European Commission

Community Research

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Project report

Chemical Analysis

Evaluation of dairy product quality taking into account within-lot variation

COMPETITIVE AND SUSTAINABLE GROWTH

Report EUR 19501

European Commission

bcr information

CHEMICAL ANALYSIS

Evaluation of dairy product quality taking into account within-lot variation

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Contract No SMT4 – CT96-2111

FINAL REPORT

Research Directorate-General

1999

EUR 19501EN

EUROPEAN COMMISSION
Community Research
DG Research/C – Competitive and Sustainable Growth Programme

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Published by the EUROPEAN COMMISSION
Directorate General Research

Cataloguing data can be found at the end of this publication.

Luxembourg: Office for Official Publications of the European Communities, 2000

ISBN 92-828-8737-5

Printed in Belgium

ABSTRACT

THE EVALUATION OF DAIRY PRODUCT QUALITY TAKING INTO ACCOUNT WITHIN-LOT VARIATION.

For butter and skimmed milk powder within-lot variation is not negligible as compared with method variation. Both components of standard deviation have been taken into account in designing a statistical process control (SPC) system. In the case of moisture in butter the within-lot (process) standard deviation varied between 0.04% and 0.411%. The within laboratory repeatability (measurement) standard deviation ranged from 0.023% to 0.065%. For skimmed milk powder estimates of the within lot standard deviation for moisture ranged from 0.093% to 0.205%, measurement standard deviation ranged from 0.025% to 0.091%. Estimates of the within lot standard deviation for fat ranged from 0.037% to 0.259%, measurement standard deviation ranged from 0.013% to 0.055%. Estimates of the within lot standard deviation for protein ranged from 0.057% to 0.293%, measurement standard deviation ranged from 0.045% to 0.196%.

For factories willing to start into SPC without experience and past data a procedure is proposed which allows a start with SPC after a rather short time of investigation of the process. The frequency distribution of moisture in butter and skimmed milk powder tends to have more results below the mean value than there are above. Therefore an overall estimate of the standard deviation from the data could overestimate the spread of the data in the upper part of the distribution. To overcome this the standard deviation is estimated from larger data sets of production data only on the basis of the data above the median of the frequency distribution, or alternatively if sufficient factory data is available an approach based on calculation of the 95% quantile of the data is recommended.

SPC of production data should be carried out using Shewhart control charts, a chart for individual values and a moving range chart. The quantitative measurements made by the factory should also be controlled, by regular assessment against reference laboratory values, using Shewhart control charts. The factory must have clearly defined rules to detect out-of-control conditions and a written out-of-control action plan.

Total costs associated with official control using existing methods are, for butter 570 thousand Euro; for skimmed milk powder 335 thousand Euro. For butter introduction of autocontrol, augmented with a 20% official control check, offers cost savings of nearly 60%. For skimmed milk powder the cost savings are nearly 40%.

The Dairy Industry in 4 Member States was consulted regarding the acceptability of introducing such an approach and favourable feedback has been obtained. Manufacturers already keep records but there is clearly scope for improving the use of SPC, as precision data are generally not routinely recorded. Fixed and documented sampling schemes are already in place for taking samples and there is a willingness to adapt these to comply with the proposals provided that manufacturers can be convinced of their cost effectiveness. Most manufacturers already participate in some form of external control and would be willing to formalise this further.

In order to disseminate the concepts involved in the project and the findings a Video has been produced.

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Abbreviations list.

Technical abbreviations

ANOVA: Analysis of Variance
ARL: Average Run Length
NIRS: Near infrared reflectance spectroscopy
QC: Quality Control
SMP: Skimmed milk powder
SPC: Statistical process control
Std. Dev. Standard Deviation

Organisation abbreviations

CAP: Common Agricultural Policy
COKZ: Centraal Orgaan voor Kwaliteitsaangelegenheden in de Zuivel
CPRO: Centre for Plant Breeding and Reproduction Research
FAO: Food and Agriculture Organisation of the United Nations
IDF: International Dairy Federation
RIKILT: Rijks-Kwaliteitsinstituut voor land-en tuinbouwprodukten
WHO: World Health Organisation

1 OBJECTIVES

The overall objective of this project was to investigate the advantages of moving from a system of official control for analysis of dairy products associated with market organisation schemes which is based on analysis of a limited number of samples to a new control system which makes use of the data which are available from the factory.

In order to obtain data essential to develop this new system work was required to focus on the collection of data associated with testing for moisture in butter and for protein, fat and moisture in skimmed milk powder.

The detailed objectives of the project were:

- Establishment of arithmetic means and standard deviations associated with manufacturer's within-lot variation.
- Establishment of a sampling plan to be respected by the factory.
- Establishment of a procedure for data evaluation based on comparison of manufacturer's data and official control data.
- Testing, and possible refinement, of the control procedure under realistic conditions.
- Recommendations for improved measures for control of quality of butter (moisture) and skimmed milk powder (protein, fat, and moisture) submitted to meet specification limits associated with market organisation schemes.
- Recommendations for extension of the model established using these materials to other applications where it is practicable to utilise the data available from the manufacturer.

2. BACKGROUND TO THE PROJECT

2.1 The need for a new approach.

The European Commission has responsibility for enforcement of the Common Agricultural Policy (CAP). Within the Commission the Directorate responsible for Agriculture is DG Agriculture The CAP has as its objective support to European agriculture. The milk and milk products sector for agricultural production falls within the scope of the CAP. The money associated with milk and milk products is substantial, it is estimated that the annual budget associated with butter and skimmed milk powder schemes administered by the Commission is in excess of 1000 Million Euro.

In order for milk products to qualify for financial assistance under the CAP they must meet certain specifications. These specifications are prescribed in a complex series of Regulations, many of which require the control authorities to take samples for chemical analysis.

The composition of the product is inherently variable no matter how carefully controlled the production process is. This variability must be adequately taken into account when interpreting specifications and deciding on granting of financial assistance.

The Commission must be confident that financial assistance is being granted only to a product which meets the specifications. Accepting sub-standard product represents payment that should not have been made. Manufacturers are aware of the specifications they need to meet and know that checks are made on the quality of their product. Also, in order to ensure that product which does meet specifications is not wrongly rejected by official control, disadvantaging the producer, a suitable sampling and analysis programme based on sound scientific principles must be in place.

2.2 Commissioning the Project

The responsibility for sampling associated with regulations in the field of Milk and Milk Products within the Commission lies with the Management Committee for Milk and Milk Products. This committee is in turn advised by a Technical Experts Group. The Group supplies technical advice to the Management Committee on method development and fine-tuning of market organisation measures.
The experts reviewed the sampling and analysis regulations in place and considered that there was substantial scope for improvement. The present regulations carry risks of a wrong decision which can be substantially reduced by adoption of an improved approach. A proposal, based on control of specified analytical parameters associated with butter and SMP, was submitted to the dedicated call for proposals published by the Science, Research and Development Directorate DG Research in 1996. The primary objective of the proposal was to investigate the advantages of moving from a system of official control based on analysis of a very limited number of samples to one which makes uses of the data which are available in the factory.
A consortium consisting of organisations concerned with the administration of the regulations, and with the analysis of samples, in 4 EU Member States, (Austria, Denmark, the Netherlands, and UK) was assembled to address the problem. These organisations were joined by an industrial partner from Denmark and advised on statistical design by a partner from Germany. Each partner involved in administration of the regulations sought, and gained, the co-operation of a representative cross section of their indigenous dairy industry. The project was co-ordinated by ADAS, one of the UK participants. Appendix 1 details names and roles of partners.
The project was supported by the European Commission, Standards Measurements and Testing Programme (SMT). The aim of this programme being to support the research necessary in order to establish the scientific and technical bases needed for the development of European written standards and of a common measurement and testing infrastructure. The programme as a whole has a substantial impact on industry as it is essential that modern industrial systems are backed up by recognised written standards and a reliable measurement and testing infrastructure if they are to develop and remain competitive. Furthermore the effective application of European policies calls for the use of measurement and testing methods which are accepted, recognised and respected in Europe and throughout the world.
This was successfully evaluated leading to an RTD contract and started early in 1997.
During the course of the project partners met at the following dates and venues.

Table 1 Project meeting details

Date	Venue	Date	Venue
19.02.97	Brussels	25/26.01.99	Wolverhampton
28.05.97	Brussels	05.05.99	Brussels
03.12.97	Brussels	07.07.99	Brussels
24.09.98	Brussels	20/21.10.99	Brussels

The project objectives also included commissioning of a video this has been produced by Take One Productions (UK).

2.3 Variability

2.3.1 The concept of variability

All processes have some inherent variability, this will be due to the manufacturing procedure itself and due to variability in the composition of the raw material. In addition to this variability all measurements have some associated degree of uncertainty no matter how carefully they are made.
The basic measure of variability is the population standard deviation, σ. In practice all members of a population cannot be examined. Therefore σ is estimated by sampling the population and measuring the variability of the members of the sample.
The standard deviation is the key statistic for many calculations in statistical quality control. The square of the standard deviation is called the variance (σ^2). An important property of variances is that they are additive for different sources acting together in a system. This property permits the splitting of variance into separate components. The two major sources are product variability from the manufacturing process (within lot variation) and the measurement system variability. These sources can in turn be further partitioned into sub-sources that have practical implications.

Product variability represents real differences in product characteristics that may be detectable by the customer. It can be split into two components; lot-to-lot variability and within-lot variability.
Lot-to-lot variability over the long term; many processes exhibit an inherent variability that extends over long production times. Some factors that can contribute to the inherent lot-to-lot variability in excess of the within lot variability include the following: raw materials variability; transport, storage and handling of raw materials, environmental (ambient conditions etc.); long term variability in the continuous process - process ageing etc.; equipment differences; personnel differences; batch to batch variability.
Current regulations consider each lot separately. The only consideration given to lot-to-lot variability is in the derogation allowing up to 1 in 5 analytical results to lie within the range of specification limit plus (or minus) critical difference. This aspect of control is not based on sufficiently sound statistical principles and is intended to

prevent manufacturers from consistently producing material which is close to, or just out of, specification.

Within-lot variability over the short term; this component represents variability among units within lots. Factors contributing to the within-lot variability in butter and SMP manufacture are given in Section 2.3.2.

International standardised methods introduced in recent years are required to include information on their precision. The precision is determined by means of collaborative trials involving a number of competent laboratories each analysing portions of the same samples. Collaborative trials allow 2 important precision characteristics, reproducibility and repeatability, to be determined. Reproducibility is a measure of the absolute difference that can be expected between 2 results obtained on the same test material by different operators in different laboratories. Repeatability is a measure of the absolute difference that can be expected between 2 results obtained on the same test material by the same operator working in a short time interval, same apparatus etc. Taken together these 2 statistical parameters can be used to calculate a critical difference value. The critical difference is used to apply a tolerance value to specification limits. Current guidelines on interpretation of results in the EU Milk and Milk Products sector permit results to be outside specification provided that the value lies between the specification limit and the specification limit plus (or minus) the critical difference. Such results are permitted provided that they do not occur more than once in 5 analyses.

In cases where laboratories apply methods other than those stipulated in the Regulations (i.e. routine methods) the precision figure will differ, however it is still possible to derive them for any given analytical method.

Internationally accepted procedures therefore already exist for deriving the precision associated with the measurement of the parameter.

The total variance associated with within-lot sampling is comprised of 2 components.

$$s^2_{total} = s^2_{sample} + s^2_{measurement}$$

The measurement variance can be determined using samples that are known to be homogeneous. The sample variance can be determined by analysing samples from throughout the whole lot and determining the total variance, thence

$$s^2_{sample} = s^2_{total} - s^2_{measurement}$$

The variance of the sample is also made up of two components, that due to the population (s^2_{pop}) and that due to the sampling (s^2_{sig}). The variance due to sampling should be negligible. The variance due to the population is the one that is of most concern, i.e. the actual variation in the analyte.

$$s^2_{sample} = s^2_{pop} + s^2_{sig}$$

One of the objectives of the project was to determine each of the major components associated with the within-lot variation.

2.3.2 Sources of variability

Measurement system variability includes the variability in the reported results for the entire measurement process from sampling through to testing. The variability of the test method itself plays a major part but other factors also add to measurement variability. These include: the test method; sampling procedure; sample preparation;

calibration (for each sample); within sample variability. Other factors contribute including the sampling and testing operators.
The precision characteristics, repeatability and reproducibility associated with internationally recognised official methods have been determined. The precision associated with factories "in-house" methods may be known to the individual factories but had not been extensively studied.
Factors associated with analytical variability include instrument calibrations, operator training/ability, and ambient conditions in the laboratory.
Variability in butter composition.
Butter is basically the fat in the milk and is usually divided into 2 categories: sweet cream butter, acidified or soured cream butter made from bacteriologically soured cream. Butter may also be classified according to the salt content: unsalted, salted and extra salted.
The butter making process involves quite a number of stages, butter can be made in churns in a batch process but the great proportion of butter now is made in a continuous process.
A number of factors contribute to the variation in composition of butter including; cream ripening temperature; butterfat percentage; sources of cream; speed of churning during manufacture - plant control; churning recovery; working of butter; holding time prior to packing (surface evaporation); and type of butter e.g. salted/unsalted.
Variability in skimmed milk powder composition
With skimmed milk powder the type of dryer used, the relative humidity and ambient air temperature can have an effect on the moisture content, the skill of the operator is also a factor in control of the moisture and fat content. The composition of the source milk can affect protein content.

2.4 Reference analytical methods.

The following reference analytical methods are applicable to checking the factory procedures.

Table 2 Reference Analytical Methods.

Product	Analyte	Reference method
Butter	Moisture	Commission regulation 880/98[1]
SMP	Moisture	IDF 26A:1993[2]
SMP	Fat	IDF 9C;1987[3]
SMP	Protein	IDF 20B:1993[4]

There is also an internationally recognised standard which covers the process of taking samples and storage and transport to the laboratory. (IDF 50C:1995; Milk and Milk Products Guidance on Sampling)[5].
Manufacturers use a variety of methods for the analysis of moisture. Manufacturers methods of analyses involve either monitoring by e.g. near infra-red reflectance

spectroscopy, or, in the case of moisture in butter, often involve a rapid method of driving off moisture prior to gravimetric analysis.

3. REVIEW OF EXISTING SAMPLING PROCEDURES RELEVANT TO STUDY

3.1 EU Regulations concerning butter and skimmed milk powder.

The rules controlling butter claiming financial aid through community schemes are detailed in a number of regulations. These regulations give differing instructions regarding sampling. All regulations include a specification for maximum water contents (16%) as one of the quality parameters to be tested.
Commission Regulation 454/95, Annex V[6], details the number of samples to be taken for a range of lots sizes e.g. for 20 - 25 tonnes 7 samples are taken, for > 25 tonnes 7 + 1 per 25 tonnes or part thereof.
The analytical control permits compositing of up to 5 samples to 1 sample. This means that for a 20 tonne lot of butter in effect only 2 samples are analysed.
The regulation also gives guidelines to be followed in the event of a samples failure.
Other regulations concerned with public storage aid for butter and sale of butter at reduced prices do not specify a sampling plan.
The detailed rules of application for the public storage of skimmed-milk powder (SMP), are given in Commission Regulation 322/96[7].
This regulation lays down quality requirements for powder bought by the intervention agencies. The quality requirements cover an extensive range of chemical and microbiological characteristics. From these 3 were selected which are monitored in the factory. Protein content, (31.4% minimum of the non-fat dry matter); fat content, (1.00% maximum); and water content, (3.5% maximum). The regulation also specifies reference methods of analysis for these parameters. Manufacturers offer SMP for sale to the intervention agencies, the minimum quantity offered for sale being 20 tonnes. Annex IV to the regulation stipulates the sampling and analysis scheme.
The number of packages to be selected for offers up to 800 25-Kg bags (20 tonnes) must be at least 8.
The number of packages to be selected for offers containing more than 20 tonnes is at least 8 plus 1 for each additional 800 bags or fraction thereof. The weight of samples to be taken for each sample is specified at 200 g. Grouping of samples (compositing) is allowed, no more than 9 samples can be combined.
The regulation gives guidelines to be followed in the event of sample failure. Where a composite sample shows a defect with regard to 1 parameter the quantity from which the sample came is rejected. The entire lot is therefore at risk from analysis of one single sample. Also, when a composite sample shows a defect with regard to more than 1 parameter the quantity it came from is rejected, and the inspection applied to remaining quantities from the plant is increased, the number of samples taken is doubled. Again, where a composite shows a defect with regard to one or more parameters the quantity the sample came from is rejected.
The Expert Chemists Group within DG Agriculture drew up this sampling scheme. It is based on BS 809:1974[8] (Methods of Sampling Milk and Milk Products, now

superseded). This standard details the number of samples to be taken for increasing numbers of units. The number of samples to be selected for 800-999 units being 9. The standard makes no reference to compositing of samples.
Because only 1 sample is analysed and an average figure determined this regime gives a low chance of detecting defective part of the lot. If 20% of the lot contained product that was outside specification the chances of detecting this are only (1- 0.80) = 0.20. Even allowing for a substantial increase in analytical control, with subsequent increase in costs, whereby the 9 samples were analysed individually, the chance of detecting at least one defective unit in a lot containing 20% defective units is $(1 - 0.80^9) = 0.86$.
Under the Guidelines for Interpretation of Results issued by DG Agriculture[9], there is scope for allowing results outside the specification limit. These guidelines are designed to take account of the inevitable variability in the analytical determination, and are based on internationally recognised statistical standards for the determination of analytical tolerance limits. However, no account is taken of the inherent variability in the product itself.

3.1.1 Risk assessment of current official control system for butter

The current official control system for butter offered under the intervention scheme is detailed in Annex V of Commission Regulation 454/95[6]. From a statistical point of view these rules are unclear and incomplete. For example:

- it is undefined when a sample 'fails'. There is no attention for measurement uncertainty.
- the rules allow a lot to be divided (so that only part has to be rejected), but nowhere is described how this division should be made.
- one may or may not combine samples before analysis; however, this has a very large influence on the effectiveness of the control system.
- if individual samples are analysed there is no rule how to act when one or two repeated analyses conform to the specification; it is also unclear whether the rule for the maximum allowable number of failures includes the repeated analyses.

The rules of the current system for individual samples are too complex for an analytical evaluation of risk, but for combined samples no repeated analyses are made which allows a simple calculation.
Due to the problems mentioned above, some interpretations and choices have to be made. These were made as much as possible to correspond with current practice in the Netherlands. Calculations were made for a lot size of 45 tonnes, which is fairly typical for large factories. For a lot of 45 tonnes 8 samples have to be taken, and it was assumed that there was an ordering of these 8 samples corresponding with the production order. The first 4 and the last 4 samples were combined for analysis. In correspondence with current practice a sample was considered to fail if the measurement result rounded to 2 decimals was higher than 16.05 % (thus the actual 'failure limit' was 16.055 %). According to the rules it was assumed that any failing sample results in the rejection of half of the lot (22.5 tonnes).

Product variability was modelled with a normal distribution with a standard deviation of 0.10 %. Measurements were assumed to be unbiased with a random error from a normal distribution with standard deviation 0.05 %.
Under this model any lot with a mean of 15.82 % or higher will give more than 5 % measurements higher than 16 %, and should therefore be detected. However, the risk model shows that a reliable detection (95 % probability of a failing result) is obtained only for lot means of 16.17 % or higher.
Table 3 shows that the 454/95 system (using combined samples and current interpretations) will almost never detect problems with lots having an average moisture content up to 15.9 %, and that even lots with an average of 16.0 % have a very large probability of not being detected.

Table 3. Risk assessment of Regulation 454/95 control system for lots as described in the text.

Lot mean (%)	Probability of rejection using combined samples according to 454/95 rules
15.80	0 %
15.90 (rejectable quality)	1 %
16.00 (rejectable quality)	22 %
16.10 (rejectable quality)	74 %
16.20 (rejectable quality)	98 %

The conclusion is that the current official control system is not able to reliably detect non-conforming lots unless the average moisture content is well above 16.1 %. There is a large risk that butter produced from a process with average moisture content around 16 % will pass the system undetected.

3.2 Acceptance Sampling

The sampling plans referred to above are not based on sound statistical principles. In effect every sample taken must meet the specification. Although in practice this criterion is blurred by an allowance in the guidelines for interpretation of results that one result in 5 may lie within the range between the specification and specification limit plus (or minus) the analytical critical difference.
The application of an acceptance sampling approach offers advantages. Acceptance sampling involves application of a predetermined plan to decide whether the batch of goods meets the defined criteria for acceptance. The aim of any acceptance sampling is to see that the customer gets the quality required, while remembering that resources for testing are limited. It is not necessary for every item to be in compliance with the specification limit for the lot as a whole to be accepted. The principle is not widely applied, but has been adopted in existing EC Legislation concerning poultry.
The Codex Alimentarius Commission, an international body operating under FAO/WHO makes recommendations for sampling of milk a milk products. These recommendations include reference to adoption of International Standards on sampling which involve the principle of acceptance sampling. (IDF 113A:1991[10] Milk and Milk

Products Sampling, Inspection by Attributes; IDF 136A:1992[11] Milk and Milk Products Sampling, Inspection by Variables).
Acceptance sampling takes into account the mean value obtained from the set of analyses, and the variability (standard deviation) of the results. Elaborate sampling plans have been derived, these deal with different sampling frequencies and different acceptable quality levels.
Acceptance sampling, as described in existing standards, provides a good statistical basis for an approach to take into account variation within-lot. The schemes involve multiple sampling. If an approach such as this was to work on a practical basis it would be necessary to use factory control data to prevent considerable increase in analytical costs.
However, acceptance sampling as described in the existing standards recommended by Codex has 2 associated problems which preclude its adoption for the problem being addressed by the project. Firstly the statistical basis behind the approach requires discreet items, and butter, (SMP) is a continuous item within the lot. Secondly this approach assumes that the variability associated with the actual measurement (analyses) can be ignored. In the case of analyses associated with butter and SMP this is not the case, the analytical variance being is smaller than process variance but cannot be ignored. This approach therefore provided a useful basis from which to work but the problem required development of a more refined procedure which could cope with both measurement and process variability, and could make full use of existing factory control data.

3.3 Practical Experience in the Netherlands

The project was able to draw on the experience of two relatively large Netherlands factories who participated in pilot studies concerning autocontrol. Drawing on the experiences it was realised that lack of data would make it impossible to obtain statistical guarantees for amounts of butter smaller than about 50,000 kg from data on such an amount alone, The number of samples typically obtained in the Netherlands for this amount of butter is 20-40, which is insufficient to obtain a precise estimate of the 95% quantile. Conversely an undisturbed batch, e.g. the amount between two silo changes, is often smaller than 50,000 kg. Therefore it was considered essential to use data from an extended period (e.g. one year) to obtain the statistical guarantee that at least 95% of the butter complies with the 16% requirement. The second basic decision to emerge from this exercise was the avoidance of limit checks per batch or lot should be complimented by an obligation for the factories to use statistical process control. This was necessary to obtain confidence in the stability of the factories production within the extended period for which a statistical guarantee was obtained.
Factories should therefore aim at stable moisture content in the produced butter. Oscillating between a high target value and a low target value (in case of problems) should not be considered as normal practice.
Factories should also sample systematically at least once for each 3000 kg of product. Individual measurement values should be entered on a Shewhart control chart as soon as they become available. Changes in process conditions (e.g. cream silo change, product change) should also be indicated on this chart.

Factories should implement statistical process control (SPC) to gain control over variation from special causes (causes operating only at specific times). Specifically, factories should have clearly described rules to detect out-of-control conditions and written out-of-control action plans aimed at removing the cause of variation.
In order to control the measurement process, a comparison should be made at least once per week between factory and external measurements. If the factory has autocontrol using ex-package samples, the measurement process control can be made by analysing ex-packaging samples both with the usual factory method and externally. If the factory has autocontrol using ex-churn samples, ex-package samples should be analysed externally, and an estimate from ex-churn samples at the appropriate time of production should provide the factory value for comparison. The external measurements provide reference values, either results obtained with the reference method of analysis in the official control laboratory, or the average result of several competent laboratories in a ring-testing scheme. Differences per week should be entered on a control chart. Changes in measurement methods should be indicated on this chart.

4. REVIEW OF EXISTING FACTORY PROCEDURES

4.1 Butter manufacture

Butter manufacturers already monitor parameters such as moisture as part of their routine quality control. Moisture levels will vary during production and the manufacturers aim to keep the product within acceptable quality limits.
A questionnaire was constructed in order to gain an overall impression of the procedures currently adopted by manufacturers in the production and process control of butter manufacture. This was sent to 4 manufacturers in each of 5 EU countries; UK, Ireland, Netherlands, Denmark, and Austria. Responses were received from 2 UK, 3 Irish, 3 Dutch, 2 Danish and 4 Austrian manufacturers. Full details of the original questionnaire and the responses from factories are given in Appendix 2.
The current practices can be summarised as follows.
Production capacity per day;
Overall capacity ranged from 7 to 250 tonnes per day. Austrian responses reflected smaller producers, with daily capacity ranging from 7 to maximum 50 tonnes per day. Responses from the other manufacturers (11) reflected larger production, ranging from 100 to 250 tonnes per day, with an average value of 130 tonnes per day, mostly in the region of 100 tonnes per day.
Silos in use daily;
Cream vats/silos in use daily varied considerably, from 1 to 14, most responses were in the region of 4 to 6 silos.
Churning;
The number of continuous churns in regular use varied from 1 to 3 (7 x 1, 6 x 2, 3 x 3). Churn capacity, ranged from 1.2 to 8 t/hr. Austrian manufacturers employed lower capacity churns, 1.2 to 3.0 t/hr. Capacity for other manufacturers was predominantly 5 t/hr. Manufacturers predominantly dedicated churns to the same butter type, i.e.

lactic/sweet cream, but in 5 cases out 15 this was not the case. Only in 3 cases was all cream churned from raw milk which was separated on site.

Use of intermediate holding trolley:

All but 2 manufacturers employed an intermediate holding trolley between the churn and package filler. The maximum delay time between churning and initial packing of the butter varied from "immediate" to 2 to 3 hours.

Batch size and composition:

Overall this ranged from 1.3 tonnes to 75 tonnes. Austrian batch sizes were smaller, ranging from 1.3 tonnes to 15 tonnes. Responses from other manufacturers ranged for 20 to 75 tonnes, with an average value of about 30 tonnes, mostly in the region 20 to 30 tonnes. Batch size was given as a specific tonnage figure for 2 manufacturers (1 UK, 1 Netherlands), and was given as fixed by the size of the cream vat in 3 cases (1 Danish, 2 Austrian). Three manufacturers responded that batch size was not fixed (Netherlands, Denmark, and Ireland). The remaining manufacturers (7) replied that batch size was one days production. All manufacturers considered that production within batch was always continuous and homogenous.

Austrian manufacturers do not make up a batch from more than 1 days production, however responses varied from other countries, and in 5 cases out of 11 a batch could be made from more than 1 days production. One Netherlands manufacturer stated that a batch is a days production but the batch could be made up of more than one days production, this was qualified that it was an overlap between Sunday night and Monday morning. One Irish manufacturer responded that a batch was 1 days production but a batch could be made up of more than 1 days production.

In 2 cases from the Netherlands and 1 from Ireland batches could be made up of more than 1 dairies production, for all other manufacturers this is not the case.

Butter unit sizes:

Unit sizes normally produced showed a wide variation from 7g to 25 kg.

Routine sampling for moisture:

All but 1 (Denmark) manufacturer routinely monitor moisture at the point of exit from the churn. Sampling frequency ex-churn for production control ranged from every 15 minutes to every 30 minutes, on average about 3 per hour.

Samples were taken from a completed batch (after production) by 11 of the 15 manufacturers. However the frequency of sampling was considerably less than that maintained for ex-churn sampling. In general the responses indicated that this type of sampling is routinely undertaken to an extent of 1 or 2 samples per batch. Existing factory control at this stage in production therefore does not appear to offer the increase in data required for the project.

Automatic in-line moisture adjustment:

Dutch (3), Danish (1) UK (1) and Austrian (2) manufacturers reported using automatic in-line moisture adjustment, the remaining manufacturers (8) adjust moisture manually. All adjust the moisture very quickly if tests indicate this is necessary, most indicating that immediate action is taken.

Use of pre-set limits to trigger adjustments:

All but 2 (Austria and Ireland) manufacturers responded that pre-set limits were used to trigger adjustments. Of these 8 replied that records were kept of the changes made. Those using pre-set limits reported a range of target limits. Limits reported were;

target 15.5%, target 15.8± 0.2%, 15.8%, max. 15.9%, max. 16.05 (4), max. >16.0%, max. 16.05% (2), 16.0± 0.1%. Manufacturers also reported minimum moisture limits, 15.2%, 15.3%, 15.4%, 15.7% and 15.8% .

Record keeping:

All manufacturers kept records of their moisture results, in 8 cases the records were in the form of control chart, 6 of these 8 maintained precision data, e.g. standard deviations. Only 5 manufacturers maintained precision data for the measuring instrument (Infrared analyser).

All but 2 (Austrian) manufacturers kept records of all process control data, e.g. breakdowns, changes, times etc. All responded that they would be willing to keep such records in future as part of an improved system of control.

Methods of analysis:

Two manufacturers used infrared analysers calibrated to gravimetric moisture methods. All other manufacturers reported using a variety of variations on the gravimetric method involving moisture loss on heating. In most cases rapid methods were used.

Moisture control checks were made also by an external laboratory in the 3 Dutch laboratories, 3 of the 4 Irish manufacturers, both Danish manufacturers and 1 of the 4 Austrian manufacturers. Frequency of these ranged from 12 a year to 5 per lot.

Use of fixed sampling plan:

All but 2 (Austrian) manufacturers claimed to follow a fixed sampling plan. Of those following a fixed plan 5 considered that the plan conformed to a national of international system. In one case this referred to ISO 9002, 3 other manufacturers gave no details of the sampling plan and 1 Dutch manufacturer cited COKZ certification.

Involvement in intervention or subsidy schemes:

All but 1 manufacturer submits butter under such schemes. Typical consignment sizes submitted to the authorities range from minimum 2 tonnes to 40 to 60 tonnes.

The number of production batches typically contained within a single consignment was normally one, but could be up to 4.

This work indicated that there is already a considerable amount of record keeping and control in place which could be readily adapted to a unified statistical process control scheme. It also revealed that in order to keep in line with industry practice is would be necessary to consider data generated ex-churn, therefore a process would need to be in place to ensure that the ex-package butter was in control based on ex-churn measurements.

4.2 Skimmed milk powder manufacture

A questionnaire was constructed to gain an overall impression of current manufacturing procedures and process control in SMP production. Responses were received from 2 UK, 1 Dutch and 3 Austrian manufacturers. Full details of the responses are given in Appendix 3.

The current practices can be summarised as follows.

Production capacity

Production capacity varied from 20 tonne to 100 tonnes per day, with the Austrian manufacturers generally being smaller producers. Production was generally 25-Kg

bags but the Netherlands producer reported a 30 tonnes bulk tank. A variety of dryers and fluid beds were used in production.

Number of silos

Manufacturers employed between 2 and 7 liquid skim milk silos daily and between 4 and 24 SMP silos. The liquid skimmed milk was normally not from raw milk produced on site.

Batch size.

Typical batch size varied for 16 to 120 tonnes and in most cases the batch size was not fixed, commonly being 1 days production, though it was noted that in many cases a batch consisted of more than 1 days production. In most cases production within 1 batch was considered to be homogeneous in the opinion of the manufacturers.

Sampling frequency and sampling point

Sampling frequency during manufacture varied from on-line to 1 sample per day for moisture; sampling for fat analysis varied from every 2 hours to daily with 1 manufacturer not routinely sampling for fat; there was no reported routine sampling for protein during manufacture. The sampling point appears to be at the bag filling stage, the majority of manufacturers reported that samples were also taken from sealed bags on occasions.

Sampling frequency after production varied; for moisture manufacturers commonly sampled at 1 per 5 tonnes; sampling for fat was less frequent, Austria sampling at 1 per 5 tonnes but others less often; sampling for protein was still less frequent, varying from none to 1 per 5 tonnes. Manufacturers maximum delay between manufacture and bagging ranged from 1 to 4 days.

Setting of limits

All manufacturers reported use of manual in-line moisture level adjustment, though the period between adjustment and sampling varied from immediately to the following production day. In all cases pre-set limits were used to trigger process adjustments. These limits varied from 0.5% below specification to $\pm$ 0.2%, target limits such as 3.5% were quoted in some cases. All but 1 manufacturer reported that records were kept of any process adjustments.

Analytical methods

Analytical methodology varied, moisture being analysed by oven drying and NIRS; fat by Gerber and protein by Kjeldahl. The responses on occurrence of control checks by external laboratories varied, some manufacturers employing these but normally with rather infrequent testing which was undertaken by control authorities.

Record keeping & sampling plans

All manufacturers kept records of moisture, fat and protein results but these were hardly ever in the form of control charts and maintenance of precision data was also exceptional. This does however confirm that the basis for statistical process control exists within the factories and could be extended with little significant additional costs. All manufacturers considered that a fixed sampling plan was in use for routine daily control but only 1 considered that this conformed to any national system. All manufacturers kept records of all process control data, e.g. breakdowns or changes in operator. These records could be used to supplement statistical process control. Few manufacturers reported that they submitted SMP under market organization schemes. Of the 2 that did typical consignment varied from 25 to 100 tonnes and both undertook

their own analyses of consignment for a variety of chemical parameters. In 1 case a sampling plan was followed to obtain the samples.
As with the exercise undertaken on butter production, this investigation confirmed that routine data are already being generated, and these form a good basis for development of a unified SPC scheme.

5 SUMMARY OF DATA GENERATED ON VARIATION

5.1 Moisture in butter

The Statistics department of the Free University of Berlin generated two reports. These considered measurement data submitted by official control laboratories and factories in Austria, Denmark, the Netherlands and the UK.

5.1.1 Summary of Report 1 "Preliminary Investigation of Butter Moisture Data from Austria and Netherlands".

This report, dated May 1998, was prepared by the Freie Universitaet Berlin, Institut fur Statistik und Oekonometrie and is summarised as follows.

Three Austrian creameries provided data on butter moisture over a period of 16 to 21 days. Samples were taken ex-churn every 15 to 30 minutes, respectively.

Statistical analyses were carried out for each of the 3 creameries. These included: univariate analysis of the values ex-churn and ex-package; scatterplots of the values ex-churn and ex-package; mean and standard deviation per lot for the values ex-churn; comparison of the values ex-churn and ex-package, using a plot of differences between the means per lot of the ex-churn data and the values ex-package, or the means for Austria 2 and 3 respectively; Q-Q plots for the data ex-churn and ex-package; comparison of two methods (operator and factory laboratory) analysing the data ex-package of Austria 3; estimation of the variance components between and within lots, using the data ex-churn.

Table 4. Butter moisture data from Austrian creameries.

		N	Mean %	Std Dev.%	Skewness
Austria 1	Ex-churn	412	15.95	0.23	-0.906
	Ex-package	90	15.80	0.19	-0.698
Austria 2	Ex-churn	171	15.76	0.19	-0.217
	Ex-package	90	15.84	0.15	-0.068
Austria 3	Ex-churn	285	15.82	0.20	-1.240
	Ex-package (1)	146	15.90	0.14	-1.408
	Ex-package (2)	70	15.85	0.16	-0.452

For Austria 1 the distribution is slightly skewed to lower values. The ex-churn data indicate that in the production process the mean of the data is close to the upper limit, however after packaging all but 4 of the values are equal or lower than 16.0%; the mean falls to 15.80% and the distribution is more skewed to lower values. The data showed that mean and standard deviation vary from lot to lot. The analysis of variance for data ex-churn showed a within lot variation $s_e^2 = 0.04\%$; and between lot variation $s_A^2 = 0.0145\%$.
A discrepancy was revealed between the values ex-churn and ex-package for Austria 1. The data overall are inconclusive regarding whether or not moisture levels are increased or decreased in the transition between ex-churn and ex-package. In the case of Austria 1 the mean value for moisture decreases, whereas for Austria 2 and Austria 3 there appears to be a small increase in moisture levels. A decrease in the moisture level might occur if there was some evaporation of moisture prior to the samples being packaged. It is more difficult to speculate why an increase in moisture can occur, unless there is some inadvertent small introduction in moisture due to some washing out process in pipes, or some condensation is occurring. The observation was made for Austria 2 that the difference ex–churn and ex-package was random. There are added complications in ensuring that samples taken ex-churn are accurately replicated by samples ex-package when undertaking comparison. There were always several values of ex-churn but only one or two values ex-package which could not always be attached exactly to a certain value ex-churn. Overall these data serve to illustrate that factories should be permitted to use ex-churn data, particularly as in many cases this data predominates, but they must be able to demonstrate that the ex-package material itself is in control and that a task of the project is to develop a suitable process which would satisfy the control authorities that this was the case.

Austria 2 has a similar ex-churn mean and standard deviation to that ex-package. The distribution is slightly skewed to lower values. The analysis of variance for data ex-churn showed a within lot variation $s_e^2 = 0.03\%$; and between lot variation $s_A^2 = 0.0055\%$.

Austria 3 also shows similar data for the mean and standard deviation ex-churn and ex-package (by 2 methods). The distribution of data ex-churn and ex-package (method 1, operator analyst) is slightly skewed to lower values. The data ex-package of the laboratory (method 2) do not imply this skewness. The analysis of variance for data ex-churn showed a within-lot variation $s_e^2 = 0.036\%$; and between lot variation $s_A^2 = 0.00278\%$.

The skew in the distribution of the data is probably attributable to the fact that adjustments are made to the moisture levels throughout the process. These are particularly evident during start-up periods of the production when there are likely to be particularly low moisture values. This phenomenon is observed regularly and has also been reported in the Dutch study where typically a median value can be 0.02% higher than the mean value.

The Q-Q plots generally indicate that the assumption of a normal distribution of the data is permissible, although the histograms show a slight skewness in all situations. A proposal from the Dutch to use only data above the median overcomes this problem and leads to smaller, but more realistic, values which more accurately reflect the overall process variation above the median, i.e. towards the upper specification limit.

The variance analysis and estimation of the variation between and within lots was undertaken for all data sets ex-churn. Data from Austria 1 were problematic due to inhomogeneous variances per lot. The ranges within each individual lot varied considerably. This is likely to be due to the inclusion of start-up values in the data. These may indicate particularly low moisture values and thus there will be quite a large range in the values of individual standard deviations. It is noted that following the Dutch proposal to use only the values above the process median would considerably reduce the variation in values for individual within-lot standard deviations. Estimators for within-lot variation vary between 0.03% and 0.04%. The between-lot-variation differs between data sets, (Austria 1, 0.015%; Austria 2, 0.006%; Austria 3, 0.003%)

Three Dutch creameries provided Netherlands data on butter moisture over a 2-week period in June/July 1997. Some problems were experienced in the legibility of data, available copies of hand-written sheets were partly illegible increasing the risk of incorrect results. These (avoidable) practical considerations serve to reinforce the requirement for the project to implement a robust and practical data recording system usable in a manufacturing environment, and to ensure that the factories introduce adequate training to operators who understand the need for accurate and legible recording of data which can be unambiguously checked at a later date. There was also some difficulty concerning the definition of a lot. However the problems associated with lot definition are alleviated by subsequent decisions in the project concerning the use of statistical process control involving long term variation.

Netherlands A, the variance of the "botermaker" is larger than the online variance. Means and standard deviations per lot of the online meter data are similar and small with few exceptions. The scatterplots of differences comparing the two measurement methods show no systematic pattern.

Table 5. Butter moisture data from Netherlands creameries.

		N	Mean %	Std.Dev%	Skewness
N'lands A	Online meter	302	15.88	0.10	-3.401
	Botermaker	320	15.88	0.17	-2.692
N'lands B	Wolbern	622	15.77	0.21	-2.454
	NIRS	613	15.75	0.22	-2.091
N'lands C	In line	188	15.87	0.08	-2.320
	Operator	188	15.83	0.11	-0.676
N'lands A	Package line 1	347	15.84	0.12	-0.484
	Package line 2	109	15.88	0.12	-2.637
	Package line 3	163	15.88	0.12	-2.437

The upper limit of 16% is respected in each case.

Data from Netherlands B also showed the measurement methods to be very similar. The values of means and standard deviations per lot reveal the inhomogeneity of variances, probably due to the varying number of observations per lot, and to the inclusion of start-up data in the lot which can introduce a comparatively large variability.
Netherlands C is peculiar in that the data is very similar, variation, total and per lot, is slightly larger in the case of measurement method "operator" than "in-line".
Unlike the Austrian data the assumption of normal distribution cannot be maintained for the Dutch data. Thus the results of variance analysis and estimation of variance components must be considered carefully, however the adoption of a system based on consideration of results exclusively above the process median should overcome this problem.
The variance components within lots are all similar except for Netherlands A "on line" meter. Between the lots they vary between 0.003% and 0.023%. Netherlands C is problematic because the model is insignificant at the 5% significance level.

Table 6. Variances associated with Netherlands creameries ($\%^2$m/m).

Data	Method	Var. within lot	Var. between lots
N'lands A	On line meter	0.008	0.003
	Botermaker	0.027	0.0035
N'lands B	Wolbert	0.023	0.0195
	NIRS	0.025	0.023
N'lands C	In line	0.007	Not significant
	Operator	0.013	Not significant

Table 7. Univariate analysis of ex-package data for Netherlands A (%m/m).

Package line	Mean	Std.dev.	Min.	Max.	Observations
Package line 1	15.84	0.118	15.21	16.52	347
Package line 2	15.88	0.12	15.32	16.05	109
Package line 3	15.88	0.12	15.27	16.10	163

The data on the packaging lines shows that all three lines have very similar characteristics.

In addition to the data from Austria and the Netherlands the UK provided factory data from 20 data sets from a range of UK factories.

Overall consideration of the factories showed that, except for Austria 1, the upper limit of 16% was respected in all cases. The overall means of UK factories were much lower than the others, between 15.44% and 15.77%, Austrian means were between 15.76% and 15.95%, whereas Dutch means were between 15.76% and 15.95%. The distributions, in all cases were slightly skewed the left. Distribution characteristics within lots could not be investigated because there was not enough data per lot.

Table 8. Summary of data from factories (% m/m)

Country	Within-lot standard dev.	Between-lot standard dev.
UK	0.17 – 0.29	0.13 – 0.18
Austria	0.17 – 0.20	0.05 – 0.12
Netherlands.	0.09 – 0.16	0.05 – 0.15

The standard deviations within lots vary between 0.09% (Netherlands) and 0.29% (UK), between lot standard deviations varied from 0.05% to 0.18% Due to some problems associated with the Dutch data it is advisable to give these a lower weight than the others.

5.1.2 Summary of Report 2 and Supplement to Report 2 "Further Investigation of Butter Moisture Content Data from the UK, Denmark and the Netherlands".

These reports, dated August 1998, were prepared by the Freie Universitaet Berlin, Institut fur Statistik und Oekonometrie and are summarized as follows.

This report considered the data from two UK factories (factories 1 and 2), data from 2 Danish factories (factory H and V) and one Netherlands factory (NL B).

Each of the two UK data sets consisted of 80 measurements of moisture on 20 samples taken on one particular day in time intervals of 15 minutes. Each of the samples was split into two sub-samples, one of the sub-samples analysed twice at the factory, the other twice in the official control laboratory. The data permit a break down of variance into 4 components,

the component due to time, i.e. within-lot variation
the component due to laboratory difference
the interaction component
the residual component, i.e. the component due to repetition of measurement.

Data are summarized in Table 9 (Two extremely high values in the set of data from factory "2" were retained). The control laboratory rechecked these and confirmed the figures, the factory rechecked that there had been no transcription error, and the statistician therefore made the decision to leave these data in the evaluation. An explanation for this may be that the control laboratory received a different sample, or that moisture somehow got into the sample container.) The data showed a rather large variation in time but generally the differences between the results of the two laboratories and the differences between the two repeated measurements were small.
The data from the Danish factory "H" had the same structure as the UK data. There were 20 samples each with 2 samples analysed twice in the factory and the control laboratory. For the Danish factory "V" only control laboratory data were supplied in the first instance due to a misunderstanding at the factory. Subsequently data were supplied from Denmark for both these factories, and consisting of 19 (factory H) and 20 (factory V) samples analysed with the same structure as the UK data.

The Dutch data consist of two data sets "FMG" and "HCT" each of 12 samples. The Danish dairy V (first run) and the Dutch data allow only to split the variance into time (within-lot) and the residual (measurement) component as data on parallel sub-samples are not available from two different laboratories in these cases.

The UK data showed a rather large within-lot variation but the differences between the results of the two laboratories and the difference between the repeated measurements are rather small. The variation in the Danish and Dutch data is small compared to the UK data.

For Denmark in the case of factory H a systematic difference was observed with the values in the control laboratory always lower than the factory for both runs. This could be due to the calibration of the factory method which may not have previously been checked against the official Danish laboratory. This observation serves to highlight the need to investigate calibration of the factory method, which is recommended in the project proposals.

For each data set a two-way analysis of variance, (in the case of Danish factory V and the Dutch data a one-way analysis of variance) was performed. The ANOVA showed that there was always a highly significant component for within-lot variation at the $\alpha = 0.001$ level. Thus the inhomogeneity in the product during production of one lot is significantly larger than the variation due to the measurement process or the component due to the differences between the two measurement methods. In addition to inherent product variation lots are also subject to large variations at start-up when adjustments are made to the moisture level. In the case of the UK data there is a significant interaction and a non-significant component ($\alpha = 0.05$ level) due to the laboratory. The interaction component reflects for factory 2 the extremely high values at one sampling time and for both laboratories a laboratory component which is not constant over time. The observed difference of the methods in the Danish set for factory H is also manifested in a significant result for the method factor ($\alpha = 0.05$). This factor will be addressed by a suitable factory qualification procedure which requires the factory to demonstrate that the measurement process is free of any significant bias. The interaction component is non-significant in this case ($\alpha = 0.05$).
For the UK data and Danish factory H the hierarchical model of the analysis of variance with the laboratory factor nested into the time is the appropriate model to be used.

Table 9. Components of standard deviation in UK, Danish and Dutch factories %m/m.

	UK		Netherlands	
	1	2	FMG	HCT
Standard deviation due to time (within-lot variation)	0.411	0.317	0.053	0.064
Laboratory component of Standard deviation	0.042	0.160	-*	-*
Repeatability Standard deviation	0.036	0.048	0.026	0.023

	Denmark			
	H	V	H 2nd run	V 2nd run
Standard deviation due to time (within-lot variation)	0.108	0.095	0.16	0.04
Laboratory component of Standard deviation	0.093	-*	0.094	0.046
Repeatability Standard deviation	0.065	0.040	0.031	0.023

*Data only available from a single laboratory.

The overall conclusions drawn in the report were that the variations due to measurement are rather small but cannot be ignored and must be taken into account when laying down limits of variation. A general variation value as the basis for control procedures is not recommended because the within-lot variation varies between 0.04% and 0.411%. The within laboratory repeatability standard deviation (measurement standard deviation) ranged from 0.023% to 0.065%. An acceptable basis could be a fixed upper limit for the variation and individual values based on previous analysis, which can be adjusted if necessary.

Factory data were also taken from 3 UK creameries comparing moisture levels from samples taken immediately after the churn with levels in the corresponding packaged butter. The differences in times between taking the samples varied between 10 and 30 minutes. The data showed that moisture levels ex-churn were on average about 0.05% to 0.1% higher than those in the corresponding packet samples. Although this trend was sometimes reversed on individual samples, overall there appeared to be a small moisture loss. No statistical evaluation was made of the data but the from visual inspection the ex-churn data appeared to be more variable than corresponding ex-package data. The inclusion of a holding tank after the churn is consistent with these observations as some moisture evaporation and some homogenising of the butter might be expected.

5.2 Moisture, fat and protein in skimmed milk powder.

This report, dated August 1999, was prepared by the Freie Universitaet Berlin, Institut fur Statistik und Oekonometrie and is summarized as follows.

Skimmed milk powder data were supplied from Austria, the Netherlands and the UK. One data set (from the Netherlands) consisted of quality control data for moisture collected during two weeks of regular production. All the other data sets were obtained following the scheme proposed by the project team: i.e. by taking 20 consecutive samples, dividing each of these into two sub-samples A and B and obtaining duplicate measurements at each sub-sample A in the factory and at each sub-sample B in the control laboratory.

5.2.1 Statistical analysis of the production data.

A one-way analysis of variance gave the following estimates of the within-lot and between-lot components of variance. (Moisture data)

Table 10. Components of variance from Netherlands production data.

Component of variance	Lots defined by day	Lots defined by silo
Between-lot	0.0348%	0.0742%
Within-lot	0.0816%	0.0423%

As expected, the within-lot component of variance is smaller for the lots defined by silo than by day because lots by silo are smaller than lots by day. On the other hand the between-lot component of variance is larger for the lot defined by silo than by day. It should be noted that the within-lot component of variance includes the components of variance due to measurement, this cannot be estimated separately for these data.
For cases where data exist the near infra-red measurements and the factory laboratory measurements were compared using a paired t-test. The systematic difference between the near infra-red measurements and the factory laboratory measurements, expressed as the difference between their means, is 0.92% and is significant at the $\alpha = 0.05$ level.

5.2.2 Statistical analysis of data obtained according to the scheme.

a) Data from Austria

Austria delivered data from 2 dairies. The Austria 1 data set consisted of measurements of moisture fat and protein. At one production day samples were taken hourly. For moisture each of ten samples was measured once in the factory and in duplicate in the control laboratory. For fat each of ten samples was measured in the control laboratory, but only 5 samples once in the factory. For protein only 5 samples (every second) were measured once in the factory and in duplicate in the control laboratory.
The Austria 3 data set consisted of measurements of moisture, fat and protein. As in Austria 1 at one production day samples were taken hourly. For moisture each of the 20 samples was measured in duplicate in the factory and in the control laboratory. For fat each of the 20 samples was measured once in the factory and in duplicate in the control laboratory, however each of the factory results was reported as <0.5% which makes statistical consideration of the results impossible. For protein only 10 samples (every second) were measured in duplicate in the factory and control laboratory.

Moisture
For moisture in almost all cases the mean of the two measurements in the control laboratory was larger than the mean of the two measurements in the factory. Austria 3 was working to a stable process average whereas Austria 1 started with a rather large process average of about 4.0% ending at 3.25%, similar to Austria 3.

For Austria 1 the estimate of the measurement standard deviation was 0.0247% with a process standard deviation of 0.2039%. The measurement bias of the factory Austria 1, expressed as the difference between the means of the measurements results of the factory and control laboratory was –0.109%, significant at the $\alpha = 0.05$ level.
For Austria 3 the measurement standard deviation of the factory was larger than that of the control laboratory, therefore the data from each of the two sources were analysed separately with a one-way analysis of variance. Estimates of the measurement standard deviation were; in the factory 0.0914%, and in the control laboratory 0.0458%. The latter value is rather high compared with that obtained in the same laboratory with the data of Austria 1, however the variance ratio was in the range of possible random variation. Estimates of the process standard deviation are; in the factory 0.0208%, and in the control laboratory 0.0916%. These two estimates of the same parameter differ largely but are not small compared with the estimate of the process standard deviation in Austria 1. The combined estimate of the process standard deviation is 0.0664%. The measurement bias of the factory Austria 3, expressed as a difference between the means of the results of the factory and the control laboratory is –0.1025%, significant at the $\alpha = 0.05$ level.

Fat

For fat the measurement results of the factory Austria 3, were all reported as <0.5% and could not be used for further analysis. There were only 5 measurements results for Austria 1, three being 0.5% and two 0.3%, which again could not be further processed. According to the values obtained in the control laboratory both factories were working to a stable process average of about 0.8%. The estimate of the measurement standard deviation for Austria 1 was 0.0288% with a process standard deviation of 0.0448%. For Austria 3 the measurement standard deviation was 0.0298% with a process standard deviation of 0.0657%. There was good agreement of the estimates of the measurement standard deviation of the control laboratory, 0.0228% based on the Austria 1 data and 0.0298% based on the Austria 3 data. The estimates of the process standard deviation in the two factories differed only slightly.

Protein

For protein, Austria 3 was working to a stable process average of about 35.5%; the process average in Austria 1 was less stable lying between 36.5% and 37.5%. The means of the measurement results of Austria 1 were all larger than those of the control laboratory whereas those from Austria 3 and the control laboratory did not differ significantly at the 5% significance level. For Austria 1 only the measurement results of the control laboratory could be analysed, as there were no repeated measurements in the factory. The measurements standard deviation was 0.1955% and process standard deviation 0.2925%. The measurement bias of Austria expressed as the difference between the means of factory and control laboratory was –0.448% and was significant at the $\alpha = 0.05$ level. For Austria 3 the estimate of the measurement standard deviation was 0.1796% in the factory and 0.1749% in the control laboratory, which was in very good agreement amongst each other and with the result obtained with the data of Austria 1. Estimates of the process standard deviation were 0.0772% in the factory and 0.1173% in the control laboratory, with a combined estimate of process standard

deviation of 0.0993%. The measurement bias of Austria 3, expressed as the difference between the means of factory and control laboratory was –0.014% which was not significant at the $\alpha = 0.05$ level.

b) Data from the Netherlands

Data from the Netherlands consisted of quality control data from one factory collected hourly during production. Twenty group samples were collected and the characteristics moisture, fat and protein measured in the factory and control laboratory. The production run covered powder, which went to two separate towers. In the investigation the two sets of production data were treated as one set consisting of data for the first tower followed by data for the second. For the estimation of the measurement standard deviations, the comparison of the measurement standard deviations, the comparison of the measurement methods (NIRS and reference) and the comparison of the measurement results for the two laboratories this combination is not relevant. However, the estimated process standard deviation was an average of the within-lot standard deviation of the two towers, this was reasonable because the estimation of the process standard deviation should include the effect of such changes in the production process. Moisture was measured in the factory with each of two measurement methods (NIRS and reference) and in the control laboratory once with NIRS and in duplicate with the reference method. For fat the same measurement method was applied. For protein only measurement results for the control laboratory existed. Protein was measured once with NIRS and in duplicate with the reference method.

Moisture

For moisture, the variation in time, i.e. the process variation, was rather large when compared with the measurement variation. There were no systematic differences between the factory results and the results of the control laboratory, or between the two measurement methods (NIRS and reference). Estimates of the measurement standard deviation were; factory (NIRS) 0.0067%, factory using reference method 0.0529%, and control laboratory (reference method) 0.0351%. The measurement standard deviation of NIRS in the factory was much smaller than that of the reference method, whereas the standard deviations of the reference method in both laboratories were approximately equal. The systematic difference between the means of measurement methods obtained with NIRS and the reference method in the control laboratory was 0.026% which is not significant at the $\alpha = 0.05$ level. However, in the factory the systematic difference was 0.081% and is significant at the $\alpha = 0.05$ level.

A comparison of the measurement results across laboratories, separately for NIRS and the reference method showed that the measurement bias for the factory for NIRS, expresses as the difference between the means of factory and control laboratory, was 0.015%, not significant at the $\alpha = 0.05$ level. Whereas the measurement bias of the factory for the reference method, expressed as the difference between means of the factory and control laboratory was –0.040% which is significant at the $\alpha = 0.05$ level.

The three estimates of the long-term process standards deviation were from NIRS data for the factory 0.1271%; from the factory using the reference method 0.1268% and from the control laboratory using the reference method 0.1259%. All are in very good agreement so that 0.13% can be used as a reliable estimate.

Fat

Fat data from the factory showed measurement results >0.6% at the starting times for the two towers, other than this all results lay between 0.3% and 0.6%, but as results were only reported to 1 decimal place the analysis of the data can only be interpreted as rough results. The NIRS results from the factory were always smaller, by about 0.2%, than all the other corresponding measurements. The estimates of the measurement standard deviation are: factory NIRS 0.0316%, factory reference method 0 (all 20 duplicate measurements reported as equal), control laboratory reference method 0.0271%. Hence a rough estimate of the measurement standard deviation is 0.03%.
The systematic difference between the means of the measurement results obtained with NIRS and the reference method in the control laboratory was 0.035% which was significant at the $\alpha = 0.05$ level. In the factory this systematic difference was –0.205% which was highly significant at the $\alpha = 0.05$ level. The estimates of the process standard deviation were: factory NIRS 0.0884%, factory reference method 0.0366%, control laboratory reference method 0.0561%. The agreement between these three estimates was quite good and the value of 0.06% can be used as an estimate.

Protein

The estimate of the measurement standard deviation of the reference method was 0.0448%. The systematic difference between the means obtained with NIRS and the reference method was –0.215% which was significant at the $\alpha = 0.05$ level. The estimate of the process standard deviation, based on measurements with the reference method was 0.0568%.

c) Data from the UK

The UK delivered four data sets of three dairies with the structure proposed by the working group: 20 samples measured twice at the factory and twice in a control laboratory. One data set (UK B) consisted of 25 samples, but in this case fat and protein were measured only once in the factory. The September protein data of UK C were measured in the factory with a special method with results completely different from the other data. For this reason, these data were excluded from the analysis.

Table 11. Summary of the most important results of univariate analysis of UK data.

All values in %	UK A	UK B	UK C September	UK C November
Moisture				
Overall Mean	3.79	3.15	3.31	3.41
Overall Variance	0.04	0.03	0.04	0.03
Overall N	80	100	80	80
Mean (factory/control)	3.74/3.85	3.17/3.13	3.23/3.38	3.29/3.52
Variance (factory/control)	0.04/0.03	0.04/0.02	0.03/0.03	0.02/0.02
Fat				
Overall Mean	0.75	1.06	0.71	-
Overall Variance	0.04	0.07	0.08	-
Overall N	80	75	80	-
Mean (factory/control)	0.68/0.83	1.03/1.08	0.44/0.98	-
Variance (factory/control)	0.02/0.05	0.08/0.07	0.01/0.003	-
Protein				
Overall Mean	37.86	36.85	36.85	-
Overall Variance	0.25	0.15	0.04	-
Overall N	80	75	40	-
Mean (factory/control)	37.69/38.04	37.31/36.62	-/36.85	-
Variance (factory/control)	0.38/0.06	0.03/0.05	-/0.04	-

Moisture

Overall consideration of the data showed that for UK A there was a slight trend downward with one extremely low factory value. UK B appeared to show higher values after the 11th sample. In the scatterplots for UK C there were systematic differences between the factory and control results particularly for the November results where the control laboratory were always higher. Estimates of the measurement standard deviation were: UK A factory 0.0327%, control laboratory 0.0864%; UK B factory 0.0791%, control laboratory 0.0907%, UK C (September) factory 0.0271%, control laboratory 0.0543%, (November) factory 0.0278%, control laboratory 0.0352%. The variation between minimum and maximum values is significant.

The measurement biases of the factories, expressed as differences between the factory and control means were UK A 0.0115:, UK B –0.039%, UK C (September) 0.159%, UK C (November) 0.227%. All were significant at the $\alpha = 0.05$ level except UK B. A slight significant difference, with values in the factory smaller than the control laboratory was the normal case. This was in line with the observations made in Austria, with the control laboratory obtaining higher moisture values and might be attributable to environmental factors affecting the moisture levels.

Estimates of the process standard deviation were UK A factory 0.2052%, control laboratory 0.1386%; UK B factory 0.1867%, control laboratory 0.0934%, UK C (September) factory 0.1613%, control laboratory 0.1713%, (November) factory 0.1436%, control laboratory 0.1207%. The variation in these estimates is insignificant even between the three different dairies. The process standard deviation is about 3 to 5 times larger than the measurement standard deviation.

Fat

In the case of UK A control laboratory results were systematically larger than the factory results. The fat data for UK B rise above the specification limit (1%) to 1.6% between samples 16 and 25, this was found by both control and factory laboratories. The fat data from UK C were consistently low, approximately 0.4%, it is very likely that the control results, approximately 1% fat, are correct. Estimates of the measurement standard deviation were UK A factory 0.0265%, control laboratory 0.0125%; UK B control laboratory 0.0269%, UK C (September) factory 0.0548%, control laboratory 0.0252%. The estimates vary between 0.013% and 0.055% but have to be interpreted with care because measurement results differ only slightly in the last decimal digit. The measurement biases of the factories, expressed as differences between the factory and control means were UK A 0.130%, UK B 0.069%, UK C (September) 0.546%. All were significant at the $\alpha = 0.05$ level except UK B
Estimates of the process standard deviation were UK A factory 0.1295%, control laboratory 0.2288%; UK B control laboratory 0.2588%, UK C (September) factory 0.0441%, control laboratory 0.0513%. The process standard deviation in UK C was smaller than the other two dairies. In this dairy it is of the same magnitude as the measurement standard deviation while in the other dairies it was about 5 to 10 times larger.

Protein

The UK results showed a downward trend after sample 11, and after this sample the factory results were always smaller than the control laboratory results. In the case of UK B control laboratory results were always smaller than those of the factory were. UK C protein measurement results were not correct and cannot be used. Estimates of the measurement standard deviation were UK A factory 0.1296%, control laboratory 0.1118%; UK B control laboratory 0.1354%, UK C (September) control laboratory 0.1202%. These are in very good agreement. The measurement biases of the factories, expressed as differences between the factory and control means were UK A –0.348%, UK B 0.695%, both were significant at the $\alpha = 0.05$ level. Estimates of the process standard deviation were UK A factory 0.6084%, control laboratory 0.2149%; UK B control laboratory 0.1681%, UK C (September) control laboratory 0.1297%. With the exception of the UK A results these are of the same magnitude as the measurement standard deviations.

Table 12. Summary of estimates of process and measurement standard deviations for moisture, fat and protein.

Dairy	Estimated			
	Process standard deviation		Measurement standard deviation	
	Factory	Control	Factory	Control
Moisture				
Austria 1		0.204		0.025
Austria 3	0.021	0.092	0.091	0.046
NL (NIR)	0.127		0.007	
(ref. meth.)	0.126		0.053	0.035
Dairy Crest	0.205	0.139	0.033	0.086
Express	0.093		0.079	0.091
Leckpatrick, Sept. 98	0.161	0.171	0.027	0.054
Leckpatrick, Nov. 98	0.144	0.121	0.028	0.035
Fat				
Austria 1		0.045		0.023
Austria 3		0.066		0.030
NL (NIR)	0.088		0.032	
(ref. meth.)	0.037	0.056		0.027
Dairy Crest	0.229		0.027	0.013
Express	0.259		0.027	
Leckpatrick, Sept. 98	0.044	0.051	0.055	0.025
Protein				
Austria 1		0.293		0.196
Austria 3	0.077	0.117	0.175	
NL (ref. meth.)	0.057		0.045	
Dairy Crest	0.215		0.130	0.112
Express	0.168		0.135	
Leckpatrick, Sept. 98	0.130		0.120	

Conclusions

Estimates of the within lot (process) standard deviation for moisture ranged from 0.093% to 0.205%, measurement standard deviation ranged from 0.025% to 0.091% (excluding Netherlands NIR). Estimates of the within lot (process) standard deviation for fat ranged from 0.037% to 0.259%, measurement standard deviation ranged from 0.013% to 0.055%. Estimates of the within lot (process) standard deviation for protein ranged from 0.057% to 0.293%, measurement standard deviation ranged from 0.045% to 0.196%.

The results of the analysis show that, for all characteristics investigated: moisture, fat and protein, the process standard deviation, i.e. within-lot standard deviation, is (much) larger than the measurement standard deviation. However, the measurement standard deviation has to be taken into account in addition to the process standard deviation.

The process standard deviation is different for the quality characteristics moisture, fat and protein and for different dairies. Therefore, a general value as the basis for statistical process control and the measurement standard deviation for each of the quality characteristics is not recommended. Each dairy has to investigate the process standard deviation and the measurement standard deviation for each of the quality characteristics intended to be used for statistical process control.

6 RECOMMENDATIONS FOR ADOPTION OF A CONTROL SCHEME

Details of the recommended procedures for adoption of an autocontrol scheme are given in Appendix 4 as Flow Charts.

6.1 Framework document for factory autocontrol system.

A factory quality autocontrol system using existing data to replace external quality control of butter

1. Quality control of butter

The quality of butter should be guaranteed to consumers. For this purpose, European and national legislation requires the inspection of produced butter for several quality characteristics. The most stringent control is prescribed for characteristics where producer and consumer interests may seem opposite, such as the moisture content. Typically, producers will tend to add as much water as allowed by the legal quality requirement. This legal requirement (e.g. maximum 16 % moisture) represents the consumer interest of not buying water for the price of butter. Therefore, an intensive quality control program is essential to maintain the balance between producer and consumer interests.

2. Current situation

Typically, butter producers already make a large internal control effort in order to optimize and control their production process. However, these data are not used by official authorities who have their own end product inspection programs. For example, lots offered for intervention are inspected by taking a fairly small number of samples which are then combined to generate only 2 or 3 bulk samples for analysis (EC-Reg. 454/95[6]). Failing samples lead to rejection of all or part of the lot with associated financial penalties. The current system is not based on sound statistical principles. This makes consumer protection less than optimal, whereas the consequences of this external control may be unexpected for the producer.

3. Factory quality autocontrol

European and national authorities are now in discussion to open the possibility of quality autocontrol systems with the intention to use internal factory data obtained under such systems for official control purposes. Ultimately no separate end product

control would be performed, thus eliminating unexpected lot rejection or fines. The butter producer will be completely in control of the quality of his product and will show this to the official control authority in a standardized manner. Based on this information, the control authority will periodically (e.g. yearly) issue a permit to the factory for continuing with the autocontrol system for the next period.
The proposed quality autocontrol system consists of three parts:
i) a procedure in which the producer qualifies for participation in the program **(qualification procedure)**
ii) **statistical process control** (SPC) of the production process and the measurement process,
iii) a reassessment of the qualification procedure after six months in the first place and annually later on **(reassessment procedure)**.

4. Qualification

The official control authority is involved in parts i) and iii) of the quality autocontrol system, qualification and reassessment of the factory. Based on an audit and on information supplied by the factory, the control authority will judge (in a standardized manner) whether the implementation of the quality autocontrol system provides the necessary information for protecting consumer interests. If not, the control authority will cooperate with the factory to repair the defects found. When successful, the factory receives a permit for the next period of autocontrol.
Evaluation Procedure B is the procedure for first-time qualification (part 1) when historical data (from 6 recent months) are available allowing quantification of the performance of the production process and the measurement process. If such data are not available, the factory may choose to operate evaluation Procedure A which should within about two months provide enough information for a first-time qualification assessment.
The qualification procedure consists of an evaluation of the moisture measurement method of the factory and an evaluation of the production process with respect to moisture (or to other quantitative characteristics of the dairy product).

4.1 Evaluation of the measurement process of the factory

The producer shall make the following information available to the control authority:

- a basic document describing in detail the measurement method, including calibration, and its application,
- adequate training reports of the operators which demonstrate their competence, including use of reference materials where these are available,
- a confirmation that each alteration in the measurement method and each change of operators will be recorded,
- evidence of satisfactory method performance, (e.g. by use of Certified Reference Materials where these are available or by comparison with a reference laboratory e.g. the official control laboratory).

In evaluation procedure A the evaluation of the measurement process of the factory is combined with the evaluation of the production process. Its purpose is to demonstrate that the measurement process is stable and has negligible bias, and to end up with a reliable estimate of the within laboratory measurement standard deviation under repeatability conditions.
By agreement of the partners sufficient information from former internal or external quality control of the measurement process can be used instead of the proposed procedure for the evaluation of the measurement process.
It is also necessary to control the measurement process and demonstrate this control, Procedure D gives details of how this is to be achieved.

4.2 Evaluation of the production process with respect to moisture in butter.

In the specific case of moisture in butter, the process control data being used for the program to demonstrate that lots of butter are in compliance with the quality requirement for the moisture content may consist either of

- ex-churn data, or of
- ex-package data.

If ex-churn data are used the qualification procedure includes an extra step to assure that ex-churn and ex-package data being based on the same time of production do not differ significantly.

In order to evaluate the production process with respect to moisture the producer either

- has to run evaluative procedure B. In order to do this he has to supply a complete record of statistical process control data for a period of at least six-months immediately prior to the time of demonstration. These data should come in the form of quality control charts, the time intervals between successive measurements being not larger than one hour. The calculation of the control limits should be explained. These control charts should show not more than 1 in 100 out of control signals, and the action taken for each out of control signal should be recorded,
- or the producer has to run the evaluation procedure A.

5. Statistical process control

The backbone of the system is part iii), regular quality assurance. The factory should implement its internal quality control based on sound statistical principles. A quality assurance protocol is made up jointly by the factory and the official control authority. Essential elements are a minimum sampling intensity and the use of statistical process control (SPC) for the production and the measurement processes. For example, in the case of moisture in butter at least one sample per hour should be taken and the measurement results plotted on Shewhart control charts to control the production process. Control of the measurement process requires the use of reference materials or, if these are not available, regular measurement comparisons with other laboratories. But apart from checks on the measurement and the production process, ultimately no external controls are made on the end product during regular operation, and all products from the factory would be allowed on the market.

One of the most important aspects of SPC is the elaboration of out-of-control action plans. Based on the experience of factory personnel it should be clear which actions are taken if measurements fall outside limits on Shewhart control charts. In many applications in industry it has been shown that introduction of SPC leads to a smaller process variation. Thus, a less variable and consequently better product quality may be obtained. This is a reason on its own to participate in a quality autocontrol system. As a bonus, with less variability a higher set level for the moisture content may be possible.

6. Starting with quality autocontrol

i) For factories new to autocontrol the following stepwise list may be used.
ii) Establish a contact with the control authority. Statistical advice from an expert with experience in SPC will generally also be necessary for a successful implementation.
iii) Establish contact with an appropriate reference laboratory (e.g. the official control laboratory) and ensure that the measurement procedure is in line with reference values, for example by using Certified Reference Materials where available, and is under control (see Procedure D).
iv) Adapt the internal quality control system if necessary to bring it into conformity with requirements of the autocontrol system as described in 5, and Procedure C.
v) Obtain data on the production and measurement processes, either by following a preliminary two-months evaluation procedure (see evaluation procedure A), or, if this is already established, by gathering information of 6 months from the quality control system (see evaluation procedure B).
vi) If the data show that the quality requirements are not met, adjust the production process (e.g. the set moisture level) and/or the measurement process (e.g. its bias and precision). After such adjustments gather new data.
vii) On request an audit will be held by the official control authority. A factory visit will be made in this step. Results from i)-v). should normally be sufficient to allow the control authority to issue a permit for quality autocontrol (however the details of official EU requirements still have to be finalized).

7. Assurance of validity of process control data

The control authority has the right to choose lots randomly, take duplicate samples out of them, or to appoint the samples already tested in the factory to be sent to the control authority, measure the moisture (or other characteristic) content and compare the results with the process control data. In case nonconformity of the production or measurement process is detected these processes have to be reassessed immediately. The reasons for the differences have to be investigated. No lot rejections may be based on the result of the validity assurance procedure.

8. Reassessment procedure

The reassessment procedure for the measurement method and for the production process is equal to evaluation procedure B, the qualification procedure for first-time

qualification when historical data are available. It has to be repeated periodically starting six months after qualification and continuing yearly after reassessment.

6.2 Procedure A: Qualification (first-time) of a factory wishing to adopt a quality autocontrol system for dairy products without having appropriate quality control data from 6 recent months.

General

This evaluation procedure is intended for factories that want to apply for participation in an autocontrol system, but have no data from 6 recent months of operation to allow the certifying authority to undertake an assessment using historical data. An alternative to this evaluation procedure is therefore for the control authority to use data where the factory already applies a suitable and approved control procedure.

This evaluation procedure yields, in approximately 2 months;

- a determination or a check of the upper limiting value μ_U of the process average μ which ensures that no more than 5% of the true moisture values are larger than 16%,
- preliminary data necessary for a determination of the control and warning limits of the control charts for individual values and moving ranges of moisture. How these data are to be used for autocontrol is described in procedure C.
- The evaluation procedure also tests the equality of measurement standard deviation between factory and assessor laboratory,
- and tests for systematic differences between factory and assessor laboratory.
- Production control of moisture in butter can be based on ex-churn or ex-package measurements (or both). Since ex-churn measurements are obtained earlier than ex-package measurements there is a faster feedback and corrective action can be taken as soon as possible. On the other hand, the consumer is not interested in the production process but in the properties of the produced (and packed) butter and, hence, more in ex-package measurements. Experience shows that in many cases ex-package measurements are on average lower than ex-churn measurements so that ex-churn moisture control assures an even better ex-package control. However, the situation might be different and therefore, one needs to evaluate the difference between ex-package and ex-churn measurements if production control is based on ex-churn measurements. For this situation the evaluation procedure includes a comparison of ex-package and ex-churn measurements.

Step by step procedure

1. Decide whether production control will be based on ex-churn or ex-package measurements.

2. At each of m = 30 (or more) days within a period of two months, take a sample (ex-churn or ex-package, as decided before, and sufficiently large to be divided and used as outlined below). Mark each of the samples with the day it has been drawn.
3. Divide each of the 30 samples into two subsamples A and B, subsample A to be analysed in the factory, subsample B to be analysed in an independent assessor laboratory (probably the official control laboratory). Mark each of the subsamples with the day it has been drawn.
4. Analyse each subsample in the factory and in the assessor laboratory in duplicate, under repeatability conditions, i.e. same measurement system, same operator, short intervals of time between consecutive measurements. The method of analysis in the factory should be the same as that used for autocontrol. In order to avoid daily delivery of samples from the factory to the assessor laboratory form groups of subsamples, e.g. for one week, and make sure that each group of subsamples is analysed in both laboratories at one and the same day. Add the day of analysis to the table of measurements.
5. Only in the case where the comparison of ex-churn and ex-package data is included: For each of the samples taken according to 2. ex-churn take a matching ex-package sample, i.e. an ex-package sample the material of which has been produced at a time as close as possible to the production time of the material of the ex-churn sample, allowing for any known delay time between when the butter leaves the churn and when it is packaged. Analyse this sample in duplicate in the factory at the same time as the matching ex-churn sample. The method of analysis for ex-churn and ex-package samples should be the same.
6. The statistical analysis starts with the following table of measurement results:

Table 13. Template for measurement results.

					Only in the case of ex-churn control
Sampling Date	**Sample Number**	**Date of analysis**	**Measurement Result**		**Ex-package measurement in the factory** 1 y_{iC1} 2 y_{iC2}
			in the factory 1 y_{iA1} 2 y_{iA2}	**In the assessor laboratory** 1 y_{iB1} 2 y_{iB2}	
	1 2 . . m = 30				

7. Plot the measurement results against the sample number and check for irregularities, especially for outliers, for trend or cyclic variations or other patterns. If some of these are observed investigate their reasons. If there is evidence of unstable situations correct the results if possible, or repeat the measurements. Under the advice of a statistician outlier tests can be applied.

8. Compute the estimate of the within laboratory standard deviation under repeatability conditions,

in the factory,

$$s_A = \sqrt{\frac{1}{2m}\sum_{i=1}^{m}(y_{iA1} - y_{iA2})^2}$$

in the assessor laboratory,

$$s_{bA}^2 = \frac{1}{m-1}\sum_{i=1}^{m}(\bar{y}_{iA} - \bar{y}_A)^2 .$$

9. Only in the case where the comparison of ex-churn and ex-package data is included: Since this comparison will not be carried out all the time the following steps are not based on the extra ex-package measurements. However, with these measurements a check of stability of the measurement process of the factory is possible:

Compute the estimate of the within laboratory standard deviation under repeatability conditions in the factory, based on the ex-package measurements,

$$s_C = \sqrt{\frac{1}{2m}\sum_{i=1}^{m}(y_{iC1} - y_{iC2})^2} .$$

Test the null hypothesis that the theoretical variances σ_A^2 and σ_C^2 are identical, i.e. that the variability of the two sets of data is, statistically, the same,

$$H_0 : \sigma_A^2 = \sigma_C^2 ,$$

with the F-test (significance level α), i.e. compare the test statistic

$$F_B = \max\left\{s_A^2/s_C^2,\ s_C^2/s_A^2\right\}$$

with the critical value $F_{\nu_1;\nu_2;1-\alpha}$, where $F_{\nu_1;\nu_2;1-\alpha}$ is the $(1-\alpha)$-quantile of the F-distribution with ν_1 and ν_2 degrees of freedom ; $\nu_1 = \nu_2 = m$ [F-test tables are standard statistical tables]. Reject the null hypothesis if

$$F_B > F_{\nu_1;\nu_2;1-\alpha} .$$

Rejection of the null hypothesis indicates an irregular measurement process: either the results from the ex-churn are more variable than those ex-package or vice versa. This should be investigated and improved before the following steps are carried out.

Where H_0 is not rejected, s_A^2 and s_C^2 are not statistically different and could be averaged in order to obtain a better estimate of the within laboratory standard deviation under repeatability conditions in the factory. However, this is not recommended in order to avoid two different procedures in each of the following steps.

10. Test the null hypothesis that the theoretical variances σ_A^2 and σ_B^2 of the two laboratories under repeatability conditions are identical, i.e. that the variability of the two sets of data, from the factory and assessor laboratory, is, statistically, the same,

$$H_0 : \sigma_A^2 = \sigma_B^2,$$

with the F-test (significance level α), i.e. compare the test statistic

$$F_B = \max\left\{s_A^2/s_B^2, s_B^2/s_A^2\right\}$$

with the critical value $F_{\nu_1;\nu_2;1-\alpha}$, where $F_{\nu_1,\nu_2;1-\alpha}$ is the $(1-\alpha)$-quantile of the F-distribution with ν_1 and ν_2 degrees of freedom; $\nu_1 = \nu_2 = m$. Reject H_0 if

$$F_B > F_{\nu_1;\nu_2;1-\alpha}.$$

Where the null hypothesis is not rejected the measurement standard deviation under repeatability conditions in the factory is assumed to be equal to the corresponding standard deviation of the assessor laboratory.

There is no imposed upper limit for the factories within laboratory measurement standard deviation under repeatability conditions. However, working to a high measurement standard deviation has the consequence that, for an upper specification limit the target for the process average has to be fixed at a rather low level (or alternatively. at a rather high level in case of a lower specification limit). This might be unacceptable for economical reasons. Hence, a ratio of the estimates of the standard deviation of the factory and the assessor laboratory which is larger than 2 requires an investigation of the measurement process of the factory and a corrective action.
The estimate s_A of the measurement standard deviation under repeatability conditions in the factory is used for the design of process control.

11. Estimate the long-term process standard deviation:
For each sample i compute the mean of the two measurement results in the factory (laboratory A),

$$\bar{y}_{iA} = \frac{1}{2}(y_{iA1} + y_{iA2});$$

the overall mean of these mean values $\bar{y}_{iA}$ is

$$\bar{y}_A = \frac{1}{m}\sum_{i=1}^{m}\bar{y}_{iA}$$

and the variance is

$$s_{bA}^2 = \frac{1}{m-1}\sum_{i=1}^{m}(\bar{y}_{iA} - \bar{y}_A)^2 .$$

Repeat the procedure of the assessor laboratory (laboratory B) to get s_{bB}^2.
The estimate of the long-term process standard deviation is

$$s_{process} = \sqrt{\frac{1}{4}\left(2s_{bA}^2 + 2s_{bB}^2 - s_A^2 - s_B^2\right)} .$$

Note: This estimate includes a component due to measurement error which is extra to that under strict repeatability conditions. Since the samples have been analysed in groups so that all measurements of a group have been obtained under repeatability conditions, an analysis of variance within and between groups would make it possible to estimate a component of long-term measurement standard deviation separate from the long-term process standard deviation in the true sense. This analysis-of-variance procedure is not precribed here in order to keep this evaluation procedure simple. Nevertheless, its use is recommended if it can be applied in practice.

12. Test the measurement bias of the factory for significance:

The null hypothesis that the bias Δ_A of laboratory A, the factory, against laboratory B, the assessor laboratory, is zero,

$$H_0 : \Delta_A = 0,$$

i.e. there is no systematic difference between measurement results of these two laboratories obtained at identical samples, against the alternative hypothesis

$$H_1 : \Delta_A \neq 0 \ ,$$

is tested with the paired t-test (significance level α).

For each sample i; i = 1,..., m the mean difference d_i, i.e. the difference between the mean of the two measurement results obtained in laboratory A and the mean of the two measurement results obtained in laboratory B,

$$d_i = \frac{1}{2}(y_{iA1} + y_{iA2}) - \frac{1}{2}(y_{iB1} + y_{iB2})$$

and their overall mean

$$\bar{d} = \frac{1}{m}\sum_{i=1}^{m} d_i = \bar{y}_A - \bar{y}_B$$

and the standard deviation

$$s_d = \sqrt{\frac{1}{m-1}\sum_{i=1}^{m}(d_i - \bar{d})^2}$$

are computed. The test statistic is

$$t_B = \sqrt{m}|\bar{d}|/s_d \ ;$$

it is compared with the critical value $t_{\nu;1-\alpha/2}$, where $t_{\nu;1-\alpha/2}$ is the $(1-\alpha/2)$-quantile of the t-distribution with $\nu = m-1$ degrees of freedom [t-tables are standard statistical tables]. If

$$t_B > t_{\nu;1-\alpha/2}$$

the null hypothesis is rejected. This is statistical evidence of a laboratory bias of laboratory A, the factory, against laboratory B, the assessor laboratory. The overall mean $\bar{d}$ of the differences is an estimate $\hat{\Delta}_A$ of this bias. Since it is assumed that the measurement process of the assessor laboratory is unbiased $\hat{\Delta}_A$ is an estimate of the laboratory bias of laboratory A, the factory.

A 95% confidence interval for the laboratory bias Δ_A of laboratory A, the factory laboratory, is

$$\left[\hat{\Delta}_A - t_{\nu;0.975}\frac{s_d}{\sqrt{m}}, \hat{\Delta}_A + t_{\nu;0.975}\frac{s_d}{\sqrt{m}}\right],$$

i.e. the inequality

$$\hat{\Delta}_A - t_{\nu;0.975}\frac{s_d}{\sqrt{m}} \leq \Delta_A \leq \hat{\Delta}_A + t_{\nu;0.975}\frac{s_d}{\sqrt{m}}$$

holds at the confidence level 95%.

If, after an eventual reinvestigation and adjustment of the measurement process, the one sided upper confidence limit

$$UA = \hat{\Delta}_A + t_{\nu;0.95}\frac{s_d}{\sqrt{m}}$$

remains positive, it has to be taken into consideration when determining the upper limit μ_U of the process average (see step 14).

13. Only where the comparison of ex-churn and ex-package measurement is included, test whether a systematic difference exists between ex-package and ex-churn measurement results:

The null hypothesis that there is no systematic difference between ex-package and ex-churn measurement results,

$$H_0 : \Delta_C = 0,$$

against the alternative hypothesis

$$H_1 : \Delta_C \neq 0 \quad ,$$

i.e. ex-package measurement results are systematically different from ex-churn measurement results, is tested with the paired t-test (significance level α).

For each sample i ; $i = 1, \ldots, m$, the mean difference c_i, i.e. the difference between the mean of the two measurement results ex-package and the mean of the two measurement results ex-churn,

$$c_i = \frac{1}{2}(y_{iC1} + y_{iC2}) - \frac{1}{2}(y_{iA1} + y_{iA2}) \ ,$$

and their overall mean

$$\bar{c} = \frac{1}{m}\sum_{i=1}^{m} c_i = \bar{\bar{y}}_C - \bar{\bar{y}}_A$$

and the standard deviation

$$s_c = \sqrt{\frac{1}{m-1}\sum_{i=1}^{m}(c_i - \bar{c})^2}$$

are computed. The test statistic is

$$t_B = \sqrt{m}\,\bar{c}\,/s_c \quad ;$$

it is compared with the critical value $t_{\nu;1-\alpha/2}$, where $t_{\nu;1-\alpha/2}$ is the $(1-\alpha/2)$-quantile of the t-distribution with $\nu = m-1$ degrees of freedom. If

$$t_B > t_{\nu;1-\alpha/2}$$

the null hypothesis is rejected. This is statistical evidence of a systematic difference between ex-churn and ex-package results.

The overall mean $\bar{c}$ of the differences is an estimate $\hat{\Delta}_C$ of this systematic difference. If $\hat{\Delta}_C$ is negative ex-package measurement results are systematically smaller than ex-churn measurement results and vice versa.

A 95% confidence interval for the systematic difference Δ_C between ex-package and ex-churn measurements of moisture is

$$\left[\hat{\Delta}_C - t_{\nu;0.975}\frac{s_c}{\sqrt{m}}, \hat{\Delta}_C + t_{\nu;0.975}\frac{s_c}{\sqrt{m}}\right] ,$$

i.e. the inequality

$$\hat{\Delta}_C - t_{\nu;0.975}\frac{s_c}{\sqrt{m}} \leq \Delta_C \leq \hat{\Delta}_C + t_{\nu;0.975}\frac{s_c}{\sqrt{m}}$$

holds at the confidence level 95%.

If the one sided upper confidence limit

$$UC = \hat{\Delta}_C + t_{\nu;0.95}\frac{s_c}{\sqrt{m}}$$

is positive, it has to be taken into consideration when determining the one sided upper limit μ_U of the process average (see step 14).

14. Determination of the upper limit μ_U of the process average:
In order to be in conformity with the upper specification limit USL=16% for moisture in butter the process average μ has to be fixed at a level not larger than

$$\mu_U = USL - 1.645 s_{total},$$

where

$$s_{total} = \sqrt{s^2_{process} + s^2_A}$$

is the estimate of the total standard deviation, $s_{process}$ is the estimate of the long-term process standard deviation (derived in step 11), s_A is the estimate of the measurement standard deviation under repeatability conditions in the factory (derived in step 10) and the factor 1.645 is the 95%-quantile of the standardized normal distribution, i.e. the calculation is based on the assumption that the quality characteristic "moisture" of the production process and its measurements are normally distributed.

Note that a larger standard deviation of measurement, s_A, results in a smaller value for the upper limit μ_U of the process average.
If the upper confidence limit UA for the laboratory bias Δ_A of laboratory A, the factory laboratory, is positive, it has to be included into the computation of μ_U.
If the upper confidence limit UC for the systematic difference Δ_C between ex-package and ex-churn measurements of moisture is positive, it also has to be included into the computation of μ_U. Hence, the upper limit of the process average is

$$\mu_U = USL - 1.645 s_u - UA - UC$$

where the last two terms are only included when positive.

15. μ_u and s_{total} as determined above are used to calculate the control and warning limits of the control charts; see procedure C.

Example
Since the proposal for procedure A is new, data from practical applications of it do not exist. Therefore, data have been simulated for the following situation : m = 30 days have been sampled ex-churn out of a process with constant process average 15.8% and long-term process standard deviation $\sigma_{process}$ = 0.1%.
The measurement process of laboratory A, the factory, has a bias of Δ_A = - 0.05% and a standard deviation under repeatability conditions, σ_A = 0.06%.
The measurement process of laboratory B, the assessor laboratory, has no bias and a standard deviation under repeatability conditions, σ_B = 0.03%.

Process variation and measurement error are normally distributed and the measurement error is added to the process variation.

In addition $m = 30$ matching ex-package samples have been chosen and analysed in the factory.

Their average moisture is 15.7%, i.e. it is systematically 0.1% smaller than the average moisture ex-churn, $\Delta_C = -0.1\%$.

The statistical analysis starts with the data of the following table:

Table 14. Example of butter moisture data

Sampling date	Sample number	Date of analysis	Measurement result in the factory		in the assessor laboratory		Ex-package measurement in the factory	
			1	2	1	2	1	2
			y_{iA1}	y_{iA2}	y_{iB1}	y_{iB2}	y_{iC1}	y_{iC2}
	1		15.78	15.72	15.76	15.72	15.93	15.56
	2		15.61	15.67	15.68	15.72	15.61	15.64
	3		15.70	15.57	15.76	15.75	15.66	15.57
	4		15.79	15.79	15.93	15.88	15.63	15.57
	5		15.59	15.60	15.65	15.62	15.57	15.73
	6		15.78	15.89	15.79	15.83	15.33	15.59
	7		15.73	15.64	15.77	15.73	15.58	15.65
	8		16.01	15.76	15.99	15.98	15.72	15.46
	9		15.79	15.76	15.79	15.87	15.74	15.70
	10		15.62	15.65	15.79	15.70	15.76	15.75
	11		15.80	15.84	15.86	15.93	15.56	15.71
	12		15.79	15.73	15.75	15.76	15.52	15.64
	13		15.52	15.64	15.65	15.60	15.71	15.69
	14		15.63	15.56	15.81	15.81	15.71	15.66
	15		15.76	15.84	15.86	15.90	15.58	15.68
	16		15.70	15.63	15.78	15.74	15.78	15.52
	17		15.49	15.65	15.69	15.72	15.82	15.68
	18		15.64	15.73	15.76	15.72	15.77	15.86
	19		15.68	15.62	15.69	15.70	15.64	15.75
	20		15.68	15.73	15.75	15.71	15.65	15.42
	21		15.86	15.80	15.87	15.91	15.51	15.69
	22		15.62	15.53	15.62	15.70	15.64	15.47
	23		15.71	15.91	15.91	15.94	15.56	15.57
	24		15.91	15.92	15.89	15.91	15.60	15.64
	25		15.79	15.84	15.89	15.82	15.72	15.69
	26		15.74	15.77	15.79	15.78	15.53	15.60
	27		15.83	15.77	15.86	15.84	15.70	15.76
	28		15.73	15.71	15.76	15.77	15.36	15.60
	29		15.65	15.64	15.71	15.78	15.72	15.71
	30		15.85	15.80	15.88	15.95	15.60	15.51

The plot of the measured moisture values against the sample number shows no irregularities. However, the moisture values measured by laboratory A, the factory, are most often smaller than the corresponding moisture values measured by laboratory B, the assessor laboratory.

The estimates of the within laboratory standard deviations under repeatability conditions are

in the factory $s_A = 0.0640$

in the assessor laboratory $s_B = 0.0327$.

The null hypothesis that the theoretical variances σ_A^2 and σ_B^2 of the two laboratories under repeatability conditions are identical,

$H_0: \sigma_A^2 = \sigma_B^2$,

is tested with the test statistic

$F_B = s_A^2 / s_B^2 = 3.85$

which is larger than the critical value for the significance level $\alpha = 5\%$,

$F_{30,30;0.975} = 2.07$

Hence, the null hypothesis $H_0: \sigma_A^2 = \sigma_B^2$ is rejected.

The estimate $s_A = 0.0640$ of the measurement standard deviation under repeatability conditions in the factory is used as the basis of process control.

The null hypothesis that the bias Δ_A of the factory is zero,

$H_0: \Delta_A = 0$,

is tested with

$\bar{d} = -0.0665$,

$s_d = 0.0501$

and the test statistic

$t_B = 7.267$

which is larger than the critical value for the significance level $\alpha = 5\%$,

$t_{29;\,0.975} = 2.045$.

Hence, the null hypothesis $H_0: \Delta_A = 0$ is rejected.

The factory A has a bias which is estimated by $\hat{\Delta}_A = \bar{d} = -0.0665$. The 95% confidence interval for the laboratory bias Δ_A of laboratory A, the factory laboratory, is [-0.0852, - 0.0478],

i.e. the laboratory bias Δ_A lies (at the confidence level 95%) between - 0.0852% and - 0.0478%.

The laboratory should investigate this bias and take an appropriate action.

In order to estimate the long-term process standard deviation the mean value $\bar{y}_{iA}$ and the mean value $\bar{y}_{iB}$ for each sample i; $i = 1, ..., m$ (which are not presented in the table) and their overall means

$\bar{\bar{y}}_A = 15.791$; $\bar{\bar{y}}_B = 15.725$

(which have been used already for the bias test) and variances

$s_{bA}^2 = 0.00979$; $s_{bB}^2 = 0.00853$

are computed, and the estimate becomes

$s_{process} = \sqrt{(2 \cdot 0.00979 + 2 \cdot 0.00853 - 0.0640^2 - 0.0327^2)/4} = 0.0887$.

The null hypothesis that there is no systematic difference between ex-package and ex-churn measurement results,

$H_0 : \Delta_C = 0$,

is tested with

$\bar{c} = -0.0868$

$s_c = 0.1498$

and the test statistic

$t_B = 3.175$

which is larger than the critical value for the significance level α = 5%,

$t_{29;0.975} = 2.045$.

Hence, the null hypothesis $H_0 : \Delta_C = 0$ is rejected. $\hat{\Delta}_C = \bar{c} = 0.0868$ is an estimate of the systematic difference between ex-package and ex-churn measurement results, i.e. ex-package measurements are estimated to be in the average 0.0868% smaller than ex-churn measurements. The 95% confidence interval for the systematic difference Δ_C between ex-package and ex-churn measurements of moisture is [-0.1428, -0.0309], i.e. the systematic difference Δ_C lies (at the confidence level 95%) between -0.1428% and - 0.0309%.

Since this is a simulated example it is possible to compare the results of the application of evaluation procedure A with the true values (see the following table).

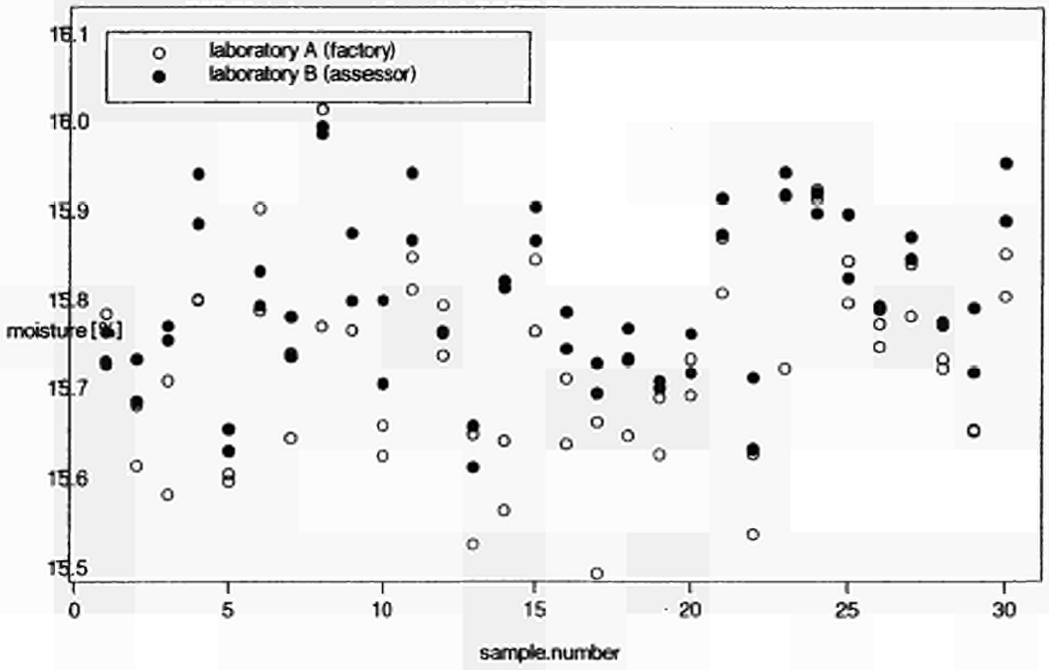
Since the upper confidence limits *UA* for the laboratory bias and *UC* for the systematic difference between ex-package and ex-churn results are both negative, they are not taken into consideration in the determination of the upper limit μ_U of the process average. This becomes

$\mu_U = 16 - 1.645 \sqrt{0.0887^2 + 0.0640^2} = 15.82$,

i.e. the process average for moisture should not be larger than 15.82% in order to assure that no more than 5% of true individual moisture values are larger than 16%.

Table 15. Summary of example statistics

	result of evaluation procedure A	true value
Standard deviation under repeatability conditions Laboratory A Laboratory B	 0.0640% 0.0327%	 0.06% 0.03%
Measurement bias of Laboratory A Confidence interval (1-α-95%)	- 0.0665% - 0.0852%... - 0.0478%	- 0.05%
long-term process standard deviation	0.0887%	0.10%
Systematic difference between ex-package and ex-churn results confidence interval (1-α=95%)	- 0.0868% - 0.1428%...- 0.0309%	- 0.10%



6.3 Procedure B. Qualification (or re-qualification) for a factory with QC data for at least 6 recent months.

Qualification (or requalification) of a factory wishing to adopt (or continue with) a quality autocontrol system for dairy products on the basis of appropriate quality control data from at least 6 recent months.

This procedure describes how to evaluate the production and measurement processes of a factory on the basis of available control data from at least six recent months.
The following data should be available:

A. Measurements from the production process at a specified minimal frequency (for butter at least one measurement per hour). The total number of measurements should be at least 1000. Measurements may have been made ex-churn or ex-package. Data should be available in electronic form, and plotted on daily control charts (see Procedure C). The data will be used to check that the production process was in control, and to calculate quantiles ($\tilde{x}$, $x_{0.95}$) and the total dispersion in the upper half of the data (s_{total}).
B. Regular comparisons (at least once per week) of factory and external measurements. Factory measurements should have been made by the same method as used in production control. External measurements should provide reference values for the samples analysed, and may be provided by an official control laboratory or be calculated as consensus values (excluding the factory itself) in proficiency test schemes. Samples to be analysed may be either ex-churn or ex-package samples, irrespective of the type of samples analysed for production control. Usually

measurement comparisons will be made by analysing two subsamples of the same sample both in the factory and externally. However, if production control uses ex-churn samples, it is also allowed to make a direct comparison between factory measurements of ex-churn samples and external measurements of corresponding ex-package samples (in which case the data mentioned under point 3 are not needed). Data should be available in electronic form, and plotted on a control chart (see Procedure D). The data will be used to check that the measurement process is in control, and to calculate the maximal uncertainty due to measurement error (*UA*).

C. (Needed only if production control is on ex-churn samples and if no comparisons ex-churn vs. ex-package are included in the regular comparisons mentioned under point 2) Incidental comparisons of ex-churn and corresponding ex-package samples, both analysed with the same measurement method. Ex-churn and ex-package samples should be taken such that they correspond as much as possible (although always imperfectly) with the same produce (e.g. by taking an ex-package sample 10 minutes after the corresponding ex-churn sample). The data will be used to calculate the maximal uncertainty due to differences between ex-churn and ex-package product (*UC*).

In as far as these data are not available, Procedure A (or relevant parts of it) should be followed in order to collect the necessary information.

- The evaluation procedure yields:
- a conformity check, ensuring that no more than 5 % of the true values of the characteristic exceeds the limiting value (e.g. no more than 5 % of the true moisture values in butter are larger than 16 %).
- the data necessary to construct control charts for statistical quality control of production in the following period (see Procedure C).
- the data necessary to construct a control chart for measurement comparison (see Procedure D).

Experience shows that the distribution of such production data is very likely to be skewed to the left, i.e. the left tail of the distribution is larger than the right one. The variance of such a distribution can be thought as a weighted average of the variance of the values of the distribution being smaller than the median of the distribution and the variance of the values being larger than the median. The former one would be larger, the latter one smaller than the averaged variance. If the variance or the corresponding standard deviation is estimated from production data the estimate s overestimates the spread in the upper part (above the median) of the distribution, i.e. it overrates the right tail of the distribution. Since the manufacturer, in order to determine the upper limit μ_U of the process average small enough to ensure that not more than 5% of the moisture values lie above the upper specification limit 16.0%, has to fix it at

$$\mu_U = 16\% - 1.645 \cdot s$$

(assuming normality) he would end up with an unnecessary and hence, uneconomically small value of the upper limit μ_U of the process average.

Therefore, the evaluation procedure consists of an estimation of the standard deviation based on the individual values being larger than the median, only.

Step by step procedure

1. Inspect the control charts with the data points (or a plot of the measured values against their inspection times or number if the graphical representations of the control charts are not available) for irregularities, especially for outliers, for trend or cyclic variations or other patterns. If some of those have been detected their causes should be investigated.
2. Arrange the n measurement values x_i; $i = 1, ..., n$ in ascending order,

$$x_{(1)} \leq x_{(2)} \leq ... \leq x_{(n)}.$$

3. Determine the median $\tilde{x}$ as the value which divides the ordered data set into 50% of the data being smaller and 50% being larger than $\tilde{x}$. For n odd,

$$\tilde{x} = x_{\left(\frac{n+1}{2}\right)},$$

for n even,

$$\tilde{x} = \frac{1}{2}\left[x_{\left(\frac{n}{2}\right)} + x_{\left(\frac{n}{2}+1\right)}\right].$$

4. For each measured value x_i being larger than the median $\tilde{x}$, compute the squared deviation from the median, $(x_i - \tilde{x})^2$. The estimate of the total standard deviation is then for n odd,

$$s_{total} = \sqrt{\frac{2}{n-1}\sum_{i=(n+3)/2}^{n}(x_{(i)} - \tilde{x})^2},$$

for n even,

$$s_{total} = \sqrt{\frac{2}{n-2}\sum_{i=\frac{n}{2}+1}^{n}(x_{(i)} - \tilde{x})^2}.$$

5. Determination of the upper limit μ_U of the process average:
In order to be in conformity with the upper specification limit USL=16% for moisture the process average μ has to be fixed at a level not larger than

$$\mu_U = USL - 1.645\, s_{total},$$

where the factor 1.645 is the 95%-quantile of the standardized normal distribution, i.e. the calculation is based on the assumption that the quality characteristic "moisture" of the production process and its measurements are normally distributed (at least in the upper part, above the median, of the distribution).
In addition, the measurement process of the factory has to be checked for bias against the assessor laboratory, following evaluation procedure A or a similar scheme. If the

upper confidence limit UA for the laboratory bias Δ_A of laboratory A, the factory laboratory, is positive, it has to be included into the computation of μ_U.
In case production control is based on ex-churn measurements an eventual systematic difference between ex-package and ex-churn measurements has to be evaluated following evaluation procedure A or a similar scheme. If the upper confidence limit UC for the systematic difference Δ_C between ex-package and ex-churn measurements of moisture is positive, it also has to be included into the computation of μ_U.
Hence, the upper limit of the process average is

$$\mu_U = USL - 1.645\, s_{total} - UA - UC$$

where the last two terms are only included when positive.

6. Conformity check for the process average.

The conformity check can be made in either of two ways:

a) by requiring that the empirical 95%-quantile of the measurements $x_{0.95}$ is not higher than a value equal to the limit (e.g. 16 % for moisture in butter) minus terms describing the measurement bias and, if relevant, the uncertainty on the difference between ex-churn and ex-package product

$$x_{0.95} \leq USL - UA - UC$$

where the last two terms are only included when positive.

b) by requiring that the empirical median of the measurements (conventionally often called the 'process average') is not higher than a limit value calculated by assuming a half-normal distribution for the highest 50 % of the data, minus terms describing the measurement uncertainty and, if relevant, the uncertainty on the difference between ex-churn and ex-package product:

$$\tilde{x} \leq USL - 1.645\, s_{total} - UA - UC$$

where the last two terms are only included when positive.

7. μ_U and s_{total} as determined above are used to calculate the control and warning limits of the control charts; see Procedure C.

General remarks

If the distribution of the data is skewed (with a longer tail to the left) the upper limit μ_U of the process average being determined under the assumption of normality is unnecessarily small so that the fraction of values being larger than 16% is (much) smaller than 5%.
However, if the determination of μ_U is based on s_U, the „upper" standard deviation, the value μ_U – if being used as the process average – produces a fraction of values being larger than 16% which is expected to meet the requirement to be less than 5%.

6.4 Procedure C: Design and use of quality control charts for control of quantitative dairy characteristics during production.

General

The evaluation procedures for the measurement process and the production process result in an estimate s_{total} of the total standard deviation and a determination of the upper limit μ_U of the process average.

Shewhart chart for individual values

A Shewhart chart for individual values has to be designed which has an average run length ARL = 100 in case the process average (or process median) is equal to the upper limit μ_U. The factory must chose a value for a centre line (CL) with due regard to the requirements that no more than 5% of the true values are larger than the specification limit (e.g. for moisture no larger than 16%). The upper permissible value for CL is μ_U

The upper control limit is

$$UCL = CL + 2.326\, s_{total}$$

and the upper warning limit is

$$UWL = CL + 1.645\, s_{total}.$$

An out of control situation, i.e. a process average larger than μ_U, is signalised if

1) the actual measured value x_t is larger than the upper control limit UCL,

2) the actual measured value x_t and the preceding value x_{t-1} have both values between the upper warning limit and the upper control limit,

3) no out of control situation was signalised at one of the last 9 inspection times, however, each of the last 10 measured values $x_t, x_{t-1}, \ldots, x_{t-9}$ is larger than the central value μ_U.

If any of these occurs this initiates an immediate investigation, and (temporary) diversion of the product.

Moving range chart

The Shewhart chart for individual values shall be combined with a moving range chart for the control of the standard deviation.

The moving range chart uses the moving range

$$mr_t = |x_t - x_{t-1}|$$

as test statistic; its centre line is

$$CL = 1.128\, s_{total},$$

the upper control limit is

$$UCL = 3.64\, s_{total}$$

and the upper warning limit is

$$UWL = 2.77\, s_{total}.$$

The rules to be followed in order to detect an out of control situation are equal to the rules for the charts for individual values given above.

If the out of control situation is signalised while the individual moisture values are smaller than μ_U, the signal is neglected because it is due to large differences of moisture below μ_U which might be caused by adjustments of the process, e.g. in the start-up phase.

The out of control situation might be due to an increased process standard deviation or an increased measurement standard deviation. The investigation of both the production process and the measurement process shall indicate which one of these standard deviations has increased, and the corresponding process shall be adjusted. If during the next 10 inspections after the adjustment of the process the moving range chart again signalises an out of control situation this indicates a permanent increase of the process standard deviation or the measurement standard deviation. Hence, evaluation procedure A has to be carried out resulting in new estimates of the standard deviations, a smaller upper limit for the process average and a new design of the control charts.

On the other hand, if 10 consecutive values of the moving range fall below the central line of the moving range chart this indicates a permanent decrease of the process standard deviation or the measurement standard deviation. Hence, evaluation procedure A might to be carried out in order to redesign the control charts.

Example

By application of the evaluation procedure A for the measurement process and the production process the total standard deviation has been estimated as

$$s_{total} = 0.12\%$$

and the upper limit μ_U of the process average has been determined as

$$\mu_U = 15.83\%$$

The manufacturer decides to work with a centre line

$$CL = 15.80\%.$$

The control charts have the following limits:

Table 16. Example control chart limits.

	Individual value chart	moving range chart
central line CL	15.80%	0.132%
upper control limit UCL	16.07%	0.424%
upper warning limit UWL	15.99%	0.323%

Each of the following figures shows in the upper part the chart for individual values and in the lower part the moving range chart applied to a production process at 100 consecutive inspection times. Each of the black dots indicates an out of control signal; if it occurs on the upper control limit, the upper warning limit or the central line it is due to decision rule 1, 2, or 3, respectively.
The production process runs with the following values for process average and total standard deviation which are in this simulation *not* adjusted after an out of control signal:

Table 17. Example process averages and standard deviations

Figure	process average	total standard deviation
1	15.80%	0.10%
2	15.90%	0.10%
3	15.80%	0.12%
4	15.80%	0.15%
5	15.90%	0.05%

Figure 1 : moisture control (target process average 15.80%, target total standard deviation 0.1166%)

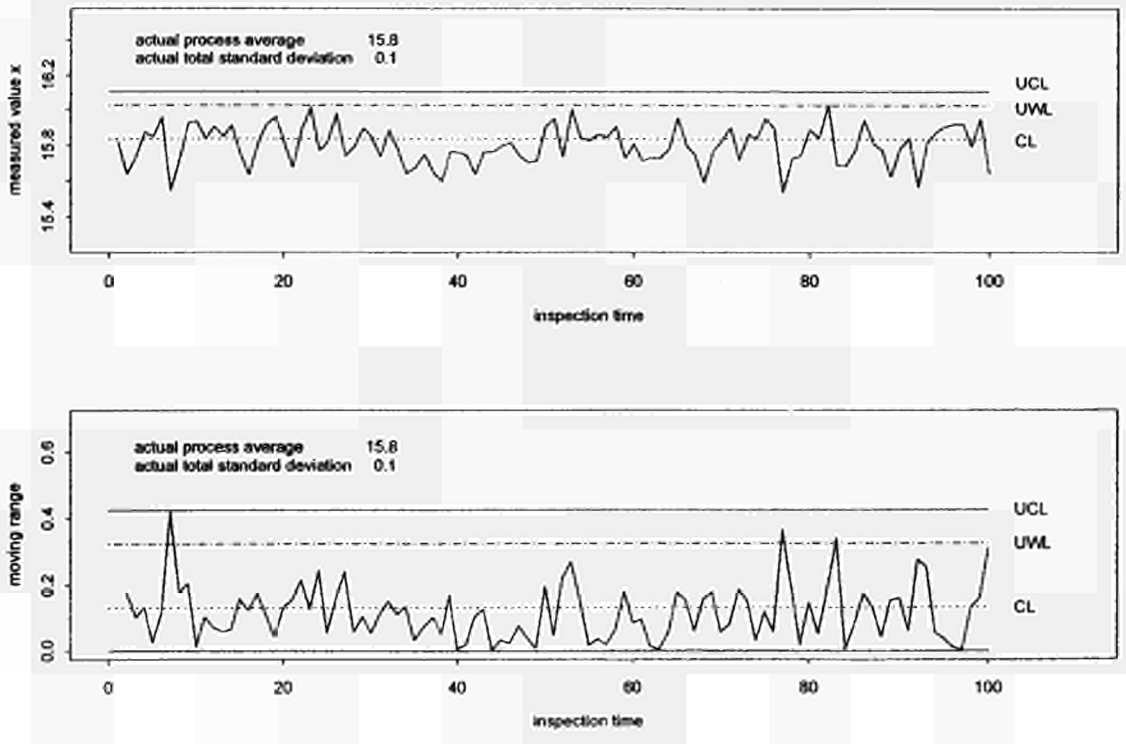


Figure 2 : moisture control (target process average 15.80%, target total standard deviation 0.1166%)

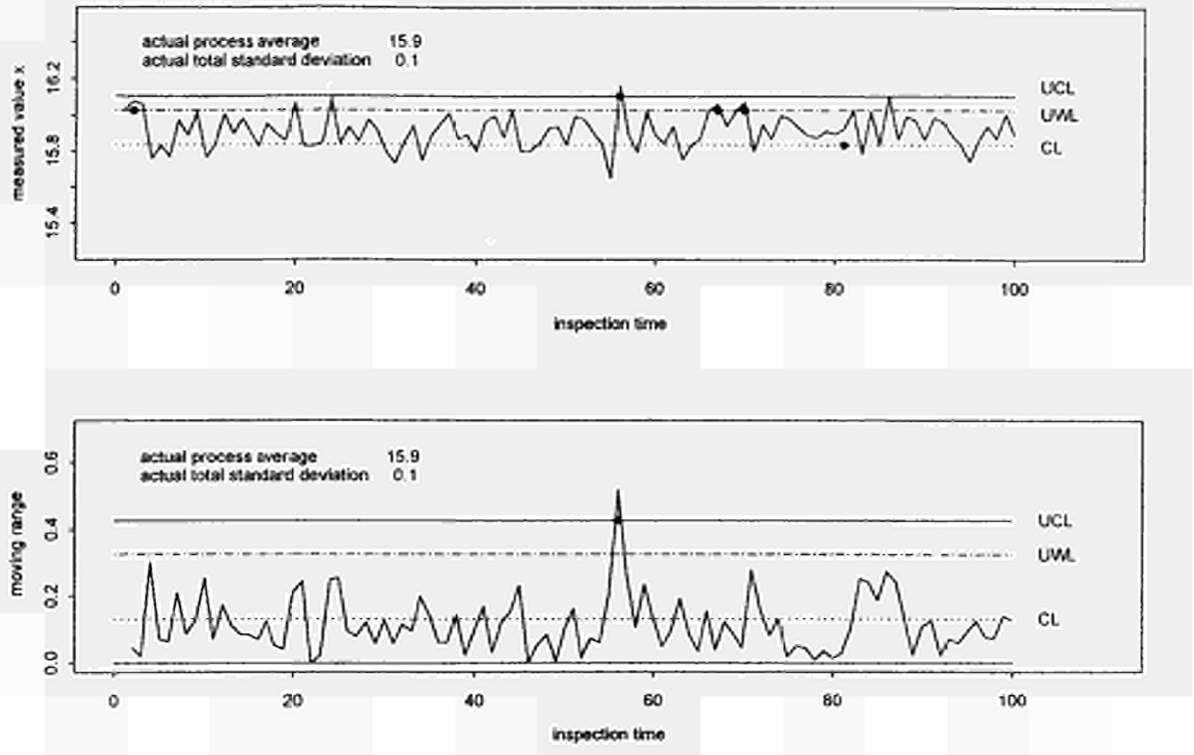


Figure 3 : moisture control (target process average 15.80%, target total standard deviation 0.1166%)

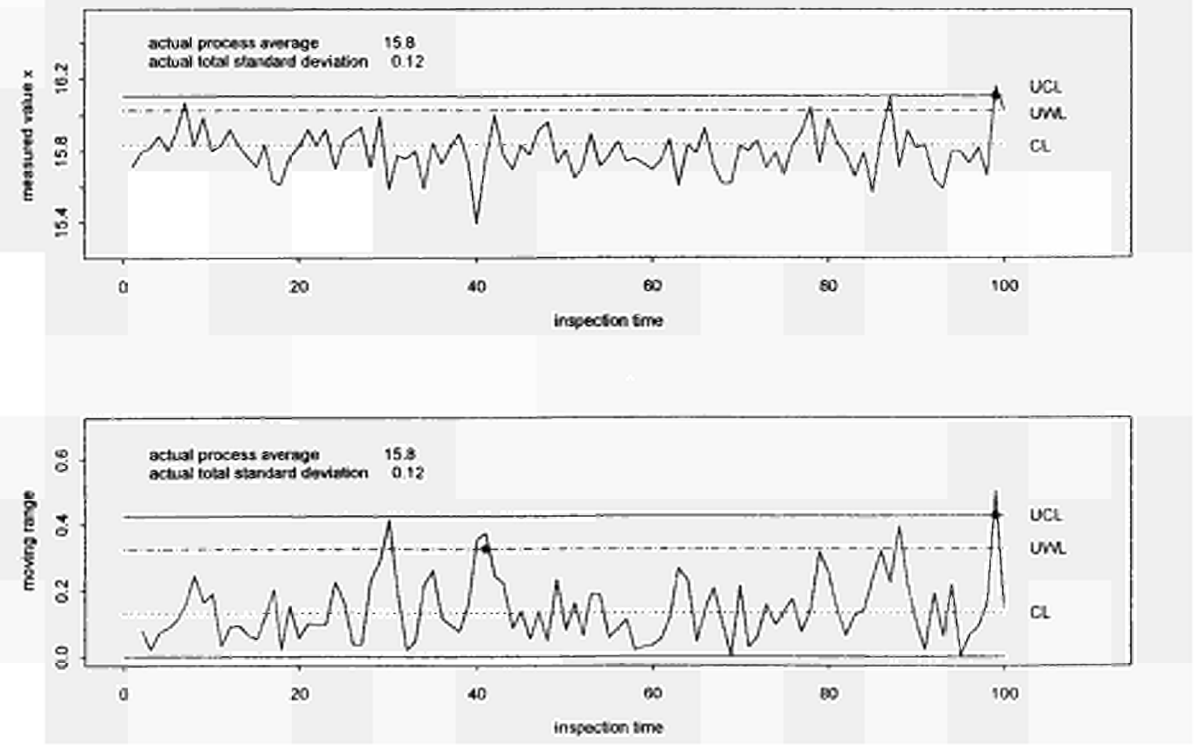


Figure 4 : moisture control (target process average 15.80%, target total standard deviation 0.1166%)

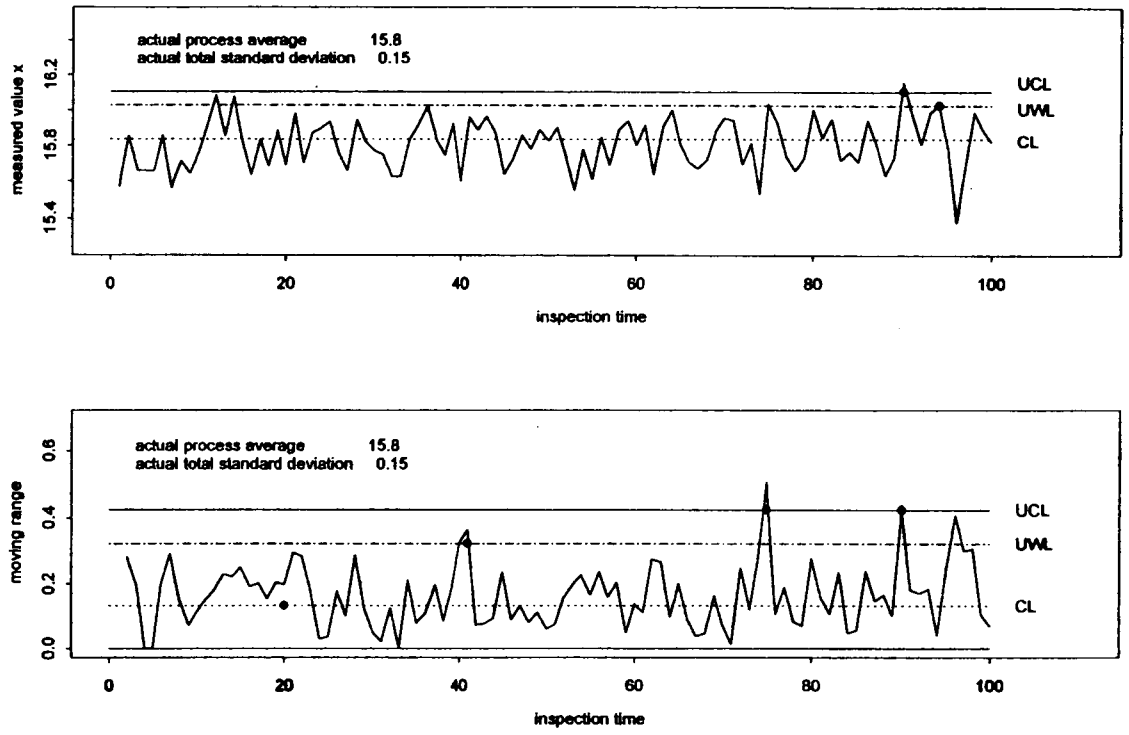
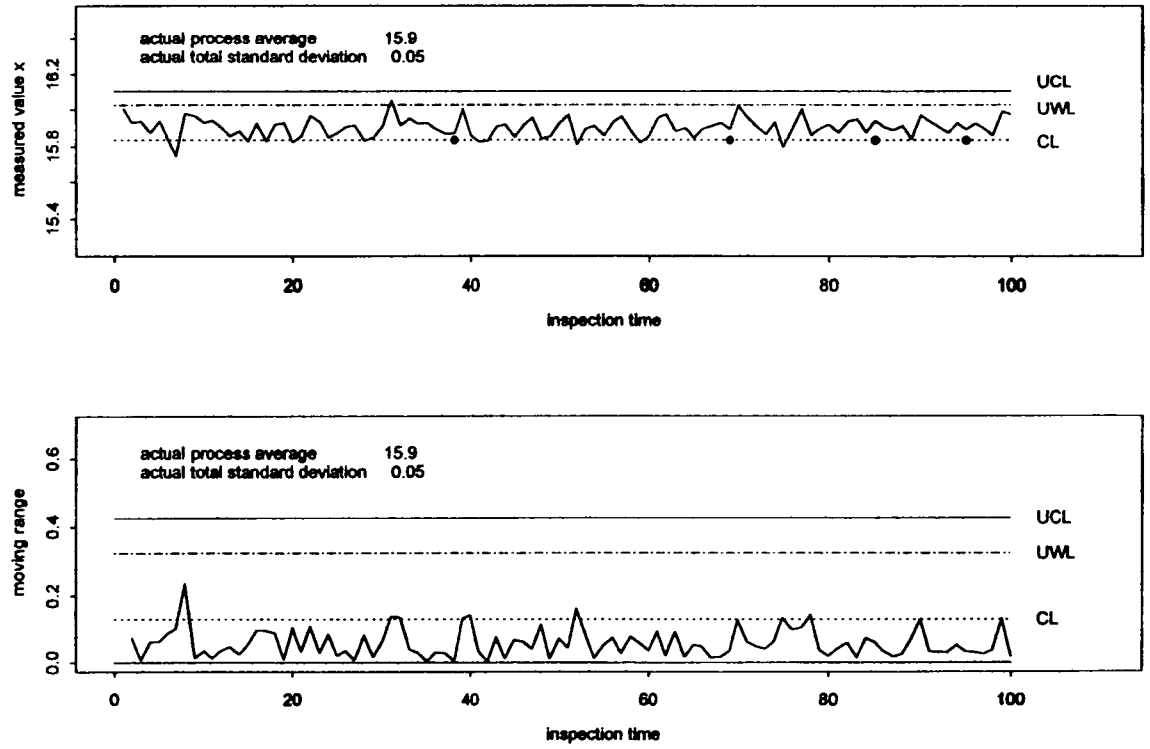


Figure 5 : moisture control (target process average 15.80%, target total standard deviation 0.1166%)



6.5 Procedure D: Design and use of quality control charts for the control of the level of quantitative measurements.

Introduction

The measurement process should be controlled using techniques of statistical process control (SPC). This procedure describes what the factory is required to do under the autocontrol system, and how the control authority should inspect the SPC. Specifically, factories should have clearly described rules to detect out-of-control conditions and written out-of-control action plans aimed at removing the cause of the unusual variation. It should be remarked that the use of SPC is profitable for many more reasons than only to fulfil the requirements of the autocontrol system. Ultimately, the use of SPC is directed at removing special process variability, and reducing the normal process variability, allowing a higher set value for the necessary water content.

In autocontrol it is of utmost importance that the factory laboratory controls the bias of its method of analysis. The first possibility to obtain this control is to check the measurement method regularly by analysing reference materials (materials with a known value of the characteristic). However, reference materials are often not available for quality characteristics such as moisture in butter.

Traditionally, a check is provided by the analysis of some samples both by the factory laboratory and by an official control laboratory. This method assumes that the official control laboratory itself has no bias, or at least knows that its bias is small.

Alternatively, the reference value may be obtained as a consensus value from all capable laboratories in a proficiency testing scheme established by some form of circulating samples among laboratories. A repeated control, as necessary in SPC, is included in the proficiency testing formalism by repeating the inter-laboratory tests with a certain frequency.

Whatever the method of comparison chosen, in order to control the measurement process, a comparison should be made at least once per week. Differences per week should be entered on a control chart. Changes in measurement methods should be indicated on this chart.

The factory should reach agreement with the official control authority on the requirements with respect to control charts (e.g. see out-of-control situations listed in Procedure C). The official control authority will check this during (re)assessments. It will also audit the actions taken by the factory in response to those situations.

If the control of the measurement process is based on comparison with external measurements, then samples to be analysed may be either ex-churn or ex-package samples, irrespective of the type of samples analysed for production control. Usually measurement comparisons will be made by analysing two sub-samples of the same sample both in the factory and externally.

There is a second possibility of guarding the measurement process. If production control uses ex-churn samples, it is allowed to consider any measurement of an ex-churn sample as an indirect measurement of a corresponding ex-package sample. It is then sensible to make a direct comparison between factory measurements of ex-churn samples and external measurements of corresponding ex-package samples. Ex-churn and ex-package samples should be taken such that they correspond as much as possible (although always imperfectly) with the same produce (e.g. by taking an ex-package sample 10 minutes after the corresponding ex-churn sample).

Shewhart chart for measurement differences per week

The differences found in the comparisons (averaged over control occasions, e.g. control laboratory's visits) are to be plotted in a control chart with the following control limits;

$$UCL = +2.576\sigma_n; \qquad LCL = -2.576\sigma_n$$

with

$$\sigma_n = \sqrt{\sigma^2_{between} + \frac{\sigma^2_{within}}{n}}$$

where $\sigma^2_{between}$ and σ^2_{within} are the variance components between and within official control occasions, calculated from data of a previous period, and where n is the number of samples (= number of differences) for each specific official control occasion.

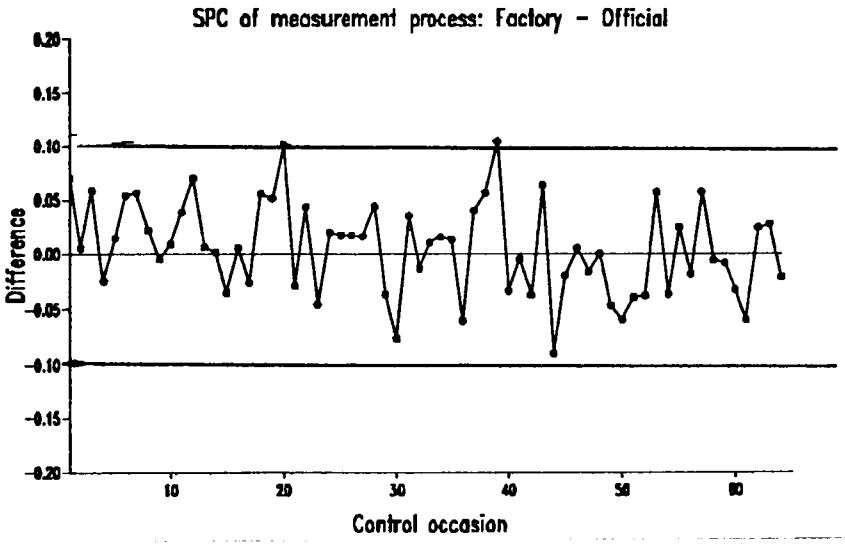


Figure 6. Example of control chart for the measurement process. Horizontal axis gives the control visit number (data from one year). Central line at 0. Control limits are at ±2.576 σ, and are variable due to a varying number of samples per control visit.

Use of the control chart in the factory under the autocontrol system

In principle, the factory should have freedom about the details of the implementation. However, for participation in an autocontrol program the following requirements should be made:

- An out-of-control situation, i.e. a process average larger than μ_U, is signalised if
  1) the actual difference d_t is larger than the upper control limit *UCL* or smaller than the lower control limit *LCL*,
  2) no out of control situation was signalised at one of the last 9 inspection times, however, each of the last 10 observed differences $d_t, d_{t-1}, \ldots d_{t-9}$ is larger or each of them is smaller than the central value *CL*.

- It should be clearly described what actions are undertaken in out-of-control situations. Actions should be directed at removing the sources of the special variation which gave rise to the out-of-control situation.
- The total frequency of out-of-control situations should be low. For example a limit can be placed on this frequency, e.g. less than 5 % of all measurement process data is allowed to be out-of control.
- All data and reports on out-of-control occasions should be made available for the official control authority.

Assessment of SPC procedure by the official control authority

During periodical audits, the control authority has to decide if the SPC operates well enough to allow participation in the autocontrol system for the next period. This check is mainly procedural. Control charts and reports on out-of-control situations should be present, and the use of control charts should be inspected on the spot.
A quantitative check is made on the number of out-of-control situations. Ultimately, the control authority should judge if the complete SPC procedure, including those aspects which are freely chosen by the factory, gives enough confidence that the measurement process in the factory is normally in control.

6.6 Advantages and disadvantages of the proposed scheme

Introduction of autocontrol would provide significantly more data on the product than the present system, and at reduced cost to the official control authority.

As the existing scheme is based on assessment of individual lots whereas the proposal assesses quality over a much longer time scale this complicates comparisons of the two systems. However making certain assumptions the following comparisons can be made.

Moisture in butter

Taking data from the Questionnaire (Appendix 2) into account, assuming a sampling rate of 3 samples per hour and a production rate of 5 tonnes per hour gives a sampling frequency of 1.7 tonnes per sample. Taking a minimum number of data points as 1000 this equates to 1700 tonnes.

Applying Regulation 454/95[6] and assuming 20 tonne lots, 1700 tonnes generates 85 lots. Regulation 454/95[6] specifies 6 samples are taken for 20 tonnes, these are composited to 2 samples.

Under these circumstances total of 170 results would be generated on products which would yield 1000 data points using the proposed scheme.

Moisture in skimmed milk powder

Taking data from the Questionnaire (Appendix 3) into account, assuming a sampling rate of 1 sample per 5 tonnes, a minimum number of data points of 1000 equates to 5000 tonnes.

Applying Regulation 322/96[7] and assuming 20 tonne lots this equates to 250 lots. Although 8 samples would be taken these would be composited to a single sample generating 250 results compared with 1000 from the proposed scheme. If the lot size is increased to 40 tonnes 9 samples would be taken per lot and composited to a single sample for analysis. This generates 125 results compared with 1000 from the proposed scheme.

Project partners have also identified the following advantages and disadvantages associated with the proposed system. These may be split into factors mainly associated with the control authorities and those mainly associated with the manufacturers.

Advantages to the Control Authorities

- Cost benefits from reduced resource used in control.
- Improved assurance of product quality leading to greater confidence in control procedures.
- More limited opportunity for payment of subsidy or aid which is not justified.
- More rational system for payment of guarantees.
- More transparency and traceability of data providing better consumer awareness and assurance.
- Closer involvement with the manufacturer leading to better knowledge of the product and better mutual understanding.
- Peaks and troughs of demand on control authority resource and laboratory resource are equalised.

Disadvantages to Control Authorities.

- Increased skill demands requiring training and one-off start-up costs.
- If SPC operated in parallel with factories using the old system control authorities would need to adapt to running 2 systems.

- Possible long-term loss of technical expertise in control authority laboratory if Certified Reference Materials become widely available and introduced as the Procedure D check instead of using the reference laboratory.

Advantages to the manufacturers.

- Competitive advantage arising from keeping up-to-date with developments in process control.
- Manufacturers would be in control of decisions made regarding the quality of the product rather than relying on control authority results.
- Reduced risk of product being offered for aid and subsequently rejected.
- Rapid release of product, less storage costs
- Much reduced risk of losing securities particularly on product exports to another EU Member State.
- Manufacturers learn how to reduce variation in the product by repeated applications of the principles of SPC.
- In the case of butter, less reprocessing of product.
- More rational system with a clearer understanding of the limits to be respected.
- Integrated quality control and quality assurance across products leading ultimately to a simplified system of setting and checking compliance with specifications.
- More productive use of existing in-line data already available.
- Better traceability of measurements.
- Rationalisation of measurement systems with a possible reduction of resource going into unnecessary measurements.
- Status of official recognition for factories process control system.

Disadvantages to the Manufacturers

- May have to lower process mean (in case of moisture in butter) to comply with limits.
- Costs of setting up the new system.
- Resistance to learning new skills.
- Cost of maintaining the new system.
- Higher skills need by staff, requiring more training effort.
- More demands and scrutiny from the control authorities at management level, possible less freedom to operate.

6.7 Model proposed organisational structure for dairy products autocontrol in the Netherlands.

Responsibilities for implementation of European legislation differ in individual Member States.
As an example, for the Dutch situation it is proposed to organise dairy product autocontrol at three separate levels:

1. Supervisory level

- Ministry of Agriculture – Industry and trade direction.
- Dairy Board and/or co-operation of dairy industries.

- Independent scientific organisation.

2. Fight-against-fraud level
- Ministry of Agriculture – Intervention Board
- Ministry of Agriculture – General Inspection Service
- Independent scientific organisation.

3. Expert level
- Dairy factories
- Official control laboratory (Dairy Board Central Laboratory)
- Independent scientific organisation.

In practice, autocontrol would operate continuously at factories, with weekly level controls by the official control laboratory, and with less frequent surprise controls (e.g. 4-6 per year) by the General Inspection Service. Qualification and re-qualification for the autocontrol system will be granted based on audits of the factory by the official control laboratory (e.g. yearly or half-yearly).
It is important to stress that under autocontrol no lots will be rejected based on analysis results by external laboratories. These external controls monitor the quality of the system not the quality of the product.
The tasks of the involved parties at the expert level can be summarised as follows:
- Dairy factories: implementation of statistical process control, availability of all relevant documents, availability of duplicate samples (period of one week).
- Official control laboratory: audits of dairy factories, certification weekly sampling at the factory, and organisation of proficiency tests for level control.
- Independent scientific organisation: Quality Assurance of autocontrol system (methodology for detecting economically important parameters, statistical methodology), analysis of fight-against-fraud control samples.

7. COST BENEFIT ANALYSIS

There are potential cost savings to be gained for official control authorities, and ultimately the European taxpayer, if the work associated with official control can be reduced whilst maintaining assurances against fraud.
Using the examples of the 4 Member States involved in collection of data for this project an assessment of cost benefit was made.
This assessment aimed to;
- obtain data associated with the costs of official control under the present system and project estimated potential savings associated with moving to autocontrol,
- provide an estimate of the total value of product associated with market organisation schemes for butter and skimmed milk powder in a year, and hence the amount of payment potentially at risk.
- Figures applicable from the 4 Member States involved in the exercise
- The total costs associated with official control using existing methods are, for butter 572 thousand Euro and for skimmed milk powder 336 thousand Euro.

- For butter introducing an auto-control scheme, augmented with 10% official control, offers cost savings of nearly 70%, reducing to nearly 60% if the official control rate was increased to 20%.
- For skimmed milk powder introducing an auto-control scheme, augmented with 10% official control, offers cost savings of nearly 50%, reducing to nearly 40% if the official control rate was increased to 20%.
- The total amount of aid associated with butter for 1998 was 180 million Euro (excluding Denmark).
- The total amount of aid associated with skimmed milk powder for 1998 was approximately 89 million Euro (excluding Denmark).

The partners agreed the design of a questionnaire which sought information on the cost of official control, including sampling, inspection and analysis, associated with moisture determination in butter. The exercise also sought to assess the costs associated with determination of moisture, fat and protein in skimmed milk powder. A further questionnaire aimed to gather information on the value of aid associated with market organisations in each country for butter and skimmed milk powder (excluding Denmark for SMP). Partners contacted the appropriate authorities in their country and provided information for collation by the project co-ordinator.
The total estimated cost associated with administration, inspection, sampling and analysis associated with butter was 571,851 Euro.
The total cost of introducing a proficiency scheme, 119,100 Euro, has to be subtracted from this figure. In addition it was considered that, at least during the introduction of auto-control, the Commission may wish to continue with official control at a reduced rate, although ultimately this could be dispensed with. Two scenarios were considered; retaining 10% official control (62,815 Euro) and retaining 20% official control (125,630 Euro).
The cost benefit associated with 10% official control is 389,966 Euro (68% saving).
The cost benefit associated with 20% official control is 327,121 Euro (57% saving).

The total estimated cost associated with administration, inspection, sampling and analysis associated with skimmed milk powder was 335,555 Euro.
The total cost of introducing a proficiency scheme, 145,573 Euro, has to be subtracted from this figure. In addition it was considered that, as with butter the Commission may wish to continue with official control at a reduced rate, although ultimately this could be dispensed with. Two scenarios were considered; retaining 10% official control (33,607 Euro) and retaining 20% official control (67,213 Euro).
The cost benefit associated with 10% official control is 156,375 Euro (47% saving).
The cost benefit associated with 20% official control is 122,769 Euro (37% saving).

An estimate of the amount of product at risk was made.
For butter in the UK the total tonnage aided under Regulation 2571/97 in 1998/99 was 81.7 million Euro, the total aid associated with Austria for butter under all regulations was 1.5 million Euro, the total estimated for the Netherlands was 47.5 million Euro. This gives an overall total for these 3 countries of 178.2 million Euro.

For skimmed milk powder the total value of aided product in the UK was estimated at 62.9 million Euro. The figure for the Netherlands was 23 million Euro and for Austria 2.7 million Euro. Giving an overall total of 88.6 million Euro.

Table 18. Assessment of cost benefit associated with butter analysis for moisture based on butter tonnage associated with intervention and subsidy schemes over 12 months.

	UK	Austria	Holland	Denmark
	Euro	Euro	Euro	Euro
1. Total cost associated with sampling, inspection and analysis (official control) for 1 year (latest figures available).	129,700	98151	200,000	144,000
2. Estimated total cost if sampling, inspection and analysis reduced to 10% system control level.	13,000	9,815	20,000	20,000
3. Estimated total cost if sampling, inspection and analysis reduced to 20% of existing level.	26,000	19,630	40,000	40,000
4. Number of lots inspected in a year.	1885	230	2000	335
5. Average lot size inspected (tonnes)	20	20	39	20
6. Average official control cost per lot inspected with present system (1/4)	70	427	100	430
7. Assessed cost of proficiency testing for a one-year period.	26,100	36,000	52,000	5000
8. Assessed cost of proficiency testing per lot (10/4)	13.8	157	26	15
9. Cost benefit (1 year) of adopting a 10% official inspection rate. 1 – (2+10)	90,600	52,366	128,000	119,000
10. Cost benefit (1 year) of adopting a 20% of existing official inspection rate. 1 – (3 + 10)	77,600	42,521	108,000	99,000

Table 19. Assessment of cost benefit associated with skimmed milk powder analysis for moisture, fat and protein based on butter tonnage associated with intervention and subsidy schemes.

	UK	Austria	Holland
	Euro	Euro	Euro
1. Total cost associated with sampling, inspection and analysis (official control) for 1 year (latest figures available).	84,480	16,467	234,608
2. Estimated total cost if sampling, inspection and analysis reduced to 10% of existing level.	8,500	1,647	23,460
3. Estimated total cost if sampling, inspection and analysis reduced to 20% of existing level.	17,000	3.293	46,920
4. Number of lots inspected in a year.	550 inc rejects	103	344
5. Average lot size inspected	60T	24 & 120	32T
6. Average official control cost per lot inspected with present system (1/4)	153.6	160	682
10 Assessed cost of proficiency testing for a one year period.	53,125	10,608	81,840
11 Assessed cost of proficiency testing per lot (10/4)	96.6	103	238
12 Cost benefit (1 year) of adopting a 10% of existing official inspection rate. 1 – (2 + 10)	22,855	4,212	129,308
13. Cost benefit (1 year) of adopting a 20% of existing official inspection rate. 1 – (3 + 10)	14,355	2,566	105,848

8. INDUSTRY FEEDBACK ON UPTAKE OF PROPOSALS

Project partners have worked closely with industry in their own countries. Feedback was sought from manufacturers to assess if they would be willing to adopt the new system of control if the Commission introduced it.
Manufacturers were provided with a synopsis of the project background and the proposals.
Details of the industry response are given in Appendix 5

The response from the industry is very encouraging for the project.

- All manufacturers already keep records, however there is clearly scope for improving the use of statistical process control, as precision data are not routinely

recorded in the form of standard deviations, except in the Netherlands. The willingness of manufacturers to set up a system to collect such data is encouraging.

- Fixed and documented sampling schemes are already in place for taking samples for analysis and there is a willingness to modify the sampling scheme, if necessary, in order to ensure that it complies with the proposal, assuming that manufacturers recognise the proposal as cost effective and beneficial.
- Adoption of a process average value is variable, but all manufacturers use data to make adjustments during manufacture. Data are also used by all manufacturers to reject or re-process product. In the case of butter there appears to be a need to establish further reliable relationships between ex-churn and package samples in some cases, the willingness is there to establish such relationship.
- Plotting data on a control chart is currently rare and familiarity with Shewhart and moving range charts is varied, further development work would be required here, manufacturers responded that they would be willing to adopt these charts, provided suitable guidance was provided.
- Few manufacturers have already established figures for the variability of their measurement technique; this would require further work.
- Most manufacturers participate in some form of external control scheme already and they were willing to participate in a regular scheme involving checking against the control laboratory.

9. CONCLUSIONS AND RECOMMENDATIONS

1. **Why is a new approach to control of dairy product quality needed?**

- There is no consistent approach to sampling applied to regulations associated with dairy products. For example, in Regulation 2571/97[12], butter for manufacture, no guidance is given on the number of samples to be taken. This has led to differing approaches in individual Member States.
- Where sampling strategies are in place, for example in Regulation 454/95[6] for butter, and Regulation 322/96[7] for skimmed milk powder, these are a compromise taking into account the costs associated with official control. Consequently, decisions are made on the basis of very few samples analysed. This means that there is very little information available to the control authority on which to base decisions regarding compliance with specification limits. There is an unacceptable risk that a significant amount of EU aid is being paid on product which is out of specification.
- In the milk products sector it is Commission policy to apply a tolerance to allow for analytical variability of results obtained in official control laboratories. This carries the risk that manufacturers will seek to work up to the full limit of the tolerance particularly in cases such as moisture in butter where there are significant economic consequences for the manufacturer.
- The Commission attempts to prevent manufacturers exploiting the tolerance allowance by requiring that no more than one in five results is permitted between the specification limit and the limit plus (or minus for a lower limit) analytical tolerance. This policy has no sound statistical basis. Experience in Member States,

and in discussions with third countries, has demonstrated that this rule is ambiguous and subject to dispute.

2. **What are the alternatives to the present controls?**

- It is not practical on cost considerations to improve matters by significant additional effort in official control analysis.
- Acceptance sampling provides an alternative. However, this suffers from the same disadvantage as official control analysis in that the sampling effort per lot is too high. The basic concept involves application of a predetermined plan to decide whether a batch of goods meets defined criteria for acceptance. It is also not necessary for every item to be in compliance with the specification limit for the product to be accepted.
- Acceptance sampling is not widely applied but has been adopted in EU legislation (e.g. for water content of frozen poultry) and is currently subject to active consideration by Codex.
- Acceptance sampling, as described by current international standards, has two further disadvantages. The statistical basis requires discreet items, butter and skimmed milk powder are continuous items. Secondly, it is assumed that measurement variability can be ignored. This is true in cases such as measuring the length of screws, but has been shown by the project not to be the case for products such as butter and skimmed milk powder.
- The concept of acceptance sampling overcomes the problems inherent in the current approach to interpretation of specification limits but needs to be refined to cope with both measurement and process variability.
- Factories control the quality of butter and skimmed milk powder routinely and collect considerable data on the quality of the products.
- Regulations within the dairy sector already make allowance for self checking by approved factories within Regulation 2571/97[12] (Chapter 6, Article 23 Paragraph 2) provided that Member States obtain Commission consent.
- Using the factory data provides a cost-effective answer to the need for more information on product quality.

3. **How do the manufacturers currently operate?**

- Fourteen butter manufacturers responded to a questionnaire distributed by project partners. The responses confirmed that extensive sampling and record keeping is already in place, and that factories already apply their own sampling plans. The sampling frequency adopted is more than adequate for the requirements of a sound statistical process control system for moisture in butter.
- Factories routinely make adjustments to control moisture levels, this will skew the distribution of results.
- In order to take advantage of the data collected in factories whilst reducing any additional costs which might be introduced, it is necessary to use data obtained from butter sampled at an intermediate stage in production (i.e. immediately after the churn) rather than the final product.

- Proposals would need to be flexible enough to deal with variable batch sizes, and to take account of the fact that factories use in-house routine methods of analysis and not reference methods.
- External checking of results is in place already in about half of the laboratories.
- Six skimmed milk powder manufacturers responded to a questionnaire distributed by project partners. Overall conclusions were similar to those from butter manufacturers. For moisture, extensive monitoring is already undertaken using a sampling plan with adequate sampling frequency, at least in UK and the Netherlands. Fewer data are available for fat, protein monitoring is not undertaken routinely. Adoption of statistical process control should focus on moisture control, at least during the introduction of any scheme. As factories have, in practice, no opportunity to make adjustments in protein levels there is little incentive for them to intensify protein monitoring at present.
- The sampling point is consistent with end product monitoring, thus there is no requirement for an additional check of an intermediate sample against final product quality.
- Data are likely to be skewed as adjustments are made to moisture levels during production.
- As in the case of butter, proposals would need to be able to deal with varying batch sizes and provide checks on the performance of routine in-house methods.
- External checking of results is in place for a few factories.
- For both butter and skimmed milk powder, although factories generate a considerable amount of data this is not in any standardised form which could be easily transformed into a proposal suitable for adoption by control authorities. There is a need to develop a standardised approach, based on sound statistical principles. The basic framework for developing this is already in-place in factories.

4. What are the arithmetic means and standard deviations associated with manufacturers' within-lot variation?

- Butter moisture data were collected from factories in the UK, Austria, and the Netherlands. The UK providing 20 sets of data, Austria and Netherlands data from 3 factories each.
- Except for Austria 1, the upper limit of 16% was respected in all cases. The overall means of UK factories were much lower than the others, between 15.44% and 15.77%; Austrian means were between 15.76% and 15.95%, whereas Dutch means were between 15.76% and 15.95%. The distributions, in all cases were slightly skewed to the left.
- The conclusions from this first exercise, studying factory data were as follows. Estimates of within-lot standard deviation ranged from 0.17 to 0.29% (UK); 0.17 to 0.20% (Austria) and 0.09 to 0.16% (Netherlands). Estimates of between lot standard deviation ranged from 0.13 to 0.18% (UK), 0.05 to 0.12% (Austria) and 0.05 to 0.15% (Netherlands).
- Data gathered on moisture levels in butter ex-churn and ex-package revealed that there could be a difference in moisture levels. The ex-churn data are generally higher in moisture than corresponding ex-package but this trend was sometimes reversed.

- A model procedure was developed to obtain data which could be used to assess the within-lot and measurement variances in the factory and the laboratory and to assess any bias in the factory procedure. This involved analysis of a minimum of 20 samples taken from the factory, split into two sub-samples and subsequently analysed in duplicate (under repeatability conditions) in both the factory and control laboratory. This was used as the model to collect variance data on butter and skimmed milk powder.
- The conclusions from this second exercise were as follows. For control of moisture levels in butter, variations due to measurement are rather small but cannot be ignored and must be taken into account when laying down limits of variation. A general variation value as a basis for control procedures is not recommended because within-lot standard deviation varied between 0.04% and 0.411% using data from the model. The within laboratory repeatability (measurement) standard deviation ranged from 0.023% to 0.065%. An acceptable approach might be a fixed upper limit for the variation and individual values based on previous analysis, which can be adjusted if necessary.
- Data were obtained from skimmed milk powder manufacturers in Austria, the Netherlands and UK for the quality characteristics moisture, fat and protein. Whilst moisture is regularly controlled more effort may be needed from some factories to achieve an adequate level of sampling to have effective statistical process control for fat. Comparatively little data is collected by manufacturers regarding protein levels and this should be given low priority for consideration for statistical process control.
- For skimmed milk powder the results showed that for all characteristics investigated the process standard deviation, i.e. within-lot standard deviation is (much) larger than the measurement standard deviation. However the measurement standard deviation has to be taken into account as well as the process standard deviation.
- An exercise using the model developed for collection of butter moisture data was undertaken on skimmed milk powder. Estimates of the within lot (process) standard deviation for moisture ranged from 0.093% to 0.205%, measurement standard deviation ranged from 0.025% to 0.091% (excluding Netherlands NIR). Estimates of the within lot (process) standard deviation for fat ranged from 0.037% to 0.259%, measurement standard deviation ranged from 0.013% to 0.055%. Estimates of the within lot (process) standard deviation for protein ranged from 0.057% to 0.293%, measurement standard deviation ranged from 0.045% to 0.196%.
- The process standard deviation is different for the quality characteristics moisture, fat and protein for different manufacturers. Therefore, a general value as the basis for statistical process control is not recommended. Each manufacturer has to investigate the process standard deviation for each of the quality characteristics intended to be used for statistical process control.

5. What sampling plans should be respected by the manufacturer?

- An evaluation procedure has been developed which would be applicable to a factory wishing to adopt a quality autocontrol system for dairy products without having appropriate quality control data from 6 recent months.

- This involves duplicate analysis of 30 samples taken from the factory and analysed in duplicate at factory and control (assessor) laboratories.
- This procedure should yield, in approximately 2 months, a check of the upper limiting value and the process average which ensures that no more than 5% of values are above the specification limit (or below the limit in the case of lower limits). Preliminary data necessary for determining control and warning limits for control charts can be determined. The procedure tests the equality of measurement standard deviation between factory and assessor laboratory, and tests for systematic difference between factory and assessor laboratory. The procedure also describes how the control of butter moisture using ex-churn data is evaluated.
- An evaluation procedure has been developed to enable qualification, or requalification, of factories wishing to adopt, or continue with, a quality autocontrol system for dairy products based on data from at least 6 recent months.
- In the case of moisture in butter this procedure stipulates a minimum sampling frequency and for the general case recommends that the total number of measurements should be at least 1000.
- The factory is required to make available to the control authority production data plotted on daily control charts, and evidence of external checking, at least weekly, against a recognised assessor laboratory. In the case of moisture in butter additional evidence regarding ex-churn and ex-package measurement moisture levels is required.
- The evaluation procedure yields a conformity check that no more than 5% of values exceed the limiting value (or are lower in the case of a lower specification limit); the data necessary to construct control charts for statistical control of the production in the following period; and the data necessary to construct a control chart for measurement comparison.
- Two approaches to the conformity check are recognised.
- Either by requiring that the 95% quantile of measurements is not larger than the limit (e.g. 16% for moisture in butter) minus terms describing the measurement bias and, in the case of moisture in butter, the uncertainty of the difference between ex-churn and ex-package.
- Or by requiring that the empirical median (process average) is not larger than a limit value calculated by assuming a half-normal distribution of data, again minus measurement bias and the uncertainty of difference between ex-churn and ex-package. A procedure has been developed for the design and use of quality control charts for the control of quantitative dairy product characteristics during production.
- This procedure describes the construction of a Shewhart control chart for individual values obtained from production, and the construction of a moving range chart to monitor the standard deviation.
- Rules for out of control situations are given, factories would be required to provide details of all actions taken in the event of an out of control occurrence.

6. How can the manufacturers' measurement data be verified and controlled?

- An evaluation procedure has been developed for the design and use of quality charts for the control of the accuracy of the factory measurements. This is based on the

use of a Shewhart control chart, and specifies rules to detect out of control situations.

7. Would statistical process control be acceptable to manufacturers under realistic conditions?

- Ten factories from Austria, the Netherlands and UK responded to a questionnaire designed by the project to assess the current extent of use of statistical process control and the willingness to adopt a procedure if it was introduced.
- Responses were generally favourable and encouraging, all manufacturers already kept records and worked to a document sampling scheme. However it is rare for factories to plot data on charts and few have established figures for the variability of the measurement technique.
- This feedback confirms that the industry framework is in place for adoption of statistical process control but some training of industry will be required before personnel could be expected to implement the project proposals.

8. What benefits can arise from the adoption of the statistical process control?

- For control of moisture in butter, introduction of statistical process control offers a potential cost benefit of nearly 60% on an estimated total annual cost of 570 thousand Euro for existing official control in Austria, Denmark, the Netherlands and UK, assuming a continuing 20% official control check.
- For control of skimmed milk powder, introduction of statistical process control offers a potential cost benefit of nearly 40% on an estimated total annual cost of 335 thousand Euro associated with Austria, the Netherlands and UK.
- Statistical process control encourages close co-operation between the control authority and factory.
- The control authority has more assurance that aid is being paid on products of acceptable quality.
- Risk of rejection of product is reduced to manufacturers.
- Manufacturers can release product more rapidly, reducing storage costs.
- Manufacturers would ultimately reduce variability of product leading to higher product quality and better customer satisfaction if a scheme based on sound statistical principles is introduced

9. What are the main recommendations?

- The introduction of autocontrol should be on a voluntary basis.
- A procedure has been developed for the design and use of quality control charts for the control of quantitative dairy product characteristics during production.
- This procedure involves the construction of a Shewhart control chart for individual values obtained from production, and the construction of a moving range chart to monitor the standard deviation.
- Rules for out of control situations are given, factories would be required to provide details of all actions taken in the event of an out of control occurrence.
- Factories would be required to make available to the control authority a document describing in detail the measurement method, training records, a confirmation that each alteration in the measurement method and change of operator will be recorded,

and evidence of satisfactory method performance e.g. by comparison with a reference laboratory or use of Certified Reference Materials.

- The official control authority would be required to organise a system of checking on the factory measurement process by an approved assessor laboratory. Liaise closely with the factory at the outset of statistical process control to ensure smooth introduction. Grant approvals for an agreed period, e.g. 6 months, on the basis of satisfactory evidence from the factory. Evaluate the performance of the factory process results and measurement results on a regular basis. Decide on requalification of the factory after an agreed period.
- The principles behind the processes studied as models, butter and skimmed milk production, could be applied more widely across the food sector and offer advantages of improved food safety.

10. FUTURE DISSEMINATION AND EXPLOITATION

The recommendations from this project will be adopted by DG Agriculture who were responsible for submission of the original dedicated call topic.

- The Chairman of the Expert Chemists Group of the Milk Management Committee, Professor Glaeser, will use the evidence from the report as part of the strategy to introduce the concept of autocontrol to the Management Committee. Representatives on the Expert Chemists Group who served as project partners will assist Professor Glaeser.
- Project partners in Austria, Denmark, the Netherlands and UK will contact delegates to the Management Committee in their own country to appraise them of the report and to recommend support for the introduction of an approach based on statistical process control.
- Project partners in Austria, Denmark, the Netherlands and UK will continue to foster relations with dairy product manufacturers in their own country to encourage the uptake of statistical process control.
- Information will be disseminated to appropriate technical experts in other Member States, mainly through association with the Expert Chemists Group.
- Copies of the video will be made available to assist dissemination
- Subject to the feedback from Management Committee, the project co-ordinator will pursue dissemination of results through EU Additional Measures programmes.
- The Cordis web site will be updated by the project co-ordinator.

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ACKNOWLEDGEMENTS.

Thanks are due to many people who contributed to this project.
Partners wish to express particular thanks to all those in the dairy industry in Austria, Denmark, the Netherlands and UK who so willingly gave of their time and resource to discuss the proposals with partners and to undertake additional monitoring and laboratory analysis. Thanks are also due to the laboratory staff in the official control laboratories who also undertook a significant amount of work to further the aims of the project.
The guidance and advice throughout from the Scientific Officer Dr. Achim Boenke has been much valued and appreciated, as has the continued active involvement and proposals from Professor Hermann Glaeser of DG Agriculture.
Contributions from Mr. Van der Voet of CPRO-DLO, have proved invaluable to the further development of statistical concepts.
Thanks are also due to Take One Productions for a thorough and professional job in preparing a high quality video.
Finally the project co-ordinator wishes to express his thanks to project partners for all their hard work, forbearance and assistance throughout the project.

APPENDIX 1

Identity of Project partners.

The partners in the project are as follows

Co-ordinator/Partner 1. ADAS Consulting Ltd, Wolverhampton UK; Derek Farrington

Partner No.2. Intervention Board Executive Agency, Reading UK; Roy Smyth

Partner No.3 Agrarmarkt, Vienna, Austria; Dr Bernhard Url

Partner No.4 Danish Veterinary Service, Ringsted, Denmark; Erik Wolthers (Initially Fleming Kaereby).

Partner No. 5 RIKILT, Wageningen, Netherlands, John Labrijn

Partner No. 6 Free University, Berlin Germany, Professor Peter Wilrich

Partner No. 7 (Associate Partner) Danish Dairy Co-operative, Denmark; Soholt Hansen

Partner No. 1, as co-ordinator, was responsible for overall co-ordination of the project and submission of reports and commissioning the video. ADAS was also responsible for undertaking the analyses associated with official control in the UK.

Partner No. 2 was responsible for the collection if data from the manufacturers in the UK and liaison with the manufacturers, and contributed substantially to commissioning of the video.

Partners 3,4 and 5 were responsible for liaison with the industry in their respective countries, for the collection of data and for undertaking the necessary official control analyses.

Partner No. 6 was responsible for performing the statistical design and analysis of the program, statistical reports and preparing sampling plans and recommendations. Partner 6 also provided valuable statistical guidance throughout the project.

Associate Partner No. 7 was responsible for providing feedback from the acceptability of proposals to the industry and assisting in dissemination of the Groups findings to the industry.

APPENDIX 2

QUESTIONNAIRE

EU PROJECT - DAIRY PRODUCT QUALITY-WITHIN-LOT-VARIATION
CONTRACT No. -SMT 4 - CT 94 - 2111 MOISTURE IN BUTTER

It has been agreed that there may be certain advantages in moving away from the existing system of official quality control of dairy products associated with Market Organisation schemes, currently based on analyses of a limited number of samples. A new system could make use of the data available within production factories.

A meeting of the projects partners was held in Brussels on 19 February 1997, and it became clear that there were many variables which could lead to differences in apparent moisture within butter, such as those during production, packaging and analyses. To enable these variables to be taken fully into consideration in the course of the project development, we would appreciate your co-operation with completing this questionnaire, and returning it by **20 May 1997** to the project co-ordinator, Mr D. Farrington at:-

ADAS - Wergs Road, Woodthorne, Wolverhampton, UK. - WV6 8TQ
Fax: +44 1902 693303

DEFINITIONS

Please note that the following terminology will apply throughout the project in accordance with ISO 3534-2 Part 2:

- ***Production batch***
  A definite quantity of some commodity produced at one time under conditions that are presumed uniform.

- ***Inspection lot***
  A definite quantity of some product or material, collected together and submitted for examination.

- ***Consignment***
  A quantity of some commodity delivered at one time and covered by one set of documents. It should be noted that a consignment may consist of several lots or parts of lots.

1.	NAME / ADDRESS OF FACTORY	
2.	PRODUCTION CAPACITY/DAY	
3.	UNIT SIZES NORMALLY PRODUCED	25 KG 250GM OTHER
4.	NO. OF CONTINUOUS CHURNS IN REGULAR USE	ONE TWO THREE
5.	CAPACITY OF EACH CHURN (T/HR)	
6.	ARE CHURNS ALWAYS DEDICATED TO SAME TYPES e.g. LACTIC/SWEET CREAM?	
7.	NUMBER OF CREAM VATS / SILOS IN USE DAILY	
8.	IS ALL CREAM CHURNED FROM RAW MILK SEPARATED ON SITE?	
9.	TYPICAL BATCH SIZE PRODUCED (Tonnes)	
10.	IS BATCH SIZE FIXED (e.g. 20 Tonnes/ 50 Tonnes) OR ONE WHOLE DAY'S PRODUCTION?	
11.	IS PRODUCTION WITHIN BATCH ALWAYS CONTINUOUS AND HOMOGENOUS?	
12.	IS ONE BATCH EVER MADE UP FROM MORE THAN ONE DAY'S PRODUCTION?	
13.	IS ONE BATCH EVER MADE UP FROM MORE THAN ONE DAIRY'S PRODUCTION?	
14.	SAMPLING FREQUENCY DURING MANUFACTURE (For Moisture Analysis)	
15.	POINT FROM WHICH ROUTINE SAMPLES ARE TAKEN. (DURING PRODUCTION) e.g. EX CHURN; EX FILLER; EX PACKAGE	
16.	ARE SAMPLES EVER TAKEN FROM COMPLETED BATCH (AFTER PRODUCTION)?	

17.	SAMPLING FREQUENCY AFTER PRODUCTION (IF APPLICABLE)	
18.	IS INTERMEDIATE "HOLDING" TROLLEY IN USE DURING PRODUCTION i.e. BETWEEN CHURN AND PACKAGE FILLER?	
19.	MAX. DELAY TIME BETWEEN CHURNING AND INITIAL PACKING OF BUTTER	
20.	IS MOISTURE LEVEL ADJUSTED BY AUTOMATIC IN-LINE SYSTEM?	
21.	IS MOISTURE LEVEL ADJUSTED MANUALLY? IF SO, HOW LONG AFTER SAMPLING/TESTING?	
22.	ARE PRE-SET LIMITS USED TO TRIGGER PROCESSING ADJUSTMENTS?	
23.	IF "YES" WHAT ARE THESE LIMITS?	
24.	IF PROCESS REQUIRES ADJUSTMENT IS A RECORD KEPT OF WHAT CHANGES WERE MADE?	
25.	METHOD OF MOISTURE ANALYSIS USED (Please describe system separately)	
26.	ARE ANY MOISTURE CONTROL CHECKS MADE BY AN EXTERNAL LABORATORY?	
27.	IF "YES" STATE FREQUENCY	
28.	IF "YES" STATE METHOD	
29.	DO YOU KEEP RECORDS OF ALL MOISTURE RESULTS?	
30.	ARE THESE DATA IN THE FORM OF CONTROL CHARTS?	

31.	DO YOU MAINTAIN PRECISION DATA FOR YOUR RESULTS. e.g. STANDARD DEVIATIONS	
32.	IS A FIXED SAMPLING PLAN IN USE FOR ROUTINE DAILY CONTROL? (If "yes" please detail below)	
33.	DOES SAMPLING PLAN CONFORM TO NATIONAL / INTERNATIONAL SYSTEM?	
34.	DO YOU KEEP RECORDS OF ALL PROCESS CONTROL DATA e.g. BREAKDOWNS, RESTARTS / CHANGES OF CHURN / CHANGES IN OPERATOR RAW MATERIAL, EQUIPMENT, INCLUDING A RECORD OF TIMES OF OCCURRENCE?	
35.	PLEASE STATE ANY OTHER FACTORS LIKELY TO INFLUENCE BUTTER QUALITY VARIABILITY	
36.	IF YOU DO NOT CURRENTLY KEEP THE RECORDS REQUESTED ABOVE, WOULD YOU BE WILLING TO KEEP THESE IN FUTURE AS PART OF AN IMPROVED SYSTEM OF CONTROL?	
37.	DO YOU SUBMIT BUTTER FOR INTERVENTION OR SUBSIDY UNDER MARKET ORGANISATION SCHEMES?	
38.	IF YES, WHAT IS A TYPICAL SIZE OF A CONSIGNMENT SUBMITTED FOR INSPECTION BY THE CONTROL AUTHORITIES?	
39.	HOW MANY PRODUCTION BATCHES ARE TYPICALLY CONTAINED WITHIN A SINGLE CONSIGNMENT?	

40.	DO YOU UNDERTAKE ANY ANALYSIS OF THE CONSIGNMENT SUBMITTED TO THE CONTROL AUTHORITIES YOURSELF? IF SO, PLEASE SPECIFY	
41.	IF YES, DO YOU FOLLOW A SAMPLING PLAN TO OBTAIN THE SAMPLES?	
42.	IF YES, WHAT METHODS OF ANALYSIS DO YOU FOLLOW?	
43.	PLEASE ALSO PROVIDE ADDITIONAL INFORMATION OVERLEAF	

NB - The undersigned person must agree to be willing to be contacted should further information or clarification be needed on return of the questionnaire.

SIGNATURE .....

NAME .....
(BLOCK CAPITALS)

STATUS .....
(BLOCK CAPITALS)

DATE .....

Telephone no. .....

Fax no. .....

ADDITIONAL INFORMATION

"A" PLEASE DESCRIBE BELOW, YOUR UNDERSTANDING OF "HOMONGENOUS PRODUCTION"

"B" PLEASE DESCRIBE BELOW YOUR SAMPLING PLAN FOR ROUTINE DAILY MOISTURE TESTING

"C" PLEASE DESCRIBE ROUTINE & OTHER ANALYSIS METHODS USED

"D" OTHER COMMENTS ON CONTROL OF VARIABILITY, IF ANY

1. Name and adddress of factory.	UK1	UK2	IRELAND 1	IRELAND 2	IRELAND 3	NETH.1	NETH.2	NETH.3	DENMARK1	DENMARK2	AUSTRIA 1	AUSTRIA 2	AUSTRIA 3	AUSTRIA 4
2. Production capacity/day.	240 tonnes /day	100 tonnes /day	110 tonnes /day	90 tonnes/day	100 tonnes	100 tonnes	250 tonnes /day	70 tonnes	100-140t	100,000kg	max 20t	max 50t	7t	max 8t
3. Unit sizes normally produced	25kg, 250g, other	25kg	25kg, 6g	25kg 250g	25kg, 250g, 454g, 7g	5kg, 125g	25kg, 250g	25kg, 250g	25kg, 250g, 113.5g, 227g, 454g, 125g	250g, 500-15 10g	250g. 125g	25kg, 250g, 125g	2.5kg, 20g	150kg, 125g
4. No. of continuous churns in regular use.	2	1	2	2	2	2	3	1	2	3	1	1	1	1
5. Capacity of each churn (t/hr).	5 tonnes/hr	5 tonnes/hr	5 tonnes/hr	5 & 3 tonnes	4t/h, 8t/h	5t/h & 10t/h	5t/hr	5 tonnes	5t/hr	4.5-4.5-1.5t/h	1600kg/hr	3000kg 1hr	1800kg/hr	1200kg/hr
6. Are churns always dedicated to same types e.g. lactic/sweet cream?	no	no	yes	yes	no	yes	yes	yes	yes	no	yes	yes	yes	yes
7. No. of cream vats/silos in use daily?	14	4	1 to 2	7	3	ripening 10 x 20 ton 2 x 100t/storage 4 x 80t	10	4	4 to 5	2 to 3	6	6	5	5
8. Is all cream churned from raw milk separated on site?	no	no	no	no	yes	no	no, also cream from other dairies	no	no	no	yes	no	no	yes
9. Typical batch size produced.	20 tonnes	40-60 tonnes	40 tonnes	75 & 15 tonnes	22 tonnes	25 tonnes	27.5 tonnes	26t 50t	30t	65-85 ton cream 30-40 ton butter	15	min 6	1.3	8
10. Is batch size fixed (e.g. 20 tonnes/50 tonnes) or one whole days production?	20 tonnes	1 whole day	1 day	1 whole day	order quantity	no	yes 27.5t	1 whole day	1 batch = 1 cream vat	no typically 30-40t	1 days production	fixed by size of cream vat. 6, 16, 20t	fixed by size of cream vat ca 1-3t	1 days production
11. Is production within batch always continuous and homogenous?	yes	yes	yes	yes	yes	yes, between limits	yes	yes	yes	yes	yes	yes	yes	almost
12. Is one batch ever made up from more than one days production?	yes	no	yes	no	yes	no	no	sometimes Sun evening & Mon a.m.	no	yes	no	no	no	no
13. Is one batch ever made up from more than one dairys production?	no	no	yes	no	no	no	yes	yes	no	no	no	no	no	no
14. Sampling frequency during manufacture (For moisture analysis).	Lab. prod. every 1 hr, prod. control 30 mins	every 30 mins	4/hour	every 20 mins	30 mins	every 30 min by operator every pallet (1250kg) by lab	min 3 x hour	yes	20 min	min per 3 hr typical 1 per hr	1/2 hour	min 3 per batch	every 15 min & 750kg	every 20 mins
15. Point from which routine samples are taken (during production) e.g. ex churn, ex filler, ex package.	ex churn-after texturisers ex-packing from box	ex churn, ex carton	churn on line packer box	ex churn per moisture	ex churn & ex filler	ex churn by operator ex package by lab	ex churn	yes	churn & package	package	ex churn	ex butter silo ex package	ex churn ex package	ex churn

	UK1	UK2	IRELAND 1	IRELAND 2	IRELAND 3	NETH.1	NETH.2	NETH.3	DEN.1	DEN.2	AUSTRIA 1	AUSTRIA 2	AUSTRIA 3	AUSTRIA 4
16. Are samples ever taken from completed batch (after production)?	yes	no	yes	yes	no	yes	no, out of spec butter separated and not packed	no	yes	yes	yes	yes	yes	yes
17. Sampling frequency after production (if applicable).	1x every 10th tonne 1x every 5th tonne	not applicable	1/batch	every 2 hours	n/a	every 1250kg	none	n/a	2-3 samples per batch	1 per hour	daily	1 sample/ batch	every 750kg	ca 5/day
18. Is intermediate 'holding' trolley in use during production i.e. between churn and package filler?	yes	yes	no	yes	yes	yes	yes	butter silo	yes	yes	butter silo	butter silo	butter silo	no
19. Max. delay time between churning and initial packing of butter.	2 hours	1 hour	30 mins	30 mins	10 mins	1 hour	1/2 hour	1/2 hour	15 min	10 mins	1/2 hour	1/2 hour	ca 2 - 3 hours	n/a
20. Is moisture level adjusted by automatic in-line system?	not currently	yes, with a manual facility	no	no	no	yes	yes	yes	yes & no	yes	no	yes	in line & manual adjustment	no
21. Is moisture level adjusted manually? If so, how long after sampling/testing?	yes, immediately after analysis if needed	as soon as results available (about 15 min after sampling)	yes, immediate	yes 1 minute	immediately	immediately	in line adjusted immediately after calibration/ control	yes	yes 3 mins	immediately	immediately	n/a	immediately	immediately
22. Are pre-set limits used to trigger processing adjustments?	yes	yes	yes	yes	product spec	yes	yes	yes	yes	yes	no	yes	yes	yes
23. If 'yes' - what are these limits?:	target 15.8%, if sample 0.2% below or above	max 15.9%, min 15.7%	15.5% moisture, 1.4% salt	moisture 15.8% salt 1.8%	min 15.3% max 16.0%	lactic 15.80 - 16.05%	16.00%	> 16.0	16.05	0.01%	n/a	15.4-16.0%	15.2-16.0%	16 - 0.1%
24. If process requires adjustment is a record kept of what changes were made?	yes	no	yes	yes	yes	no	yes, continuously	n/a	no	yes	yes	yes	no	no
25. Method of moisture analysis.	Rapid gravimetric, 10g butter	rapid test, factory std in accordance with BS5086	10g butter, burn off moisture, re weigh	Bunsen flame	hot plate evaporation	NEN 3706 operator, NEN 3707 lab	in line, dielectric constant, infra red, IDF 80/1977 reference calibration	flame method	NIR analyser	IDF 80/1977	IDF137/1986	IDF137/1986	IDF 137/1986	sand
26. Are any moisture control checks made by an external laboratory?	no	no	yes	yes	customer checks	yes COKZ Lewsden	yes	yes COKZ	yes	yes	no	yes (AMA QL)	no	no
27. If 'yes' state frequency	n/a	n/a	5 per lot (1000 x 25kg)	per 2 tonnes	random	8-10 a week	COKZ	1 per 40 tonnes	daily	weekly	n/a	12/year	n/a	n/a

	UK1	UK2	IRELAND 1	IRELAND 2	IRELAND 3	NETH.1	NETH.2	NETH.3	DEN.1	DEN.2	AUSTRIA 1	AUSTRIA 2	AUSTRIA 3	AUSTRIA 4
28. If 'yes' state method	n/a	n/a	same	oven 102 degrees + 2 degrees	hot plate evaporation	NEN 3707	IDF 80/1977	dry matter	IDF80/1977	IDF 80/1977	n/a	IDF 80/1977	n/a	n/a
29. Do you keep records of all moisture results?	Yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
30. Are these data in the form of control charts?	no	yes	no	yes	no	yes	yes	yes	yes	yes	no	no	no	no
31. Do you maintain precision data for your results e.g. standard deviations?	no	no	no	yes	no	yes	yes	yes	yes	yes	no	no	no	no
31(a) Do you maintain precision data for measuring instrument i.e. infra red analyser, or method used	yes-for infra red	no	no	yes	n/a	no	yes	yes	no	yes	no	no	no	n/a
32. Is a fixed sampling plan in use for routine daily control? (if 'yes' please detail below).	yes	yes	yes	yes	yes	yes	yes 3 a day for each churn	yes	yes	yes	no	yes	yes	no
33. Does sampling plan conform to national/international system?	no	no	ISO 9002	yes	no	yes COKZ certification	n/a	n/a	n/a	no	n/a	yes	no	n/a
34. Do you keep records of all process control data e.g. breakdowns, restarts/changes of churn/changes in operator raw material, equipment, including a record of times of occurrence?	yes	yes	yes	yes	yes	yes	yes	yes	yes. not with stop & start of churn	yes	no	yes	some	no
35. Please state any other factors likely to influence butter quality variability.	incoming raw materials quality	cream fat %, storage & handling, ageing temperature season	temperature, collection days, machine speeds, cream agitation	seasonality	n/a	seasonality cream (no effect on moisture)	n/a	n/a	n/a	operator, temp. production rate start/stop	n/a	quality of cream	n/a	hygiene temperature
36. If you do not currently keep the records requested above, would you be willing to keep these in future as part of an improved system of control?	yes	n/a	n/a	n/a	n/a	n/a willing to keep records	see 34	n/a	yes	yes	yes	yes	some	n/a
37. Do you submit butter for intervention or subsidy under market organisation schemes?	yes	yes	yes - sometimes	yes	yes	yes	PO butter private stock	yes	yes	yes	yes	yes	yes (packs of 20g)	no

	UK1	UK2	IRELAND 1	IRELAND 2	IRELAND 3	NETH.1	NETH.2	NETH.3	DEN.1	DEN.2	AUSTRIA 1	AUSTRIA 2	AUSTRIA 3	AUSTRIA 4
38. If 'yes', what is a typical size of a consignment submitted for inspection by the control authorities?	20 tonnes	40-60 tonnes	900 x 25kgs	25 & 50 tonnes	21 & 23 tonnes	min 1000kg usually - 20 tonnes	27.5t	1 per 40 tonnes whole production lot up to intervention limits	5 tonne	300kg - 20t	min 2000kg	2400kg	2500kg	n/a
39. How many production batches are typically contained within a single consignment?	n/a	1	1	1 or 2	1	1	n/a	n/a	1 or 2	1-3 batch	1	4	2	n/a
40. Do you undertake any analysis of the consignment submitted to the control authorities yourself? If so, please specify.	yes,H20, salt, microbiological tests, not satistically placed	moisture during production out of spec. are withdrawn and previous pallets tested until back in control	micro, PV, FFA	micro, moisture, PV, FFA	moisture at time of packing	yes NEN 3707	no	yes same samples	H20, salt, micro	water	no	H20, pH and others	H20, coliforms	n/a
41. If yes, do you follow a sampling plan to obtain the samples?	1 per 5 tonnes	see 40	yes	yes	no	as above	n/a	flame nethod	no	yes	n/a	yes	no	n/a
42. If 'yes' what method of analysis do you follow?	Unigate method based on ISO	rapid test based on BS5086	ISO 9002 detailed procedures	reference methods IDF. ISO, etc.	n/a	NEN 3707	n/a	n/a	IDF 80/1977	IDF80/1977	n/a	IDF 137/1986	IDF 137/1986	n/a

APPENDIX 3

QUESTIONNAIRE

EU PROJECT - DAIRY PRODUCT QUALITY-WITHIN-LOT-VARIATION

CONTRACT No. -SMT 4 - CT 94 - 2111

MOISTURE , FAT & PROTEIN IN SMP

It has been agreed that there may be certain advantages in moving away from the existing system of official quality control of dairy products associated with Market Organisation schemes, currently based on analyses of a limited number of samples. A new system could make use of the data available within production factories.

A meeting of the projects partners was held in Brussels on 19 February 1997, and it became clear that there were many variables which could lead to differences in apparent moisture within SMP, such as those during production, packaging and analyses. The project also aims to obtain data on the extent of fat and protein variability. To enable these variables to be taken fully into consideration in the course of the project development, we would appreciate your co-operation with completing this questionnaire and returning it by 31 July 1998 to the project co-ordinator, Mr D. Farrington at:-

ADAS - Wergs Road, Woodthorne, Wolverhampton, UK. - WV6 8TQ
Fax: +44 1902 693303

DEFINITIONS

Please note that the following terminology will apply throughout the project in accordance with ISO 3534-2 Part 2:

- ***Production batch***
  A definite quantity of some commodity produced at one time under conditions that are presumed uniform.

- ***Inspection lot***
  A definite quantity of some product or material, collected together and submitted for examination.

- ***Consignment***
  A quantity of some commodity delivered at one time and covered by one set of documents. It should be noted that a consignment may consist of several lots or parts of lots.

1. Name & Address of Factory		
2. Production capacity per day		
3. Unit sizes normally produced	25 Kg bags	1 Tonne bags
4. Give details of dryers & fluid beds in use		
5. Number of Liquid Skimmed Milk silos in use daily		
6. Number of SMP silos		
7. Is all LSM from raw milk produced on site?		
8. Typical batch size produced (tonnes)		
9. Is batch size fixed? (e.g. 20 tonnes) or one whole day's production?		
10. Is production within one batch always continuous and homogenous?		
11. Is one batch ever made up from more than one day's production?		
12. Is one batch ever made up from more than one dairy's production?		

13a. Sampling frequency during manufacture (for moisture analysis): 13b. Sampling frequency during manufacture (for fat analysis): 13c. Sampling frequency during manufacture (for protein analysis):	
14. Point from which routine samples are taken during production, e.g. ex-bag; ex-filler	
15. Are samples ever taken from completed batch (after production) i.e. from sealed bags	
16. Sampling frequency after production (if applicable) - for moisture - for fat - for protein	
17. Maximum delay between manufacture and bagging of SMP	
18. Is moisture level adjusted by automatic or manual in-line system? Give details	
19. If moisture level is adjusted manually, how long after sampling / testing?	
20. Are pre-set limits used to trigger processing adjustments?	
21. If "yes" - what are these limits?	

22. If process requires adjustment is a record kept of what changes were made?	
23. Methods of moisture, fat & protein analyses used (please describe systems separately)	
24. Are any moisture, fat or protein control checks made by an external laboratory?	
25. If "yes" state frequency	
26. If "yes" state methods	
27. Do you keep records of all moisture, fat & protein results?	
28. Are these data in the form of control charts?	
29. Do you maintain precision data for your results? e.g. standard deviations or other data	
30. Is a fixed sampling plan in use for routine daily control? (if "yes", please detail below)	
31. Does sampling plan conform to national or international system? If "yes", what system?	
32. Do you keep records of all process control data? e.g. breakdowns, changes in operators, raw material, equipment with a record of times of occurrence?	
33. Please state any other factors likely to influence quality variability	

34. If you do not keep the records requested above, would you be willing to keep these in future as part of an improved system of control?	
35. Do you submit SMP for intervention or subsidy under market organisation schemes?	
36. If "yes", what is a typical size of consignment submitted for inspection by control authorities?	
37. How many production batches are typically contained within a single consignment?	
38. Do you undertake any analysis of the consignment submitted to the control authorities? If so, please specify	
39. If "yes", do you follow a sampling plan to obtain the samples?	
40. If "yes", what method of analysis do you follow?	
41. Please also provide additional information overleaf.	

SIGNATURE .....

NAME .....

STATUS .....

DATE .....

Telephone no. .....
Fax no. .....

ADDITIONAL INFORMATION

"A" PLEASE DESCRIBE BELOW, YOUR UNDERSTANDING OF "HOMOGENOUS PRODUCTION"

"B" PLEASE DESCRIBE BELOW YOUR SAMPLING PLAN FOR ROUTINE DAILY MOISTURE TESTING

"C" PLEASE DESCRIBE ROUTINE & OTHER ANALYSIS METHODS USED

"D" OTHER COMMENTS ON CONTROL OF VARIABILITY, IF ANY

VARIATION WITHIN LOT QUESTIONNAIRE SUMMARY

	UK 1	UK 2	NETH 1	AUST 1	AUST 2	AUST 3
Name & address of factory	Leckpatrick Strabane	Express, Frome	Coberco, Lochem	Lactoprot, Hartberg	Lactoprot, Taufkirchem	ALPI Redim Innkreis
Production capacity/day	100 tonnes	90 tonnes	-	40 tonnes	20 tonnes	Ca 36 tonnes
Unit sizes normally produced	25 Kg bags	25 Kg bags	Bulk tankers 30t	25 Kg, 1t bags	25 Kg, 1t Bags	25 Kg Bags
Give details of dryers & fluid beds in use	One drier has static fluidised bed, the other has 2 x 2.5t/hr, Niro 2 stage rotary atomiser spray dryers, 2 vibro fluidisers	Niro compact static and fluid bed	Dryers: spray wheel 2 stage dryers 1 stage drier + fluid bed 1 stage drier + internal and external fluid bed 1 stage drier + internal fluid bed and 2 external fluid beds	2 falling film evaporators, 2 spray drying towers	1 falling film evaporator, 1 spray drying tower 1 roller drier	2 vacuum evaporators 1 spray driers
Number of liquid skimmed milk silos in use daily	5	7	6	6	2	2
Number of SMP silos	5	4	5	6	4	24
Is all LSM from raw milk produced on site?	No	Yes (normally)	No	No	No	No
Typical batch size produced (tonnes)	45t	120t	32t	T1: 16t T2: 25t	One days production	20-25t
Is batch size fixed (e.g. 20 tonnes) or one whole days production	Whole day	No. max. 30 hrs run at 4¼t per hour	32t or customer request	25t (a) One days production (b)	One days production	20-25t
Is production within one batch always continuous and homogeneous	No	Yes	Varies per silo tank	a. No b. Yes	Yes	Yes
Is one batch ever made up from more than one days production?	Yes	May span 2 days	Not always	a. Yes	No	No
Is one batch ever made up from more than one dairies production?	No	No	Sometimes	No	No	No

	UK 1	UK 2	NETH 1	AUST 1	AUST 2	AUST 3
Sampling frequency during manufacture: **Moisture Analysis** **Fat Analysis** **Protein Analysis**	 Hourly Every 2 hrs None	 On line moisture metre feedback to operator Not carried out Not carried out	 Hourly Every 4 hrs None	 1 sample per day 1 sample per day -	 1 sample per day 1 sample per day -	 Every 4 hours 1 sample per day -
Point from which routine samples are taken during manufacture e.g. ex-bag; ex filler	Fluidised bed drier, ex-bag on bagline before sealing	Ex-bag	End of drier at filling stage	Blended sample by auto sampling	Blended sample by auto sampling	End of fluid bed
Are samples ever taken from completed batch (after production) ie from sealed bags	Yes occasionally	No	No	Yes	Yes	Yes
Sampling frequency after production (if applicable) **for moisture** **for fat** **for protein**	 Moisture and fat every hour	 every 5t 50t composite 50t composite	 1 per 5 t 1 per 10 t	 1 per 5t SMP 1 per 5 t SMP 1 per 5t SMP	 1 per 5t SMP 1 per 5 t SMP 1 per 5t SMP	 1 per 5t SMP 1 per 5 t SMP 1 sample per week
Maximum delay between manufacture and bagging SMP	48 hours	2 days	1-4 days	3 days	3 days	1 week
Is moisture level adjusted by automatic or manual in-line system? Give details	Manual, Powder tested by infrared moisture analyser operator adjusts temperature of fluidised bed to achieve moisture target	Manual adjustment from result of meter	Manual moisture by NIR. Outlet temp adjusted or fluid bed temp adjusted	Manual adjustment	Manual adjustment	Manual adjustment
If moisture level is adjusted manually, how long after sampling/testing?	Immediately	On-going	Within 30 minutes	Following production day	Following production day	Following production day

	UK 1	UK 2	NETH 1	AUST 1	AUST 2	AUST 3
Are pre-set limits used to trigger processing adjustments?	Yes	Yes	Yes	Yes	Yes	Yes
If "yes" what are these limits	Target moisture 3.0	± 0.2%	4.0% for 1% extra 4.5% for 1% std 3.5% for 1% intervention	Ca 0.5% below specification	Ca 0.5% below specification	Ca 0.5% below specification
If process requires adjustment is a record kept of what changes were made?	Yes	No	Yes. Temp is recorded	Yes	Yes	Yes
Methods of moisture, fat and protein analyses used (please describe systems separately)	Moisture; infrared analyser, oven, Fat, Gerber	Oven drying Gerber Lactoscope	Moisture + fat by NIR during production. After production with QC methods	See C - Additional Information	See C - Additional Information	See C - Additional Information
Are any moisture control checks made by an external laboratory	Protein	No	Control by COKZ	No	Yes (AMA - QL)	No
If 'yes' state frequency	Monthly	-	5 COKZ per week	-	Depending on the number of consignments submitted to the control authority	-
If 'yes' state method	Crude Protein N x 6.38, IDF20B:1993 Pt 3	-	-	-	Moisture: FIL-IDF 26A: 1993 Fat: Fil-IDF 9C: 1987	-
Do you keep records of all moisture, fat and protein results	Yes	Yes	Yes	Yes	Yes	Yes
Are these data in the form of control charts?	Moisture production sheet Analytical results sheet	No	No	No	No	No
Do you maintain precision data for your results? eg standard deviation and other data	No	No	Comparison QC/NIR and control samples for QC methods	No	No	No
Is a fixed sampling plan in use for routine daily control? (if 'yes' please detail below)	Yes production samples lifted hourly. Chemical analysis every 2 Hrs. Micro every 3 hrs. Packing samples lifted every hour. Chemical analysis every hour. Micro composite tested every 3rd hour.	Yes	Yes	Yes	Yes	Yes

	UK 1	UK 2	NETH 1	AUST 1	AUST 2	AUST 3
Does sampling plan conform to national or international system? If 'yes' what system?	Standards outlined in Good Hygiene Practice in the manufacture of Dairy Based Products	No	No	No	No	No
Do you keep records of all process control data? eg breakdowns, changes in operators, raw material, equipment with a record of times of occurrence?	Yes	Yes	All process parameters electronically stored	Yes	Yes	Yes
Please state any other factors likely to influence quality variability	Seasonality of milk and source determines chemical composition	Ambient air temperature and relative humidity efficiency of evaporation drier	-	-	-	Temperature
If you do not currently keep the records requested above would you be willing to keep these in the future as part of an improved system of control?	Most records already kept. Protein records can be outside factories control	Yes	-	-	-	-
Do you submit SMP for intervention or subsidy under market organisation schemes	No	Yes	Last 4 years no intervention	No	Yes	No
If 'yes what is a typical size of consignment submitted for inspection by control authorities?	-	100t	-	-	Ca 25t	-
How many production batches are typically contained within a single consignment?	-	2	-	-	-	-
Do you undertake any analysis of the consignment submitted to the control authorities yourself? If so, please specify	-	Various micro analyses and chemical	-	-	Yes: moisture; Fat; Starch; Contaminations	-
If yes do you follow a sampling plan to obtain the samples?	-	Yes	-	-	No	-

Additional Information From Austria 1,2 and 3 Factories

1. Please describe your understanding of "Homogenous Production"

1	2	3
One day's production/drier	One day's production/drier	Constant quality

2. Please describe your sampling plan for routine daily moisture testing

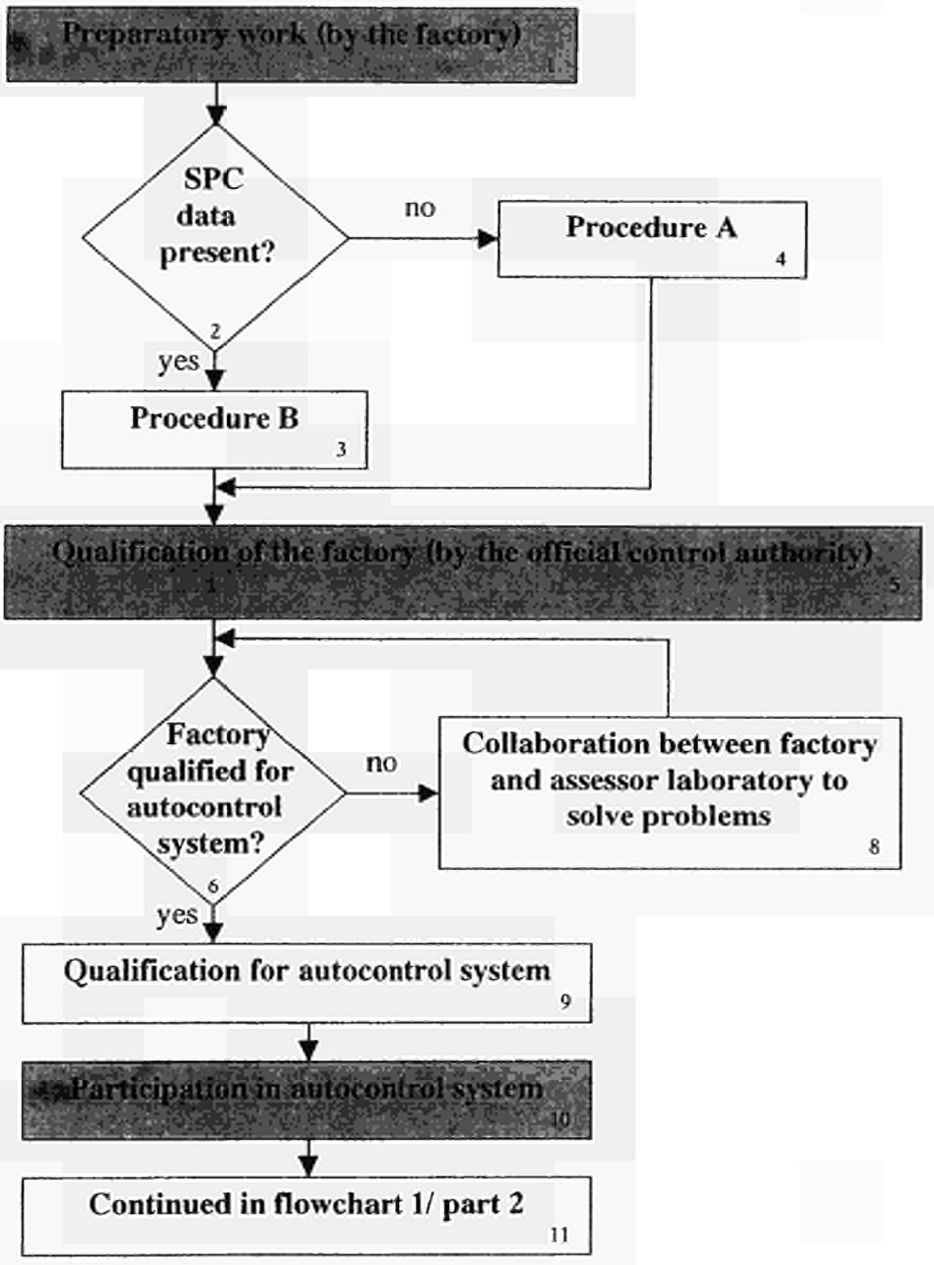
1	2	3
During production: 1 mixed sample/drier by automatic sampling After production: 1 sample/5t/one bag	During production: 1 mixed sample/drier by automatic sampling After production: 1 sample/5t/one bag	During production: 1 sample every 4 hrs After production: 1 sample/5t

3. Please describe routine & other analysis methods used

1	2	3
Moisture: Drying of a test proportion three hours at 102^{0}C Fat: butyrometic determination (Gerber- Reichert) Protein: Kjeldahl	Moisture: Drying of a test proportion three hours at 102^{0}C Fat: butyrometic determination (Gerber- Reichert) Protein: Kjeldahl	Moisture: IR - Determination FIL-IDF 26A: 1993 Fat: butyrometic determinations (gerber- Reichert) Protein: Kjeldahl

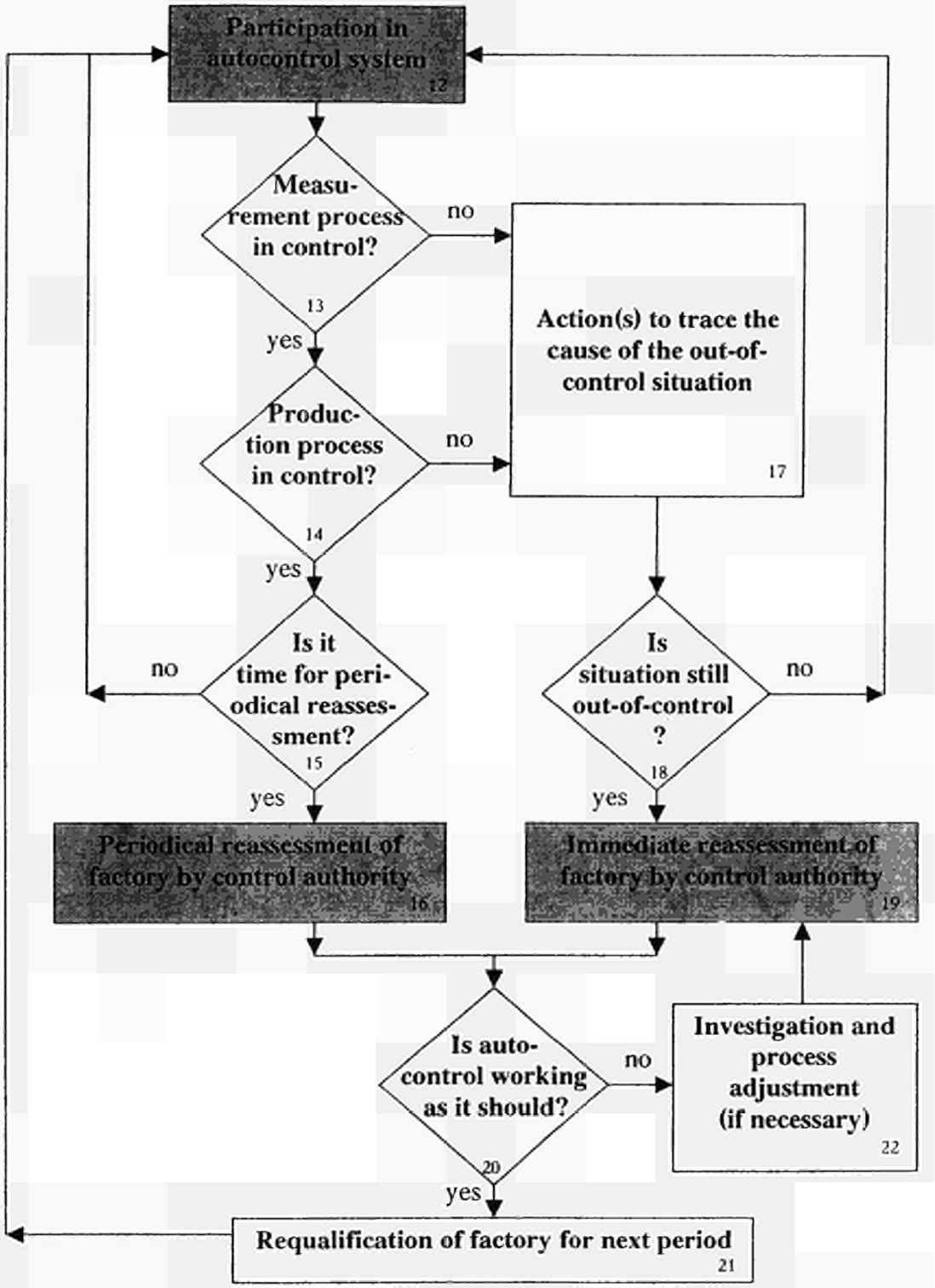
APPENDIX 4

Flowchart 1/ Part 1: Basic Design of an Autocontrol System



2: **Prerequisites** for procedure B are as follows:
a) At least 1000 measurements from the production process (ex-churn or ex-package) with a minimal frequency of 1 measurement per hour.
b) A regular comparison (at least once per week) of factory and external measurements.
c) [Only needed if entirely ex-churn-data is available.] Incidential comparison of ex-churn and corresponding ("matching") ex-package samples.
3: For details see **Flowchart 2**.
4: For details see **Flowchart 3**.

Flowchart 1/ Part 2: Basic Design of an Autocontrol System



12: Practically, the factory is working with and controlling μ_w, the upper limit of the process average, as derived from procedure A or B.

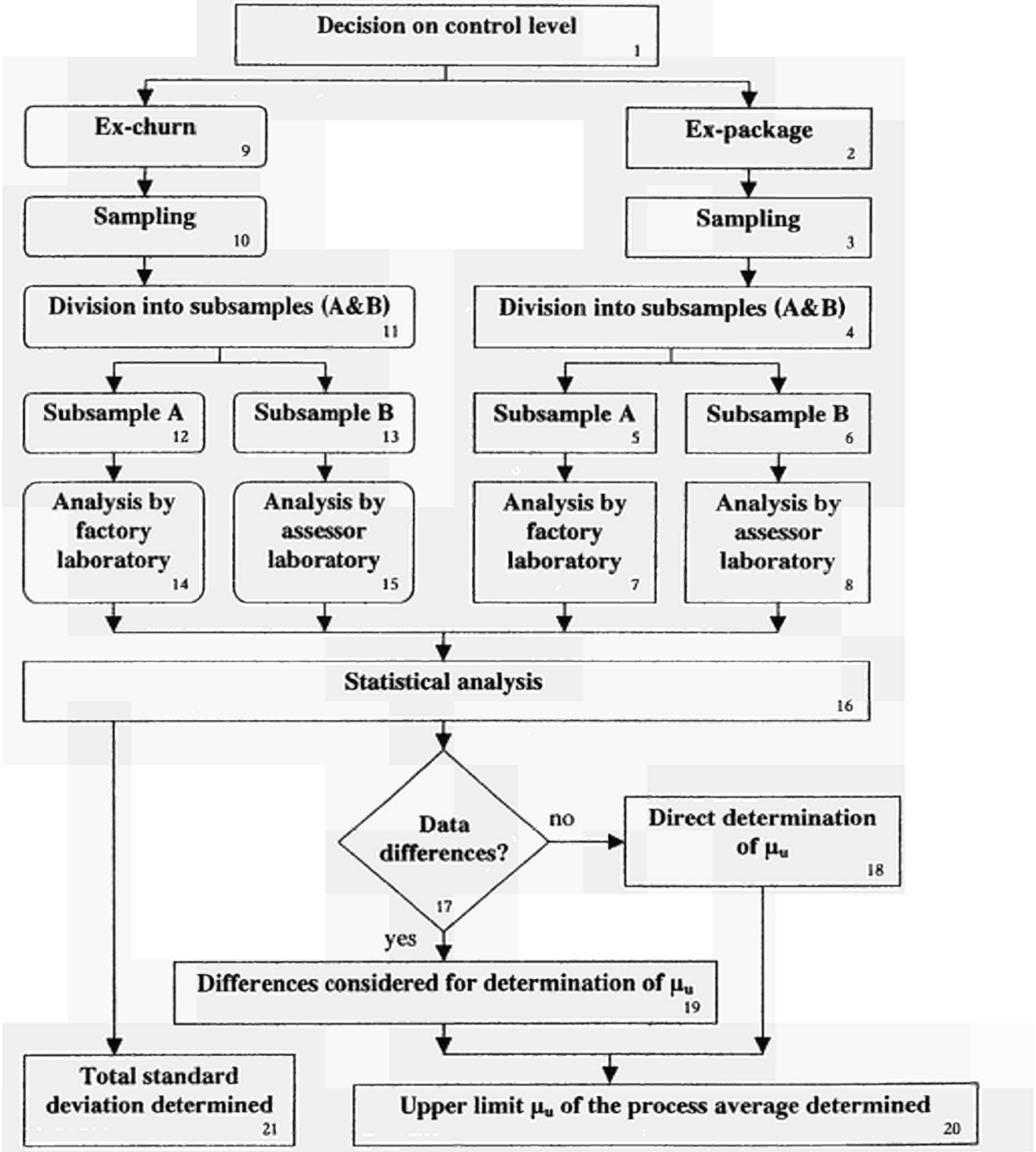
13: i.e.: Do the analyses of the factory laboratory and of the assessor laboratory yield comparable results? Procedure D details the design and use of quality control charts which are employed to continuously check this question.

14: Procedure C details the design and use of quality control charts which are employed to continuously check this question.

16: Basically a **reassessment** contains the same steps as **procedure B**.

22: Both the production and the measurement process can (should) be subjected to an adjustment.

Flowchart 2: Procedure A



1: • Basically the factory can opt for either ex-churn- or ex-package-samples as a basis for its autocontrol system.
• If a factory undertakes ex-churn SPC, procedure A demands the analysis of '**matching**' ex-package samples as well. 'Matching' means that the ex-package sample contains the same material that has been used for the ex-churn sample. (i. e. under consideration of the delay time between the exit of the churn and packaging.) This means that the factory needs to parallely analyse ex-package and ex-churn samples in the introduction phase of an ex-churn SPC-system.

3 and 10: **Sampling** on at least 30 days within a period of 2 months.

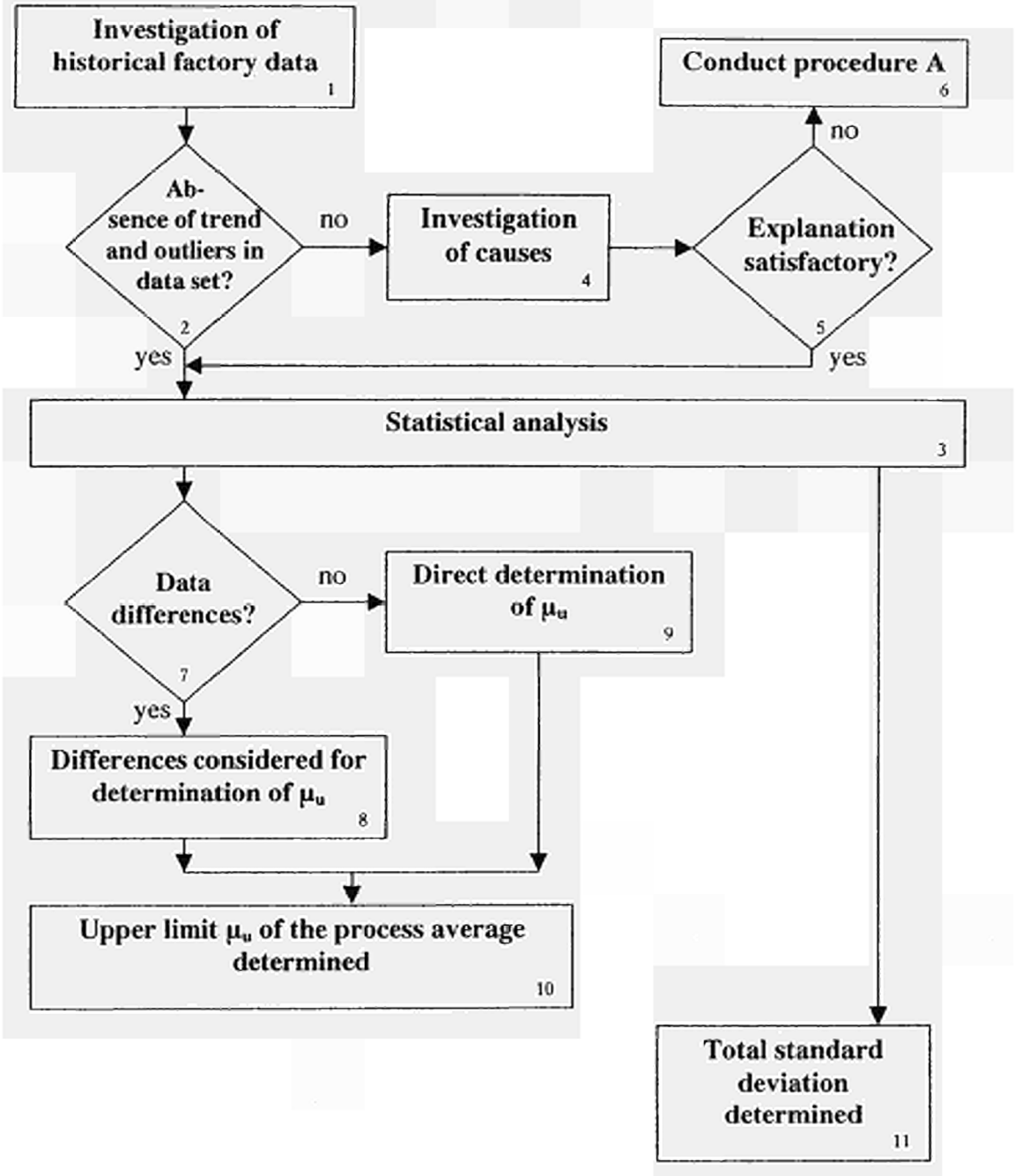
7, 8, 14 and 15: Equal methods of analysis; Analysis at the same time.

16: For the **statistical analysis** data from 7, 8, 14, and 15 are combined.

17: Variability and bias between ex-churn as well as between the factory and assessor laboratory are statistically calculated.

20 and 21: These results are prerequisites for procedures C and D.

Flowchart 3: Procedure B



7: Variability and bias between ex-churn as well as between the factory and assessor laboratory are statistically calculated.
10 & 11: These results are prerequisites for procedures C and D.

APPENDIX 5 QUESTIONNAIRE

EU PROJECT: EVALUATION OF DAIRY PRODUCT QUALITY TAKING INTO ACCOUNT WITHIN-LOT VARIATION
Contract No. SMT4-CT96-2111.

The European Commission is currently funding a project, which could lead to radical changes in the assessment of product quality. The overall objective is to investigate the advantages of moving from a system of official control for analysis of dairy products associated with market organization schemes which is based on analysis of a limited number of samples to a new control system which makes use of the data available from the factory.
The characteristics which have been chosen to develop a suitable approach are those for which manufacturers already routinely collect data as part of their routine process control. Previous questionnaires have already been circulated to manufacturers in countries covered by this project, i.e. Austria, Denmark, The Netherlands and UK. These have sought information on the existing systems of process control used by manufacturers to control moisture level in butter, and controlling moisture, protein and fat in skimmed milk powder. These have proved very valuable in evolving a new proposal.

The purpose of the present questionnaire is to seek further feedback from manufacturers to try to assess if they would be willing to adopt this new system of control if the Commission introduced it.

First some information on the existing controls:

- The existing controls are based on official sampling, taking a small number of samples, which are analysed by the official control laboratory.
- An element in the decision on payment of aid, or purchase, of the lot offered is based on whether or not the analytical results show compliance with a specification limit, e.g. 16% for moisture in butter, taking due account of the measurement error in the official control laboratory using the reference method.
- The manufacturer has recourse to appeal in the event of a disputed failure.
- Failing samples lead to rejection of all or part of the lot or to fines.
- This system is not based on sound statistical principles, and is in effect attempting to "inspect in" quality when it would be better to ensure the quality as the product is being made.

and the main features of the proposals,

- The system would be voluntary, manufacturers could opt to remain with the existing system.

- Using a system of autocontrol the internal factory data would be used for official control purposes.
- The manufacturer would be completely in control of the quality of his product and would demonstrate this to the official control authority in a standardized manner.
- Based on this information the control authority would periodically, (e.g. yearly) issue a permit to the factory to continue with autocontrol for the next period.
- The factory would need to demonstrate the quality of its process data at the outset, and there may have to be a continuous monitoring of the quality of data, however this would be at a significantly lower level than the existing control.
- The manufacturer would need to continually demonstrate the quality of the measurement process, this would be by proficiency checking in conjunction with the official control laboratory.

and the statistical principles supporting them (using moisture in butter as an example),

- The manufacturer sets a process average, which ensures that no more than 5% of total production in a given period (e.g. a year), exceeds a set limit, e.g. for moisture in butter.
- This means that that no more than 5% of "true" results from compositional analysis should be above the limit.
- A "true" result is one that would be achieved by analysis of a sample of butter in the absence of any random measurement error during the determination, and in the absence of any bias in the measurement result.
- Theoretically this would involve multiple analysis of the sample using the reference method in a reference laboratory which has proven quality control.
- Provided the precision of the measurement process, e.g. factory control, is reliably established, and traceable to the official control laboratory reference method allowance can be made for this. The precision of the measurement process is represented by the standard deviation s_w.
- The overall variability of the measurements is a combination of measurement variability and the inherent within-lot variability in the product.
- This can be assessed by determining the long term overall variation of the process, represented by the standard deviation s_{total}.
- Statistically the variability which is due to the variation within-lot alone, represented by the standard deviation $s_{process}$, can be calculated, the formula being $s_{process} = \sqrt{(s_{total}^2 - s_w^2)}$.
- The statistical basis behind the proposal is that the manufacturer would work to a process average figure which would ensure that no more than 5% of true moisture values exceed the regulatory specification limit of 16%.
- To do this the upper limit for this process average would be set at $\mu = 16\% - 1.645 s_{total}$. The multiplication factor 1.645 is appropriate to ensure that, statistically, 5% of the measurement values, and hence less than 5% of the true values, may be expected to exceed 16%.

- In practice the manufacturer would be advised to set the process average at a slightly lower level as this represents the maximum permissible value.
- Statistical process control is based on two Shewhart control charts.
- A control chart for individual measurement values is designed so that it gives only one out of control signal in a hundred inspection times if the manufacturer is running his process with a process average equal to the upper limit.
- Obviously if this process average is larger or smaller than the upper limit he will get more, or less, out of control signals respectively.
- A moving range control chart is designed so that it gives only one out of control signal in a hundred inspection times if the total standard deviation is equal to the value being established by the process evaluation.
- In practice some further work would need to be done to establish and allow for any bias in the factory results, but the basis of the control is that the manufacturers data is used to demonstrate compliance with pre-set requirements.

Whilst it may be necessary to continue with a, much reduced, level of official control to start with to satisfy the auditors, ultimately it is the intention to replace official compositional control with factory auto-control where there are appropriate data.

The following questions refer to quality assurance with particular reference to the control of moisture in butter and the control of moisture, fat and protein in skimmed milk powder.

1	Which of the following product characteristics do you currently control? Moisture in butter Moisture in skimmed milk powder fat in skimmed milk powder protein in milk powder.	 YES/NO YES/NO YES/NO YES/NO
2	Do you keep records of <u>all</u> results on composition made during production of butter (and/or skimmed milk powder)?	YES/NO
3	Do you keep records of all process control data, e.g. breakdowns, restarts, changes in churn, changes in operator, raw material, equipment, including a record of times of occurrence.	YES/NO
4	If NO would you be willing in principle to keep such records?	YES/NO
5	Do you maintain precision data for your results, i.e. standard deviations or other data?	YES/NO
6	If NO would you be willing to set up a system to collect such data?	YES/NO
7	Would you be willing, in principle, to make all internal quality assurance data available to the control authority for product involved in intervention purchase or aid?	YES/NO
8	Do you use a fixed and documented sampling scheme to take samples for analysis.	YES/NO

9	Would you be prepared to modify your sampling scheme if necessary in order to ensure that it complies with the proposal for statistical process control, assuming this new scheme is itself based on feedback from the industry which reflects good manufacturing practice?	YES/NO
10	Do you currently work to a set process average value?	YES/NO
11	Do you use the compositional results to make adjustments during manufacture?	YES/NO
12	Do you use the data to trigger investigations and action in case a pre-set limit is exceeded (or not achieved in the case of lower limits)?	YES/NO
13	Do you use the data to reject (or reprocess) butter (or SMP) from the final lot?	YES/NO
14	In the case of butter manufacture have you established a reliable relationship between the moisture results obtained when taking samples directly from the churn and moisture results obtained from corresponding samples once they have been packaged?	YES/NO
15	If NO would you be willing to establish such a relationship and make necessary changes to process average in case of any proven bias?	YES/NO
16	Do you plot data on a chart?	YES/NO
17	Are you familiar with Shewhart statistical control charts?*	YES/NO
18	Are you familiar with statistical moving range charts?*	YES/NO
19	If NO would you be willing to plot the data on a chart, assuming suitable guidance on set-up was given?	YES/NO
20	Have you established a figure for the overall variability of the product (butter or SMP) e.g. in the form of a long-term standard deviation or other suitable measure of spread of results?	YES/NO
21	Have you established a figure for the variability of your measurement technique?	YES/NO
22	Do you participate in any external quality control schemes for your measurement system?	YES/NO
23	IF NO would you be willing to participate in a regular control scheme which would involve a comparison of your process control measurement results with those obtained from the official control laboratory on the same samples?	YES/NO

* An example showing a Shewhart chart and a moving range chart is attached.

Name and address of factory._____

_____

Comments.

Please add any comments you may have, in particular if you wish to elaborate on reasons for your response.

Please respond to _____

by 31st July if possible.

Many thanks for your co-operation. Derek Farrington, Project co-ordinator.

Feedback from Manufacturers on the adoption of an autocontrol system.

	Question	UK1 (SMP)	UK 2 (Butter)	UK 3	UK4	UK 5 (SMP)
1	Which of the following product characteristics do you currently control? Moisture in butter Moisture in skimmed milk powder fat in skimmed milk powder protein in milk powder.	 NO YES YES YES	 YES NO NO NO	 YES YES YES YES	 YES YES YES NO	 NO YES YES NO
2	Do you keep records of all results on composition made during production of butter (and/or skimmed milk powder)?	YES	YES	YES	YES	YES
3	Do you keep records of all process control data, e.g. breakdowns, restarts, changes in churn, changes in operator, raw material, equipment, including a record of times of occurrence.	YES	YES	YES	YES	YES
4	If NO would you be willing in principle to keep such records?	YES	-	YES	-	N/A.
5	Do you maintain precision data for your results, i.e. standard deviations or other data?	NO	NO	NO	NO	NO
6	If NO would you be willing to set up a system to collect such data?	YES	YES	YES	YES	YES
7	Would you be willing, in principle, to make all internal quality assurance data available to the control authority for product involved in intervention purchase or aid?	YES	YES	YES	YES	YES
8	Do you use a fixed and documented sampling scheme to take samples for analysis.	YES	YES	YES	YES	YES
9	Would you be prepared to modify your sampling scheme if necessary in order to ensure that it complies with the proposal for statistical process control, assuming this new scheme is itself based on feedback from the industry which reflects good manufacturing practice?	YES	YES	YES	YES	YES
10	Do you currently work to a set process average value?	YES	NO	NO	YES	YES
11	Do you use the compositional results to make adjustments during manufacture?	YES	YES	YES	YES	YES
12	Do you use the data to trigger investigations and action in case a pre-set limit is exceeded (or not achieved in the case of lower limits)?	YES	YES	NO	YES	YES
13	Do you use the data to reject (or reprocess) butter (or SMP) from the final lot?	YES	YES	YES	YES	-
14	In the case of butter manufacture have you established a reliable relationship between the moisture results obtained when taking samples directly from the churn and moisture results obtained from corresponding samples once they have been packaged?	N/A.	YES	NO	NO	N/A.
15	If NO would you be willing to establish such a relationship and make necessary changes to process average in case of any proven bias?	N/A.	YES	YES	YES	N/A.
16	Do you plot data on a chart?	NO	NO	NO	YES	NO
17	Are you familiar with Shewhart statistical control charts?*	NO	NO	YES	YES	YES
18	Are you familiar with statistical moving range charts?*	NO	NO	YES	YES	NO
19	If NO would you be willing to plot the data on a chart, assuming suitable guidance on set-up was given?	YES	YES	YES	YES	YES

	Question	UK1 (SMP)	UK 2 (Butter)	UK 3	UK4	UK 5 (SMP)
20	Have you established a figure for the overall variability of the product (butter or SMP) e.g. in the form of a long-term standard deviation or other suitable measure of spread of results?	NO	NO	NO	YES	NO
21	Have you established a figure for the variability of your measurement technique?	NO	NO	NO	NO	YES
22	Do you participate in any external quality control schemes for your measurement system?	NO	YES	YES	YES	YES
23	IF NO would you be willing to participate in a regular control scheme which would involve a comparison of your process control measurement results with those obtained from the official control laboratory on the same samples?	YES	-	-	YES	N/A.

	Question	UK 6	Austria 1 (SMP)	Austria 2 (Butter)	Netherlands A	Netherlands B
1	Which of the following product characteristics do you currently control? Moisture in butter Moisture in skimmed milk powder fat in skimmed milk powder protein in milk powder.	 YES YES YES YES	 NO YES YES NO	 YES NO NO NO	 YES YES NO NO	 YES NO NO NO
2	Do you keep records of all results on composition made during production of butter (and/or skimmed milk powder)?	YES	YES	YES	YES	YES
3	Do you keep records of all process control data, e.g. breakdowns, restarts, changes in churn, changes in operator, raw material, equipment, including a record of times of occurrence.	YES	YES	YES	YES	Not Fully
4	If NO would you be willing in principle to keep such records?	-	-	-	-	YES
5	Do you maintain precision data for your results, i.e. standard deviations or other data?	NO	NO	NO	YES	YES
6	If NO would you be willing to set up a system to collect such data?	YES	YES	-	-	YES
7	Would you be willing, in principle, to make all internal quality assurance data available to the control authority for product involved in intervention purchase or aid?	YES	YES	-	YES	YES
8	Do you use a fixed and documented sampling scheme to take samples for analysis.	YES	YES	YES	YES	YES
9	Would you be prepared to modify your sampling scheme if necessary in order to ensure that it complies with the proposal for statistical process control, assuming this new scheme is itself based on feedback from the industry which reflects good manufacturing practice?	YES	YES	NO	YES	YES
10	Do you currently work to a set process average value?	YES	NO	YES	YES	Maximum
11	Do you use the compositional results to make adjustments during manufacture?	YES	YES	YES	YES	YES
12	Do you use the data to trigger investigations and action in case a pre-set limit is exceeded (or not achieved in the case of lower limits)?	YES	YES	YES	YES	NO
13	Do you use the data to reject (or reprocess) butter (or SMP) from the final lot?	YES	YES	YES	YES	YES

	Question	UK 6	Austria 1 (SMP)	Austria 2 (Butter)	Netherlands A	Netherlands B
14	In the case of butter manufacture have you established a reliable relationship between the moisture results obtained when taking samples directly from the churn and moisture results obtained from corresponding samples once they have been packaged?	NO	-	YES	YES	Partly
15	If NO would you be willing to establish such a relationship and make necessary changes to process average in case of any proven bias?	YES	-	-	-	YES
16	Do you plot data on a chart?	YES	NO	NO	NO	NO
17	Are you familiar with Shewhart statistical control charts?*	YES	NO	NO	YES	NO
18	Are you familiar with statistical moving range charts?*	YES	NO	NO	NO	NO
19	If NO would you be willing to plot the data on a chart, assuming suitable guidance on set-up was given?	-	YES	YES	YES	YES
20	Have you established a figure for the overall variability of the product (butter or SMP) e.g. in the form of a long-term standard deviation or other suitable measure of spread of results?	NO	NO	NO	NO	NO
21	Have you established a figure for the variability of your measurement technique?	YES	NO	NO	?	Indirectly
22	Do you participate in any external quality control schemes for your measurement system?	YES	YES	YES	YES	YES
23	IF NO would you be willing to participate in a regular control scheme which would involve a comparison of your process control measurement results with those obtained from the official control laboratory on the same samples?	-	-	-	YES	-

ADDITIONAL COMMENTS

The UK contacted 6 manufacturers, all 6 responded.
UK 1 commented that their completion of the questionnaire did not constitute a commitment in principle to participate in any new sampling regime without further explanation and consultation.
UK 3 commented that they are about to trial an on-line measuring instrument which; if successful, would provide continuous measurement of moisture, salt and curd and provide full statistical reporting of parameters; and could ultimately lead to a self controlling system. It is hoped that a similar on-line system can be employed on SMP to measure moisture, fat and protein. Their answer to question 9 was qualified as "Yes, if proven beneficial and cost effective".

Austria contacted 5 manufacturers, feedback was obtained from 3, only 2 were willing to complete the present questionnaire.
One Austrian butter manufacturers would remain in the existing system and is not willing to adopt the new system.
Austria 1 would adopt the new system in case of intervention on the market in SMP, however there is at present no intervention in Austria.
Austria 2 commented that their decision to participate in a new system has not yet been made.

Netherlands A do not plot the data on a graph but data are in the computer. Comparison with Infranalyser data is plotted in a separate sheet, not in a graph. Start/stop data is recorded for butter production. A Shewhart chart has been used, but for Netherlands A did not give any improvement. Netherlands B commented on answering Q 21 that a figure for variability of measurement has been established indirectly via analysis of the official control institute, according to official methods, to control the instrument used in production.

European Commission

EUR 19501 - EVALUATION OF DAIRY PRODUCT QUALITY TAKING INTO ACCOUNT WITHIN-LOT VARIATION.

D. S.Farrington

Luxembourg: Office for Official Publications of the European Communities

2000 112pp, num. tab., fig. - 21.0x29.7 cm

BCR information series

ISBN 92-828-8737-5

For butter and skimmed milk powder within-lot variation is not negligible as compared with method variation. Both components of standard deviation have been taken into account in designing a statistical process control (SPC) system. In the case of moisture in butter the within-lot (process) standard deviation varied between 0.04% and 0.411%. The within laboratory repeatability (measurement) standard deviation ranged from 0.023% to 0.065%. For skimmed milk powder estimates of the within lot standard deviation for moisture ranged from 0.093% to 0.205%, measurement standard deviation ranged from 0.025% to 0.091%. Estimates of the within lot standard deviation for fat ranged from 0.037% to 0.259%, measurement standard deviation ranged from 0.013% to 0.055%. Estimates of the within lot standard deviation for protein ranged from 0.057% to 0.293%, measurement standard deviation ranged from 0.045% to 0.196%.

For factories willing to start into SPC without experience and past data a procedure is proposed which allows a start with SPC after a rather short time of investigation of the process. The frequency distribution of moisture in butter and skimmed milk powder tends to have more results below the mean value than there are above. Therefore an overall estimate of the standard deviation from the data could overestimate the spread of the data in the upper part of the distribution. To overcome this the standard deviation is estimated from larger data sets of production data only on the basis of the data above the median of the frequency distribution, or alternatively if sufficient factory data is available an approach based on calculation of the 95% quantile of the data is recommended.
SPC of production data should be carried out using Shewhart control charts, a chart for individual values and a moving range chart. The quantitative measurements made by the factory should also be controlled, by regular assessment against reference laboratory values, using Shewhart control charts. The factory must have clearly defined rules to detect out-of-control conditions and a written out-of-control action plan.

Total costs associated with official control using existing methods are, for butter 570 thousand Euro; for skimmed milk powder 335 thousand Euro. For butter introduction of autocontrol, augmented with a 20% official control check, offers cost savings of nearly 60%. For skimmed milk powder the cost savings are nearly 40%.

The Dairy Industry in 4 Member States was consulted regarding the acceptability of introducing such an approach and favourable feedback has been obtained. Manufacturers already keep records but there is clearly scope for improving the use of SPC, as precision data are generally not routinely recorded. Fixed and documented sampling schemes are already in place for taking samples and there is a willingness to adapt these to comply with the proposals provided that manufacturers can be convinced of their cost effectiveness. Most manufacturers already participate in some form of external control and would be willing to formalise this further.

In order to disseminate the concepts involved in the project and the findings a Video has been produced.

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