animals and plants, storage of foods, or sanitation.

#### (O70) Confirmation if with or without irradiation

What kind of information inspectors should collect concerning the presence or absence of irradiation?

(A)

When irradiation is used, it is to be confirmed if the purpose corresponds to the above standards. The radiation dose (0.1 Gy or under) described in Q&A No. 126 can be confirmed in a pamphlet, etc., of the machine.

When the rule is established that the machine is to be used only for non-organic products and not for organic products, despite the response of "No," the machine might exist at the site. In this case,

confirm that the rule, that the machine is to be used only for non-organic products, is fully observed.

Prevention of drug contamination

5. Produced or processed foods based on the standards raw material (processing aids) section and standards specified sections 1 to 4 in this table have to be managed not to be contaminated with agricultural chemicals, cleaning agents, disinfectants, and other agents.

# (Q71) Prevention of contamination with agricultural chemicals, cleaning agents, disinfectants, and other agents

What kind of information inspectors should collect in order to confirm whether produced organic processed foods are managed not to be contaminated with chemicals, cleaning agents, disinfectants, and other agents?

(A)

It is a possibility that production machinery is washed with cleaning agents. For organic production, types of cleaning agents are not specified and it is only needed that agents are completely washed away.

Cleaning with only hot water or water does not require such confirmation. In the case of cleaning using agents, confirm cleaning procedures for complete removal of the agent. Also, confirm that whether cleaning is performed according to the procedure at the site.

In site visits, check whether there are agents such as cleaning agents in the factory. If that is the case, confirm that those agents are appropriately organized and managed to avoid misuse. Problems are pointed out on the basis of risk assessment. For example, if storage places of cleaning agents and semi-finished products are very close and the agents are left on a floor, risk would be high. When such agents put on a rack at a corner of a spacious factory and the storage place is defined, risk is low.