



REQUIREMENTS 04, Version 12

Soya Bean Primary Processor

Purpose	Specify the requirements to be met by Donau Soja soya bean primary processors.
Definition	Primary processor: company processing and/or treating soya beans chemically or physically most substantially, such as: - oil mill; - toaster; - soya bean primary processors acting as food producers; - producer of food ingredients and food additives.
Outline	<p>1 Risk assessment1</p> <p>2 Incoming deliveries of Donau Soja soya beans2</p> <p>3 Outgoing deliveries of Donau Soja soya4</p> <p>4 Soya stock management5</p> <p>5 Quality management5</p> <p>6 Product labelling6</p> <p>7 Donau Soja contract soya bean primary processor6</p> <p>8 Directly commissioned inspections6</p> <p>9 Supervisory inspections7</p> <p>10 Special form: own-use soya bean primary processor7</p> <p>11 Special case8</p>
Status	Version 12: released by the Board on 15 September 2021

1 Risk assessment

1.1 The primary processor shall be assigned a “primary processor risk level” (= P-RL) based on the quality of the soya beans delivered to the primary processor and processed there:

- P-RL 0: only Donau Soja soya beans are processed;
- P-RL 1: other GM-free soya beans (documented as being GM-free) are also processed;
- P-RL 2: other GM crops (except for soya beans) may also be processed (e.g. maize from countries of risk level 2 or 3);
- P-RL 3: option limited to **oil mills and toasters**, not possible for food producers:

If the processing lines are 100 % separated, both physically and technically, GM soya may also be present at the same site.

In particular cases, the Board of Donau Soja Association may temporarily approve chronological segregation between the processing of GM soya beans and the processing of GM-free soya beans (= dual processing).



Approval of dual processing is conditional on the following steps:

- The oil mill/toaster shall submit in writing a duly justified application for approval to Donau Soja Association.
- Donau Soja Association shall commission a chargeable audit in order to verify that chronological segregation does not pose an increased risk of GM-free soya being mixed with GM soya.
- The Board shall, when taking a decision, take into account any recommendations provided by audit bodies. The Board shall also limit the duration of the approval granted to the oil mill/toaster to one year. Additional conditions for obtaining the approval, such as an increased frequency of analyses (rapid tests, PCR testing), may be imposed on the oil mill/toaster.
- The oil mill/toaster shall demonstrate compliance with the spirit of all requirements as stipulated in the Requirements R 05 (for Compound Feed Producers) for dual processing, particularly with regard to the risk analysis (document) mentioned in paragraph 4.6 and the carry-over analysis mentioned in paragraph 4.7.
- The oil mill/toaster shall verify the correct functioning of chronological segregation by conducting rapid GM tests (Roundup Ready and LibertyLink) on the first three truck deliveries of the first Donau Soja lot following the production conversion. The oil mill/toaster shall also document the results of these tests.
- If any condition of approval is violated, any approval that has been granted may be withdrawn at any time.

For **food producers:**

No P-RL 3 possible as no GM soya beans may be processed at the entire site.

2 Incoming deliveries of Donau Soja soya beans

2.1 Before accepting delivery, the primary processor shall take one sample of each transport unit (e.g. truck) and per 100 tonnes respectively. The sample shall be divided for the following purposes:

- retained sample, which shall be stored for at least one year safely and without influencing its quality, ensuring traceability;
- rapid test (Roundup Ready and LibertyLink) and, where applicable, further testing (see 2.2).

Please note: Sampling and storage shall be in accordance with the customs of the Agricultural Products Exchange in Vienna (Börse für landwirtschaftliche Produkte in Wien) or with the GAFTA Sampling Rules No. 124 (chapter 3 „General“, chapter 4 „Method of Drawing Samples“, chapter 5 „Sample Labels“).

2.2 The primary processor shall conduct an approved rapid GM test (Roundup Ready and LibertyLink) on all samples taken for this purpose and referred to in paragraph 2.1 above. Afterwards, and depending on the test result, the primary processor shall implement the following measures:

- If the 1st rapid test does not detect any GM content: The primary processor shall accept the corresponding soya bean lot.



- If the 1st rapid test detects the presence of GM content: The primary processor shall subject the sample to two further rapid tests.
- If neither the 2nd nor the 3rd rapid test detects any GM content: The primary processor shall accept the corresponding soya bean lot.
- If the 2nd or 3rd rapid test detects the presence of GM content: The primary processor shall either not accept the corresponding soya bean lot or shall store the lot separately. In addition, the primary processor shall have a PCR test performed at a laboratory accredited for this test procedure in accordance with ISO standard 17025.
- If the PCR test detects a GM content of less than 0.9 %: The primary processor shall inform their contracted certification body of the result, and send the relevant lot certificate to this certification body. Afterwards, the primary processor shall take the appropriate measures (root cause analysis).
- If the PCR test detects a GM content of 0.9 % or more: The primary processor shall inform their contracted certification body of the result (and send the relevant lot certificate to this certification body). Afterwards, the primary processor shall take the appropriate measures. The primary processor shall remove the soya lot with a GM content of 0.9 % or more from the flow of produce and shall **not** market this lot as Donau Soja.

2.3 Depending on the risk assessment (see Annex 04), further testing may be required:

The following shall apply to Donau Soja soya beans produced in production areas of GM risk level 2 (GM-RL 2, i.e. the cultivation of GM maize is possible): If the unwanted maize content in any soya bean lot exceeds the maximum level of 0.5 %, the corresponding sample shall be additionally analysed for approved GM maize varieties using rapid tests (Roundup Ready and LibertyLink).

- If the 1st rapid test does not detect any GM content: The primary processor shall accept the corresponding soya bean lot.
- If the 1st rapid test detects the presence of GM content: The primary processor shall subject the sample to two further rapid tests.
- If neither the 2nd nor the 3rd rapid test detects any GM content: The primary processor shall accept the corresponding soya bean lot.
- If the 2nd or 3rd rapid test also gives a positive result, the primary processor shall have a PCR test performed at a laboratory accredited for this test procedure in accordance with ISO standard 17025.
- If the PCR test detects a GM content of less than 0.9 %, the primary processor shall conduct a root cause analysis together with **their own** certification body in order to determine whether the contamination occurred accidentally and/or was technically unavoidable.
- If the PCR test detects a GM content of 0.9 % or more, the primary processor shall remove the lot concerned from the flow of produce and shall **not** market this lot as Donau Soja.

2.4 The primary processor shall document the following for all incoming deliveries of Donau Soja soya beans:

- names, addresses and, where applicable, EU registration numbers (or equivalent specifications in non-EU countries) of all suppliers;



- results of rapid tests (Roundup Ready and LibertyLink) and, where applicable, of PCR testing;
- lot, quantity, quality label "Donau Soja", and lot certificates;
- delivery date, carrier and receiver;
- transfer cell.

If the primary processor accepts Donau Soja soya beans directly from the soya bean farmer:

The primary processor shall document the Declarations of Self-Commitment – Farmers (Soya Bean Producers) for all incoming deliveries. The primary processor shall comply with all requirements laid down in R02, paragraph 10.1 ("Soya bean primary processor acting as a primary collector").

- 2.5 By the 10th of each calendar month, the primary processor shall send the following information to Donau Soja Organisation (quality@donausoja.org), forwarding a copy of this information to the primary processor's contracted certification body:
- the quantity of Donau Soja soya beans (in tonnes) effectively delivered to the primary processor and processed there in the previous month, with reference to relevant lot certificates;
 - the quantity of processed Donau Soja soya invoiced and/or internally used in the previous month (all marketed Donau Soja products such as meal, oil-cake, oil, or food, plus customer names).

Please note: Licence fees shall be calculated based on the respective beans equivalent to the quantity of Donau Soja products invoiced and/or internally used; in case more than one Donau Soja product is used/invoiced, the licence fee shall be incurred only once per beans equivalent.

3 Outgoing deliveries of Donau Soja soya

- 3.1 The primary processor shall document the following for all outgoing deliveries of processed Donau Soja soya products:
- names, addresses and, where applicable, EU registration numbers (or equivalent specifications in non-EU countries) of all customers;
 - lot, quantity, quality label "Donau Soja";
 - delivery date, carrier and receiver;
 - loading cell.
- 3.2 The primary processor shall take a retained sample of each lot of processed soya products delivered, and shall store this sample for at least one year safely and without influencing its quality.

Please note: Sampling and storage shall be in accordance with the customs of the Agricultural Products Exchange in Vienna (Börse für landwirtschaftliche Produkte in Wien) or with the GAFTA Sampling Rules No. 124 (chapter 3 „General“, chapter 4 „Method of Drawing Samples“, chapter 5 „Sample Labels“).



4 Soya stock management

- 4.1 In the following cases, the primary processor shall send to their certification body quantity amendment notifications regarding the stock of Donau Soja soya beans, specifying the reason for the notification:
- carry-over: remaining stock from the previous harvest year (notification by 31 August of the current calendar year, otherwise these quantities in store shall no longer qualify as Donau Soja);
 - deviation of quantities delivered to the primary processor: incoming deliveries deviating from contracted delivery quantities.

5 Quality management

5.1 The primary processor shall operate a documented in-house QA system establishing standard operating procedures to prevent GM contamination throughout the company (including incoming delivery, processing, storage, cleaning, transportation, packing, and outgoing delivery). The primary processor shall also apply a risk-based PCR sampling plan ensuring that GM contamination is detected.

5.2 If the primary processor is a risk level 3 company (P-RL 3):

The primary processor shall document that GM and non-GM produce is separated 100 %, both physically and technically. Documentation shall be consistent and cover all stages from incoming produce to outgoing produce. (Companies which have been granted a temporary approval of dual processing in accordance with paragraph 1.1 are exempted from this provision.)

5.3 If the primary processor is an oil mill or a toaster:

The primary processor shall, in the field of activity of "production of single feed material" be in possession of a certificate of one of the following QA systems:

- AMA Pastus +;
- QS audit system of the animal feed industry;
- GMP +;
- FEMAS (Feed Materials Assurance Scheme);
- SFPS* (Swiss Feed Production Standard);
- QSGF Suisse* (quality assurance for cereals/animal feed);
- EFISC (European Feed Ingredients Safety Certification);
- FCA (Feed Chain Alliance Standard); or
- another equivalent programme.

General note: Other equivalent programmes will be released as such by Donau Soja Association.

Note to *: The standard will be recognised if the following conditions are met: A quality control plan, consisting of samples from both incoming and outgoing produce, satisfies at least the requirements of the applicable analysis plan of the AMA-feedstuff monitoring Pastus+ (version 1 valid from January 2020; annex 1 to AMA-Feedstuff guideline pastus+ and pastus+ Regulation for Small Quantities) as far as the point "sampling frequencies as well as methodology and frequency of analyses" is concerned. Inspections are performed at least once every two years. A certificate of conformity (e.g. inspection report) is provided to Donau Soja Association and/or the Donau Soja certification body upon request.



5.4 If the primary processor is an oil mill:

As for Salmonella monitoring, the primary processor shall apply the requirements for analysis according to the AMA-feedstuff monitoring Pastus+ (version 1 valid from January 2020; annex 1 to AMA-Feedstuff guideline pastus+ and pastus+ Regulation for Small Quantities):

Number of analysis to be performed per year and operating site:

Production in t \ Substance	<1000	≥1.000- <3.000	≥3.000- <5.000	≥5.000- <10.000	≥10.000- <100.000	≥100.000- <300.000	≥300.000
Salmonella	4	6	8	12	50	90	180

No strains of Salmonella are permissible.

In case of a positive finding (self-monitoring or external sampling), the required salmonella analyses need to be intensified for a period of three months, switching from a 1-fold approach to a 5-fold approach. If no positive result is obtained within that period, the 1-fold approach may be resumed.

5.5 If the primary processor wishes to market phospholipid mixtures as Donau Soja lecithins, the requirements detailed in Commission Regulation (EU) No 231/2012 for E 322 have to be complied with and compliance with these requirements has to be verified in any case.

6 Product labelling

- 6.1 The primary processor may label produce delivered (packaging) as “Donau Soja” if this produce is entirely (100 %) made up of Donau Soja soya products such as Donau Soja soya bean meal or Donau Soja soya bean oil.
- 6.2 In case of mixed products (containing both soya components and components other than soya), 100 % of the soya components shall be Donau Soja soya and all other product components shall also comply with the non-GM requirements.

7 Donau Soja contract soya bean primary processor

- 7.1 The primary processor and Donau Soja Organisation shall conclude the Donau Soja primary processor contract on the requirements to be met by the primary processor.

8 Directly commissioned inspections

- 8.1 The primary processor shall conclude an inspection contract with a certification body recognised by Donau Soja Organisation, commissioning this body to undertake chargeable inspections at the following frequency:
 - primary processors of all risk levels: first inspection;
 - primary processors of risk levels 0 and 1 (P-RL 0 and P-RL 1): additional annual inspection;



- primary processors of risk levels 2 and 3 (P-RL 2 and P-RL 3): additional inspections twice a year (one unannounced inspection).
- 8.2 The directly commissioned certification body shall take a composite sample from the entire Donau Soja soya processing line within the scope of their Donau Soja audit, and shall submit this sample for a PCR test.¹
- 8.3 If the certified primary processor suspends or terminates their Donau Soja activity, Donau Soja Organisation may, at the expense of the primary processor, demand a final inspection by the directly commissioned certification body to verify all conformities from the last audit to the date of termination of the contract. The scope of the final inspection shall be reduced compared to a normal inspection, whereby the exact scope shall be determined by Donau Soja Organisation, if necessary after consultation with the directly commissioned certification body.

9 Supervisory inspections

- 9.1 The primary processor shall accept supervisory inspections (risk-based sampling) by inspection bodies or inspectors commissioned by Donau Soja Organisation.

10 Special form: own-use soya bean primary processor

- 10.1 Agricultural processors mixing animal feed on their own holdings for feeding their own livestock shall be categorised as own-use primary processors and shall not be considered as compound feed producers. Acting as own-use soya bean primary processors, these operations may process own-harvested or purchased Donau Soja soya beans in a separate facility – solely for the purpose of feeding the livestock on their own holdings. Own-use soya bean primary processors may neither deal in Donau Soja soya beans (raw or processed) nor process them as a subcontractor.

The marketing of small quantities of the main product (such as soya bean cake) or of small quantities of by-products resulting from the own-use soya bean primary processor's own processing (such as soya bean oil or soya bean hulls) as Donau Soja produce will be approved on a case-by-case basis on application and following examination by Donau Soja Organisation.

- 10.2 For own-use soya bean primary processors, all Requirements R 04 (for Soya Bean Primary Processors) shall apply, with the following simplifications:
- Paragraph 2.5 (quantity notifications): Monthly notifications of quantities of Donau Soja soya beans may be substituted by quarterly or annual notifications.
 - Paragraph 3 (outgoing deliveries of processed Donau Soja products): For outgoing deliveries of processed Donau Soja soya products, the documentation of outgoing deliveries as well as the taking and storing of retained samples is waived. The company shall document the quantities used for feeding their livestock, including the date and the lot certificate (in case of purchased soya beans).

¹ PCR tests may only be conducted for soya beans or protein-containing soya products. Soya bean oil is not relevant for PCR analysis.



- Paragraph 5.3 (quality management/quality certification): The company may apply for a simplified QA certification. In Austria, the AMA Gütesiegel² home feed compounder certification with an additional checklist for own-use toasters is recognised as being equivalent to the QA certifications mentioned in paragraph 5.3.

11 Special case

Transfer/imposition of responsibilities of a soya bean primary processor to/on other participants in the Donau Soja system (traders in particular)

- 11.1 Specific, precisely defined tasks of a primary processor may be transferred to participants in the Donau Soja system upstream or downstream of this primary processor, following approval by the Board of Donau Soja Association.
- 11.2 A) Particularly, the purchase of Donau Soja soya beans and the associated assurance of traceability, the availability of lot certificates and the imposition of all obligations on all upstream suppliers (as provided for in the Donau Soja Guidelines and Donau Soja contracts) may be transferred by a primary processor to a trader, for instance, who will, on the one hand, organise the purchase of the Donau Soja soya beans for this primary processor and, on the other hand, buy the processed Donau Soja soya beans (e.g. Donau Soja meal) as outgoing produce from this primary processor.
- B) Specific tasks of the primary processor such as checking the incoming/outgoing produce, ensuring a QA system and a corresponding certification (paragraph 5), or conducting Salmonella analyses, may not be transferred to other participants in the Donau Soja system.
- 11.3 If a primary processor exclusively produces Donau Soja products for a third party (particularly a trader), the obligation to monthly report the quantities of Donau Soja soya beans and to pay the licence fee (paragraph 2.5) may also be transferred. In this case, the inspection which is normally to be commissioned directly by the primary processor may also be commissioned by the trader – provided that the primary processor concerned is listed as an external production site in the inspection contract of this trader and is identified as such in the certificate. In this case, the primary processor does not receive his own certificate. In very exceptional cases and if expressly authorised by the Board of Donau Soja Association, paragraph 7 (contract between the primary processor and Donau Soja Organisation) may be waived if the contract between the primary processor and the trader clearly specifies that the primary processor shall fulfil at least the obligations detailed in paragraph 11.2 B).

Transfer/imposition of responsibilities of a primary collector to/on a primary processor

- 11.4 If a primary processor exclusively buys Donau Soja soya beans from one primary collector, they may assume specific, precisely defined obligations of this collector.

² AMA Gütesiegel is the quality label of Agrarmarkt Austria (AMA).



- 11.5 Particularly, the responsibility for buying produce in compliance with the Donau Soja requirements (with Declarations of Self-Commitment – Farmers [Soya Bean Producers] and a plausibility check), checking of incoming produce (including retained samples), handling the quality management on site (paragraph 7 of R 02), as well as taking and storing retained samples in the outgoing produce department (paragraph 5.3 of R 02) shall not be transferable.
- 11.6 If a primary processor exclusively uses one primary collector, this primary processor may commission external inspections (paragraph 8 of R 02 and paragraph 3 of the Requirements for Group Certifications) as well as the organisation and processing of lot certificates. In this case, the primary collector shall not receive their own certificate.