Problems in choosing methods and tools for conformity assessment of prepackages at the manufacturer

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Abstract. In the article is a systematic analysis of the prepackaged products conformity assessment that could help in practice by applying the general provisions of the Directives to conformity assessment of prepackaged products. Manufacturers have to choose the method of conformity assessment that best suits the needs of his/her firm by choosing the optimal packing structure, methods and tools, based on the recommendations of the Article. Procedures for the maintenance of measuring instruments (calibration and verification) depend on the composition of packing line, level of automation. They shall be chosen only after the accurate identification of packaging line. When choosing the measuring instruments for packing manufacturers must provide traceability capabilities of measuring instruments used in weighing process, properly using calibration and verification results of the measuring instruments. Measurement results have demonstrated that for evaluation of average mass of prepackages procedures, mentioned below, can be applied. Statistical analysis procedure is more accurate than random sample procedure. It was proved that accuracy (repeatability and systematic error) of measurement results for sticky products is more than 2 times bigger than for powdery products (especially for low mass). Manufacturer shall pay attention to this fact while adjusting packing line for sticky products.

1. Introduction
Conformity assessment and approval is one of the conditions to implement the policy of free movement of goods. Legal basis is Council Directive 76/211/EEC of 20 January 1976 on the approximation of the laws of the Member States relating to the making-up by weight or by volume of certain prepackaged products.

Conformity assessment of prepackages is related with legal metrology, thus it provides consumers with confidence that requirements for the quantity of products are met. Extremely strict requirements are set for placing prepackages on the market and their surveillance. Conformity assessment is related with actual quantity of content of a product in prepackage, with statistical evaluation of a prepackage batch. The packer or importer shall be responsible for ensuring that prepackages meet the requirements of the Directive [1].

In the area of conformity assessment and enforcement it is possible to choose them from two or more alternatives. Such a choice should be based on scientific research. Chosen test methods and

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tools, possibilities to ensure their traceability must be optimized and fully meet the objective set for them.

Difficulties occur, and particularly manufacturers are facing the problems, in choosing forms and methods for conformity assessment of prepackaged products, measuring instruments, in providing maintenance of measuring instruments.

1. **Choice of optimal structure for the product packaging**

Actual quantity of product contents in prepackages (package and product) general imply the mass or volume of the product. Packaging process at the manufacturer or packer and its control are realized in four different stages (Figure 1).

![Figure 1. Product packaging stages](image)

In the first stage types of packaged goods, weight packages, and batch size are chosen. In the second stage sampling plan and random sample are selected. It is possible to use sampling plan and random sample presented in Directives. In the third stage method that will be used to assess the net amount of contents should be chosen. The last stage comprises control, i.e. a comparison of the net quantity of individual prepackaged products with the tolerable negative error and compliance with the average requirement (AQC) [2]. There are three general rules to follow:

- the average net content of the package in a batch may not be less than the declared quantity;
- the number of non-conforming prepackages must not exceed 2.5%;
- the prepackages having a negative error greater than twice the tolerable negative error must not be in a batch. [2]

These three rules must be implemented by the manufacturer during the product packaging and quantity control. It is therefore important to choose the product packaging structures, methods and tools properly.

Generally packing structure depends on:

- type of prepackaged product (product contains additives or not, glazed frozen product, product having liquid), its physical characteristics (liquid, powdery), and batch size for a production;
- number of measuring instruments in the packing line (automatic checkweighers, automatic gravimetric filling instruments, non-automatic weighing instruments);
- status of measuring instruments (being verified (legal metrology), calibrated).

In consideration of the above mentioned criteria product packaging organizational structures can be identified as those that are shown in Figure 2.

These criteria are related to one another. Type of packaged goods or packages and batch size determine the level of automation of packaging process. Accordingly, this level of automation determines the level of automation of chosen dosing devices and measuring instruments. Planning of packaging process itself influences the surveillance types of instruments in use.

Automatic checkweighers and automatic gravimetric filling instruments are usually used to dose and pack powdery, liquid products. Non-automatic weighing instruments are used very often for weighing hard lumps products, such as fish. Measuring instruments shall be assigned to legal or industrial metrology depending on how the weighing is carried out (individual weighing or automatic) and at what stage. This determines the choice of surveillance type – verification or calibration.
Thus, the organizational structure depends on the composition of the packing line. Certain case is when prepacking and weighing of a product is done at the same time. Another case is when a product is prepacked only by a coating, for example, by a plastic film. In a case of powdery products they are almost always prepacked and weighed at the same time. In a case of hard lumps products (such as fish) prepacking is done by automatic machine using a film coating and package sealing. Mass is measured individually by non-automatic weighing instruments. Then the non-automatic weighing instruments shall be assigned to packing line. In this case several identical non-automated packaging lines can be included in the product packing line, where each product is weighed by non-automatic weighing instruments and packing machine performs only a package sealing function. Similarly, if packing is done manually by placing the product into the package with sealing it and using non-automatic weighing instrument to weigh every prepackaged product; the non-automatic weighing instruments are assigned to the packing line.

![Diagram](image)

**Figure 2. Organizational structure of the product packaging**

In order to be able to show that the e-marked prepackages comply with the requirements, the packer must maintain his measuring equipment. The measurements of the actual content of prepackages, the density of liquid product, the weight of packaging materials and other relevant measurements must be carried out by means of a legal and suitable measuring instrument. Measuring instruments that are used directly for measuring process of quantity are assigned to legal metrology. They are subject to verification. Generally control measuring instruments are used: a non-automatic weighing instrument, a checkweigher, an automatic gravimetric filling instrument, a volumetric measure. However, in the case of non checked automatic weighing instruments, that are involved in dispensing and packaging process the weight control can be proven by checked non-automatic weighing instruments. Other measuring instruments that are not directly used for evaluation the quantity of the product in the package, for example, measuring instruments used for the monitoring of environmental conditions are not subject to legal metrology. For those measuring instruments a
different maintenance and calibration regime is necessary. The packer shall organize this regime in line with the conditions of use and behavior.

2. The adaptability of the procedures
Check of prepackages in situ can be carried out by two methods: 1) using a random sample check with selection of samples during the packaging at least once per hour, evaluating the average of actual amount, and recording defective items and 2) carrying out selective statistical check by sampling method, i.e. by sampling from the batch of prepackages. Having chosen any of these methods, decision regarding approval of prepackages or rejection of a batch is taken after whole batch is manufactured. After a rejection of batch produced it must be quarantined. To quarantine means: the prepackages will not be put onto the market.

Using the first of the above method for investigation the prepackages batch, when the average is calculated, it is important to separate an hour’s production (to identify it) because of when the average of the measuring results that relate to an hour’s production is less than the nominal quantity, the hour’s production must be quarantined. In this way the only part of the production would be quarantined, not the whole batch. Besides, choosing the batch classification into the hourly production, when the average of a sample falls below a warning limit, packers can undertake corrective action to bring the average back on target by adjusting the filling machine. It is a good practice for the packer to carry out a check on every (production) hour. Checks might be carried out at longer intervals, provided that the quantity control system is set up appropriately to take into account drift in the packing process. This also applies for monitoring prepackages below the TU1 (TU1-the nominal quantity minus the tolerable negative error) and TU2 (TU2 the nominal quantity minus twice the tolerable negative error)-limits.

3. Comparative analysis of methods
Methods using a random sample checking or statistical analysis procedures were investigated and shown in Figure 3.

![Figure 3. Algorithm for choice of methods of product mass determination in prepackage](image)

The choice of measurement method for product actual quantity depends on the product type, packaging type, and the product batch size. When using non-destructive testing to control the quantity of prepackages, random sampling testing or statistical analysis procedures can be used. When a selective statistical verification is carried out, testing method of the packaged products batch is used. It is convenient to use the method as the measurement of actual content of the product is carried out after packing the whole batch. When choosing the test of random sample during the manufacturing process a packer has to take samples of the product at least once per hour. Using „net“ weighing method the actual content of prepackage is measured directly: weighing the contents of prepackage
without package. If this method is chosen quantity control is carried out by taking samples from the production line before the product packaging operation. One relevant thing is that no product can get “lost” when weighing and packing. Measuring the content itself is the best but often not possible. Otherwise, the mass of package has to be determined beforehand. Consequently, there are two ways for determination of actual mass of product in prepackage indirectly (thereinafter tare) [3]:

- Gross mass of prepackage minus mass of individual tare (thereinafter “individual tare” method);
- Gross mass of prepackage minus average mass of tare (thereinafter “average tare” method).

The essence of all methods is calculation of prepackaged products with a negative tolerance of the product contents higher than the permissible negative tolerance. Experiments were carried out with powdery (nuts of various sorts) and sticky (dried plums, dates) products for the same batch of similar nominal mass (from 40g to 1500g). Two main characteristics were calculated, i.e. the average quantity of prepackages and repeatability of measurement results. Typical examples of the results are presented in Figure 4.

Figure 4. Typical examples of the results of the statistical analysis and of the random sample testing procedures (“average tare” method)

Summarized results of procedures (repeatability of measurement results for different nominal masses) are shown in Figure 5.

Figure 5. Results (repeatability) of the of the statistical analysis and random sample testing procedure for different methods

Results that are given in Figure 5 show that “average of plums” is usually negative and “average of nuts” is usually positive for different procedures even though the conditions and adjustment of
automatic weighing instrument are the same. That means that manufacturer have to reject whole line of products because of the one of rules (that is mentioned in chapter 1) is not satisfied.

4. Conclusions

1. Manufacturers have to choose the conformity assessment method that best satisfies the needs of his/her firm by choosing the optimal packing structure, methods, and tools, based on recommendations of the Article.
2. Procedures for the maintenance of measuring instruments (calibration and verification) depend on the composition of packing line, level of automation. They shall be chosen only after the accurate identification of packaging line.
3. When choosing the measuring instruments for packing manufacturers must provide traceability capabilities of measuring instruments used in weighing process, by properly using calibration and verification results of the measuring instruments.
4. Measurement results have demonstrated that both procedures are suitable for evaluation of average mass of prepackages from the point of view of accuracy. Evaluating trueness and precision of separate methods it can be concluded that “net” method is the most accurate. But its application at manufacturer is limited. Statistical analysis procedure is more accurate than random sample procedure. It was proved that systematic error + repeatability of measurement results for sticky products is more than 2 times bigger than for powdery products (especially for low masses up to 200 g). Manufacturer has to pay attention to this fact while adjusting packing line for sticky products.

References

[1] Council Directive 76/211/EEC of 20 January 1976 on the approximation of the laws of the Member States relating to the making-up by weight or by volume of certain prepackaged products.
[2] Welmec 6.6 2003 Guide for recognition of procedures (Vienna: BEV) p 24
[3] Meškuotienė A and Raudienė E 2009 Investigation of Product Quantity Evaluation Models in Prepackages vol 2(44) (Kaunas: Technology Matavimai) pp 14-19