



Fissler GmbH Directive for Initial Sampling

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1 Purpose of the directive/initial sampling

The objective of this directive is to govern a smooth process during initial sampling between Fissler and the supplier. In accordance with this directive, each initial sampling shall result in the creation of a initial sample test report (ISTR) with the aim of obtaining approval for the product/process. The ISTR provides verification that the products supplied by the supplier fulfil the quality requirements and specifications of Fissler. ISTR approval is a prerequisite for subsequent serial deliveries.

2 Scope of application

This directive applies to all suppliers that supply Fissler with supply parts that correspond to Q-level 1 or 2, provided no deviating provisions have been stipulated in the project order.

3 Terms

3.1 – Initial sample parts

Initial sample parts are products which have been manufactured entirely with standard equipment and under conditions similar to series production (plants, processes, testing, materials). They are to be taken as random samples from a representative production quantity and delivered in suitable packaging together with the initial sample test report to the delivery address specified in the purchase order.

3.2 – Initial sampling

Initial sample parts will be created for initial sampling. The scope and process for the initial sampling shall be agreed with the supplier in preliminary talks. The supplier must plan and implement the initial sampling in accordance with this directive.

3.3 - Supplier specification (SS) - Company standards (CS)

Fissler shall create an SS for each item including all information to describe the product and a reference to the universally applicable company standards.

3.4 – Quality levels (q-level)

Fissler products are categorised into the following quality levels:

Quality level	Description
1	Safety-relevant component with food contact materials
1.1	Safety-relevant component
1.2	Component with food contact materials
2	Component based on drawings (without packaging)
3	Other components

3.5 – Master data

Product-related master data: Item no., item description, SS no., drawing no., q-level, materials, item identification

Process-related master data: Order number, quantity, delivery date, date of manufacture, ISTR

4 Responsibilities

The supplier is responsible for the initial sampling and subsequent preparation of an ISTR in accordance with this directive. The supplier is responsible for the correctness of the test and measurement results and the complete transmission and maintenance of the formal master data. The measuring equipment used and the measuring methodology must be agreed in advance between the supplier and a quality assurance officer from Fissler GmbH. Assessment and approval of the ISTR shall be carried out by the Fissler quality management department in consultation with product development.

5 Description

5.1 ISTR - Preparation

Preliminary talks regarding the ISTR are always conducted between the supplier and a quality assurance officer from Fissler prior to the creation of the ISTR. Initial samples must be created in accordance with the stipulations of this initial sampling directive. If any deviations are determined in the initial sampling with regard to the completeness and fulfilment of the Fissler specifications, the causes thereof must be determined without prompting and corrective measures must be independently initiated by the supplier.

5.2 ISTR - Approval

The supplier shall submit sample parts together with the ISTR for approval. Serial deliveries can only take place once the ISTR has been approved. All other deliveries are sample part deliveries without quality control. After examination of the samples and documents and, if necessary, after cross-checks or further investigations, Fissler will issue an approval, approval with conditions or a rejection. The approval of the samples by Fissler does not release the supplier from his responsibility for the quality of his products. Nor does it constitute a delivery order.

5.3 ISTR - Points of contact between the supplier and Fissler

- Fissler purchasing: Purchase order for the initial sample with the ISTR, delivery conditions, deadlines, quantities, prices
- Quality management: ISTR preparation for the process and measuring methodology, followed by submission of the ISTR by the supplier for approval of the process and test viability

5.4 ISTR - Notification obligations

The supplier is obliged to notify Fissler in the following cases. In the case of changes, Fissler must be informed in good time so it can assess possible impacts in detail and, if necessary, determine the scope of a new sampling.

- | | |
|---|-----------|
| - New parts | - stage A |
| - Production shifts or amended manufacturing site plans | - stage A |
| - Changes to the production process | - stage A |
| - Use of new, modified or replacement tools | - stage A |
| - Product changes | - stage B |
| - Changes to purchased parts or materials | - stage B |
| - After tool revisions | - stage C |
| - After a long interruption to production (> 36 months) | - stage D |

5.5 ISTR - Submission stages

Submission stage:	Stage A	Stage B	Stage C	Stage D
a) Cover page	X	X	X	X
b) Stamped drawing & SS	X	X		O
c) Test report for full measurement	X			O
d) Test report for test dimensions	X	X		O
e) Test report for corrections and amendments		X	X	O
f) Material data sheet	X	X		O
g) Sample parts	X	X	X	X
h) Approval of deviations (if required)				
i) Declaration of conformity with laboratory results	X ¹	O ¹		O ¹
j) Proof of viability	X			O
k) Production control plan	X			O
l) Process flow chart	X			O
m) Machine settings report	O			O
n) Acceptance test certificate 3.1 for metal primary materials	O			O
o) FMEA process	X ²			O

Legend:

X = must be enclosed with the ISTR

X¹ = must be enclosed with the ISTR for parts with food contact

materials X² = must be enclosed with the ISTR for parts with q-level 1,

1.1 and 1.2 O = must be enclosed with the ISTR if agreed upon

O¹ = must be enclosed with the ISTR for parts with food contact materials if agreed upon

5.6 ISTR - Scope of documentation

The supply shall submit the ISTR according to the submission stages. If the supplier performed a 3D scan of the part, the .stl data or measurement data must be submitted to Fissler. If relevant for the test result, an indication of the measuring points on the sample parts must be labelled in the drawing or sketch. All requirements stipulated in the Fissler drawing, test specifications and delivery specifications must be identified and checked in the ISTR.

The tested parts must originate from a process-capable manufacturing process.

The documentation must be prepared on appropriate templates. The templates and forms found in Annex 1 can be used for this purpose. The master data stipulated in Section 3.5 must be listed on the ISTR at a minimum.

The initial sample test report must be published in German or English. The cover page must also be signed.

Unless otherwise agreed, the following minimum requirements apply with regard to the scope of documentation in the ISTR test report:

Moulded parts (plastic, silicone, etc.)

- In the case of tools with several cavities, the total number of cavities must be entered on the initial sample test report (full measurement). At least 3 labelled parts must be included for each cavity.

Metal parts

- 10 parts need to be tested and labelled for tools with single parts.
- 10 parts need to be tested and labelled for tools with multiple parts.

Other parts

- 10 parts need to be tested and labelled

5.7 Requirements for general process capability

Proof of preliminary process capability must be submitted with each delivery of initial samples. In order to determine the capabilities, the dimensions to be tested will be determined in advance between Fissler and the supplier.

The preliminary process capability (ppc) must be determined through 25 random samples with 5 parts each. For parts from different mould cavities, one part per cavity is tested for each random sample. ≥ 1.67 should be taken as the target for the ppc value.

5.8 ISTR - Delivery

The labelled and tested initial samples need to be sent to the address specified in the purchase order. The initial sample test report either needs to be enclosed or sent to the responsible employee at Fissler by email. Sample parts must be separated from other parts.

5.9 Requalification tests

In order to ensure the quality of parts, requalification tests must be carried out at 5-year intervals after the start of serial production during the series production run in the form of renewed initial sampling (submission stage A) of the parts and subsequent submission to Fissler.

6 Annexes

Annex 1: Initial sample test report