

## BASTA SYSTEM

### Corrective actions to non-conformities identified during the audit on 28.6.2019

**1/ Copies of internal routines in Czech together with descriptions of the content in English does not seem to include any specific routines regarding qualification of products for BASTA. Please clarify where this information is located.**

We treat BASTA certificate as responsibly as we do with other certificates that have been issued for our foil (eg certificate from RISE, BCCA, Kiwa Nederland, etc.).

The technician of quality is responsible for managing certifications, external product testing and supervising audits.

The working procedures of these activities are set out in internal document PP/949000/07 – Pracovní postup odd. kvality – Atesty, certifikáty a posuzování shody výrobků. This document provides, inter alia, stakeholder activities and flow charts.

Fatru, a.s.		Vydání č.: 2	Pracovní postup č. PP/949000/07
		Účinnost od: 04.06.2015	Pracovní postup odd. kvality – Atesty, certifikáty a posuzování shody výrobků

Autor: 01.04.2015  
Schválil: 01.06.2015 vedoucí odboru I&D

#### Anotace

Tento dokument stanovuje postupy při vystavování atestů a certifikátů na výrobky a dále popisuje činnosti při posuzování shody výrobků podle zákona č. 22/1997 Sb. o technických požadavcích na výrobky a o změně a doplnění některých zákonů, dle nařízení EP 10/2011 (pro výrobky určené pro styk s potravinami) a 305/2011 (stavební výrobky) ve znění pozdějších revizí, směrnice EP 2009/48/ES o bezpečnosti hraček (implementovaná do nařízení vlády č. 86/2011 Sb., zákona č. 258/2000 Sb. a příslušných nařízení vlády nebo vyhlášek ministerstva v aktuálním znění).

#### Provedení

##### Související organizační směrnice:

- [1] PV 05 - Podpisový řád
- [2] OS 04 - Řízení dokumentů a záznamů
- [3] OS 03 - Spisový, skartační a archivní řád
- [4] OS 29 - Propustkový řád
- [5] OS 16 Evidence a zavádění surovin, receptur, výrobků a zboží pro plastikářskou výrobu
- [6] OS 17 Chemické látky, směsi a předměty

#### OBSAH:

- 1 SEZNAM ZKRATEK
- 2 ÚVOD
- 3 VYSTAVOVÁNÍ ATESTŮ - OSVĚDČENÍ O ZKOUŠCE VÝROBKU
- 3.1 Postupový diagram a matice odpovědnosti pro vystavování atestů
- 3.2 Komentář
- 4 CERTIFIKACE
- 4.1 Postupový diagram a matice odpovědnosti certifikací výrobků
- 4.2 Komentář

The attachment "Documentation of company Fatra, a.s.", which was sent earlier, contain previews of individual internal documents. All these documents list the responsibilities for each specific activity.

We can highlight the document OS 16 Evidence a zavádění surovin, receptur, výrobků a zboží pro plastikářskou výrobu. Before introducing the raw material into the standard recipe, the products must be taken into account the requirements of the certificates, check of the safety data sheet, verification of physical-mechanical parameters. Laboratory tests are then carried out - the modified recipe is tested on a laboratory equipment. If the results are satisfactory, the raw material is recommended for production

testing - production of the product on a standard production equipment under strict supervision (development, technologist). The test results are recorded in the Námětové listy (company application). If the raw material meets all conditions for possible inclusion in the recipe products, it is approved and kept in the records.

**2/ In the document "Competence and responsibility" there is nothing mentioned about responsibilities for BASTA. Please clarify these responsibilities.**

Competences and responsibilities to the requirements of the certificates are stated in the individual internal documents. I repeatedly send the document "Competence and Responsibility" in Annex 1, which is an integral part of this document. Annex 1 contains extended competences and responsibilities and there are also references to internal documents.

**3/ CAS-nr is only given for the PVC-polymer and the plasticizer (85% of the product). No motivation to why CAS-nr not is noted. Only the comment "confidential". No approval from BASTA. Please, clarify.**

CAS numbers cannot be added at this time, it is confidential information of our entire production process and according to internal guidelines I cannot pass this information on without a signed confidentiality agreement. If you insist on this information, you will need to enter into a non-disclosure agreement that I attach (Contract No. 01/2019). Upon entering into this agreement, I will be able to complete the document „Assessment Document“ you have sent.

**4/ No basis for assessment has been submitted. Please fill in submitted assessment document for how you have done the evaluation that the product fulfils the BASTA criterial.**

The assessment of feedstocks will be part of the document „ Assessment Document“. I will send it to you after the conclusion of the confidentiality agreement.

**5/ No description or documents are submitted in the registration. Please, add description and relevant informative documents to BASTA online.**

We signed up for BASTA online and added all the shared information there:

- Building product declaration – 20.5.2019
- Competence and responsibility – 27.3.2019
- Documentation of company Fatra, a.s. – 27.3.2019
- EPD-FATRA\_HIF-hetero\_2017
- Certificate ČSN EN ISO 14001\_2016
- Certificate ČSN EN ISO9001\_2016

- Data Sheet – Fatrafol 810/V

Documents have also been added to the system, which have been supplemented or modified based on audit comments:

- Corective Actions – 24.9.2019
- Annex 1 – Competence and responsibility

Napajedla, 24.9.2019  
Ing. Michaela Bartuňková  
Technician of Quality

*Barbora Babišová*

**Fatra, a.s.** 084  
třída Tomáše Bati 1541  
763 61 Napajedla