United Nations ECE/CTCS/WP.7/GE.6/2017/4

Economic and Social Council

Distr.: General
18 January 2017

Original: English

Economic Commission for Europe

Steering Committee on Trade Capacity and Standards

Working Party on Agricultural Quality Standards

Specialized Section on Standardization of Seed Potatoes

Forty-fourth session
Geneva, 29 March (p.m.) – 31 March 2017
Item 4 of the provisional agenda
Sample sizes

Sample sizes

The following document contains new proposals to amend Annex IX of the UNECE Standard for Seed Potatoes. It was prepared by the Working Group with New Zealand as the lead Rapporteur. The annexes of the current document include a statistical note as well as proposals discussed at the rapporteurs meetings in Oulu, Finland, (2015) and Kimberley, South Africa, (2016) as background documents. The text of this document is submitted to the Specialized Section for review and adoption.

I. Sample sizes

A. Background to the topic

The delegates at the 42nd meeting of the Specialized Section on Seed Potatoes (13-15 October 2014, Geneva) agreed that it would be helpful to have guidance (e.g. an indicative table) in the Standard on the sample size that would ensure desired confidence levels for faults having different tolerance levels. The Specialized Section established a Working Group composed of the delegations of Finland, New Zealand (rapporteur), Sweden and the United States to propose, to the next meeting of the Extended Bureau and Rapporteurs, amendments to the Standard related to sample sizes for both field inspection and post-harvest testing.

The Working Group prepared a paper for the meeting of the Bureau and Rapporteurs (8-11 September 2015, Oulu, Finland), which is reproduced in annex II of this document. The Bureau and the Rapporteurs considered the paper and proposed the following changes to Annex II B ("Level and timing of inspection") of the Standard:

B. Proposed text for level and timing of inspection

"A minimum of two inspections is recommended for growing plants. Where possible, inspections should start at or shortly before the flowering stage.

The DA [Designated Authority] shall specify the inspection procedures. In general, the procedures should allow the inspector to inspect at random a representative sample of plants from a crop.

The number of plants inspected should be sufficient to ensure that, with an appropriate level of confidence, the tolerances given in Annex II A are not exceeded. Table YY in Annex IX provides guidance on the number of plants to sample and maximum allowable number of each fault in each sample size.

The number of plants affected by the diseases listed in Annex II, section A, points 2 and 3 and those not true to variety or of another variety (Annex II, section A, point 4) should be recorded separately in the field inspection report and each expressed as a percentage of the total number of plants inspected in the crop sample.

Observation of symptoms of the diseases specified in Annex II A 5, during inspection, or at any other time, will result in the crop being rejected, if confirmed by appropriate diagnostics.

During each crop inspection the inspector should verify the purity and identity of the variety. The first generation derived from Pre-basic TC class seed potatoes should be inspected at a more intensive rate to identify off-types."

The Bureau and the Rapporteurs proposed to continue with this work to establish a more inclusive approach to statistical methods in Annex IX - specifically to extend the scope of Annex IX to include statistical aspects applicable to field inspections. The Delegation of New Zealand is the lead Rapporteur assisted by Finland, United Kingdom and the United States of America.

At subsequent meetings (Kimberley, March 2016 and Geneva, September 2016) there was further discussion on sample sizes and the nature of the table to be inserted into Annex IX. The two main options for the table are:

1. Tolerances expressed with a confidence limit – the number of plants to be inspected in order to be certain, at a given level of confidence, that the tolerance has not been exceeded.
2. Tolerances with 95 per cent upper confidence interval for actual sample size.

B. Discussion of options

1. Tolerances expressed with a confidence limit

This is the approach proposed in annex II. Table 1 below indicates the sample sizes required for each level of confidence. As the Oulu Bureau and Rapporteurs meeting proposed that “an appropriate level of confidence” be applied, several levels of confidence are presented in the table. Note that the issue of zero tolerances requiring a census of all plants is resolved by the rewording proposed at the Oulu Bureau and Rapporteurs meeting “Observation of symptoms of the diseases specified in Annex II A 5, during inspection, or at any other time, will result in the crop being rejected, if confirmed by appropriate diagnostics”.

Table 1
Rounded minimum sample size (along with no disease in sampled plants) required for statistical proof that the true level of disease is less than the specified maximum, at confidence levels of 90 per cent, 95% and 99 per cent.

Specified maximum level of disease	Minimum sample size (along with NO disease in sampled plants) required for statistical proof that the true level of disease is less than the specified maximum, at confidence levels		
	90 %	95 %	99%
0%			
0.01%	23 100	30 000	46 100
0.1%	2 310	3000	4610
0.2%	1 150	1500	2300
0.25%	920	1200	1840
0.5%	460	600	920
0.8%	290	380	580
1%	230	300	460
1.5%	160	200	310
2%	120	150	230
6%	40	50	75

For any given crop the minimum number of plants to be sampled will depend on the class of the crop and the fault. For example, in a Certified Class II crop the tolerance for blackleg is 2%, virus 6%, and off types 0.5%. To be 95% confident that the tolerance for off types is not exceeded 600 plants need to be inspected but for virus only 50 plants need to be inspected with no virus detected. As a minimum of 600 plants will be inspected to allow the off type tolerance to be verified the number of virus and blackleg faults in the 600 inspection sample is adjusted to provide an acceptance number.

For example, if the sample size is 1,000, then for 95% confidence that the true disease % in a field is ≤ 1%, there can be up to 4 diseased plants observed (or ≤ 0.4%). As a second

example, if the sample size is 10,000, then for 95% confidence that the true disease % in a field is ≤ 1%, there can be up to 83 diseased plants observed (or ≤ 0.83%).

For 95 per cent and 90 per cent confidence the tables look like this:

Table 2
Acceptance numbers for 95 per cent confidence that the stated tolerance is not exceeded.

Tolerance (%)	*Actual sample size*									
	30 000	3 000	1 500	1 200	600	380	300	200	150	50
0.01	Nil	-	-	-	-	-	-	-	-	-
0.1		Nil	-	-	-	-	-	-	-	-
0.2			Nil	-	-	-	-	-	-	-
0.25				Nil	-	-	-	-	-	-
0.5					Nil	-	-	-	-	-
0.8						Nil	-	-	-	-
1							Nil	-	-	-
1.5								Nil	-	-
2									Nil	-
6										Nil

Table 3
Acceptance numbers for 90 per cent confidence that the stated tolerance is not exceeded.

Tolerance (%)	*Actual sample size*									
	23 100	2 310	1 150	920	460	290	230	160	120	40
0.01	Nil	-	-	-	-	-	-	-	-	-
0.1		Nil	-	-	-	-	-	-	-	-
0.2			Nil	-	-	-	-	-	-	-
0.25				Nil	-	-	-	-	-	-
0.5					Nil	-	-	-	-	-
0.8						Nil	-	-	-	-
1							Nil	-	-	-
1.5								Nil	-	-
2									Nil	-
6										Nil

At the Kimberley meeting there was a general consensus that most inspectors look at 3 000 plants or more (either through “scanning” or actual counts). That is enough to give 95% confidence that a tolerance of 0.1% is not exceeded if there are no faults. This is not enough plants to be 95% confident that a 0.01 tolerance has not been exceeded. However, in the UNECE scheme the 0.01% tolerance only applies to Pre-basic classes. In those crops the total number of plants is small and almost all plants would be viewed – i.e., a census. As a consequence, an inspection of 3000 plants is sufficient for all other seed classes and is similar to current practice.

2. Tolerances with 95 per cent upper confidence interval for actual sample size

In this approach a confidence level is not specified. Instead the upper confidence interval is calculated based on the number of plants sampled and the number of faults found. The upper limit of the 95% confidence interval is the percentage of faults that we can know, with 95% certainty, the actual number of faults does not exceed.

For example, for the 0.1% tolerance this may be looked at as 1 fault in 1000 plants sampled, or 3 in 3000 plants. However the distribution of faults in a crop is uneven and the fewer the number of plants sampled the lower our confidence in the accuracy of the estimate of actual faults. As we saw in Table 1, if we have zero faults in 3000 plants sampled we can be 95% confident that the 0.1% tolerance is not exceeded. However if we have 3 faults in 3000 plants sampled the upper confidence interval for a 0.1% tolerance is actually 0.26% (Table 4). If only 1000 plants are sampled the upper confidence interval is 0.47%.

Table 4

Upper limit of the 95% confidence interval (one-sided) for tolerances at differing inspection sample sizes and numbers of faults detected.

Required tolerance (Annexe XI)	*Inspection sample size (actual number of plants inspected*	*Number of faults detected (arithmetically allowable)*	*Upper limit of 95% confidence interval (% faults)*	*Allowable faults to be at least 95% confident of meeting the tolerance (one-sided)*
0.50%	1 000	5	1.05	1
	3 000	15	0.77	8
	6 000	30	0.68	20
0.40%	1 000	4	0.91	0
	3 000	12	0.65	6
	6 000	24	0.56	15
0.20%	1 000	2	0.63	NA
	3 000	6	0.39	1
	6 000	12	0.32	6
0.10%	1 000	1	0.47	NA
	3 000	3	0.26	0
	6 000	6	0.20	1
0.05%	1 000	0	0.30	NA
	3 000	1	0.16	NA
	6 000	3	0.13	0
	7 000	3	0.11	0
0.01%	1 000	0	0.30	NA
	3 000	0	0.10	NA
	6 000	0	0.05	NA
	10 000	1	0.05	NA
	25 000	2	0.03	NA

This is useful in circumstances where a DA either does not specify a minimum sample size, or where the actual sample size is below that required to be 95% confident of meeting the

tolerance. The buyer can review the number of plants sampled, and the number of faults found, and determine the upper confidence interval. The buyer may then decide whether to purchase the lot, or not.

The approach is similar to that described in Annexe IX Table 1, except that in Annexe IX a 2-sided confidence interval is presented. Upper and lower 95% confidence intervals could also be presented for field inspection.

C. Considerations in deciding which approach to follow

The Standard specifies tolerances for faults in seed potato classes, but does not specify the level of confidence required when meeting that tolerance. This could lead to inconsistency between DAs in interpreting the Standard, and to differences in quality of seed potatoes certified as meeting the UNECE Standard. One DA may inspect 3000 plants and find 3 faults for Blackleg in Basic II and certify this (as there is 1 fault in 1000 or 0.1%). The actual level of faults may be 0.26% (95% upper confidence interval, Table 4). Another DA may inspect 3 000 plants and reject the crop as it applies a 95% confidence limit to the 0.1% tolerance, meaning that there can be zero faults in the inspection sample (Table 1). Another DA may apply a 90% confidence limit in the same circumstances.

One approach to resolving this is to establish a confidence limit (e.g., 95%) that must be met, as described in section 2 above. This approach has the advantages of transparency and simplicity. The tables provided (Tables 2 or 3) provide the sample size required to be inspected and the acceptance numbers for higher tolerance faults. A disadvantage is that the 95% confidence limit requires a very large sample size of 30 000 plants for the 0.01% tolerance (off-types in Pre-basic).

However Pre-basic crops are generally small areas where the entire crop is likely to be scanned so a 30 000 plant inspection is probably unlikely at Pre-basic. The next lowest tolerance is 0.1%, requiring 3 000 plants to be sampled. There was consensus at the Kimberley meeting that inspectors would normally inspect 3000 plants and would therefore not need to increase their workload of certification costs. When considering the Certified classes, the lowest tolerance is 0.5%, requiring 600 plants to be sampled as a minimum.

The second approach presented is to provide guidance that will allow buyers (or importing country DAs) to determine an upper 95% confidence interval of the actual tolerance based on the number of plants sampled and the number of faults detected. For example if 3 000 plants were sampled and there were 3 faults the actual level of faults may be up to 0.26% (95% upper confidence interval, Table 4). This has the benefit of allowing DAs to adopt whatever sampling plan they feel appropriate to their circumstances while allowing the buyer to interpret the results. A disadvantage of this approach is that it does not promote consistency in the application of the UNECE Standard. Another disadvantage is that the buyer may not have access to full details of sampling and inspection results, only the certificate, and be unaware of the confidence interval.

A further disadvantage with confidence intervals is that numerous tables would need to be developed. Table 4 only deals with one number of faults (the arithmetically allowable number) for each sample size, and only a limited number of sample sizes have been included). To be able to accurately calculate the upper confidence interval there would need to be several more sample sizes for each tolerance as well as including several numbers of faults for each sample size.

In both cases the practicalities of field inspection and the sensitivity of fault detection must be taken into account. The statistics discussed in these papers assumed a reasonable level of randomness in the inspection technique but this may not always be achievable. With diminishing randomness larger sample sizes are encouraged.

Annex I

I. Statistical Notes

Statistical Notes (23 March 2015[1]) on

- methods for sampling of potato fields for diseases and/or off-types;
- sample sizes required for achieving confidence that the true % of disease or off-types is less than a specified percentage

A. Method of sampling a potato field

In the "UNECE Guide to Seed Potato Field Inspection" document dated 5 August 2014, Figures 1 and 2 on pages 10 and 11 show possible sampling patterns. I greatly prefer the method shown in Figure 1 to that shown in Figure 2.

The method could be implemented as follows. For example, suppose that a potato field has 200 rows. Then it could be divided conceptually into 10 sections of 20 rows. Within each section there are then 10 pairs of rows. The first pair of rows could be walked (inspecting the two plants on either side, i.e., both rows), for about one tenth of its length, then the inspector could move, in a perpendicular fashion, to the next pair of rows and inspect about one tenth of its length, and so on. By the end of the 10th pair of rows, one tenth of the section of field would have been sampled, regardless of how accurately the inspector guessed "about one tenth of the length" of the rows. After repeating this procedure for the other 9 sections of field, one tenth of the plants in the field would have been sampled.

The number of plants inspected can then be calculated by dividing the number of plants in the field by ten.

If less intensive sampling is desired, the 200-row field could be divided conceptually into 5 sections of 40 rows, for example. This would mean 20 pairs of rows per section, with the inspector sampling about 1/20 of each row before moving to the next pair of rows.

The random component can be incorporated by randomly deciding upon a starting point by drawing a random number between 1 and 10 to decide whether the sampling starts in the 1st pair of rows, 2nd pair (up to 10th pair). This effectively staggers or shifts the pattern of sampling so there are 10 possible patterns.

The above method has the advantage that some sampling is carried out within each row of potatoes. Hence if virus has been spread down the entire length of a particular row, this should be detected.

The method can easily be adapted to differing numbers of rows in the field. For example, if there are 160 rows, then it could be divided conceptually into 8 sections of 20 rows, or into 10 sections of 16 rows.

Officially, no account should be taken of disease observed in non-sampled plants. However, if the tolerance is 0% for a particular disease, then any sighting of this disease would mean the field does not meet the tolerance, so such sightings need to be noted. To

[1] Notes prepared by Dave Saville, Principal Biometrician, Saville Statistical Consulting Limited, Box 69192, Lincoln, 7640, New Zealand; (Email: savillestat@gmail.com; phone: 64-3-345 5799); based upon information supplied by Stephen Ogden & Champak Mehta, New Zealand Seed Potato Certification Authority; Potatoes New Zealand Inc.; P. O. Box 10232, Wellington, New Zealand.

provide for departure from the sampling pattern to check out such sightings, the inspector could carry an electric fence standard so they can mark where they had got to in their sampling, so that they can then return to this spot and carry on sampling.

B. Statistical proof that field meets the specified tolerance

If a tolerance of, for example, 0.1% is specified for the disease level in a field, then this is 1 diseased plant out of every 1 000 plants in the field. And if 1 000 plants are independently sampled and the true disease level is 0.1%, the probability of finding disease in a plant follows a binomial distribution with parameter 0.001 (1% chance of disease). In this situation, there is a 37% chance that 0 diseased plants will be found in the sample of 1,000 plants, a 37% chance that 1 diseased plant will be found, and a 26% chance that 2 or more diseased plants will be found in the sample.

Similarly, if the true disease % is slightly greater than 0.1%, there is still a high chance of observing no disease in a sample of 1 000 plants. Therefore sampling 1 000 plants and finding no disease does NOT constitute proof that the true disease level in the field is 0.1% or less.

In the next section we show that for 95% confidence that the true disease level in the field is 0.1% or less, we must sample a minimum of 3 000 plants, and observe no disease.

C. Minimum sample size required for statistical proof

1. Derivation of formula

If the true % disease is exactly 0.1%, for example, then the probability that a single randomly selected plant is NOT diseased is 0.999. Hence the probability that "x" randomly, independently selected plants are ALL not diseased is 0.999^x (0.999 to the power of x).

Now we want to find the value of "x" for which 0.999^x is equal to 0.05.

The reason is that for sample sizes larger than x, we would then have a probability of $p<0.05$ of observing NO disease in all sampled plants (if the true % disease is exactly 0.1%), so such a result is statistically inconsistent with the idea that "the true % disease is exactly 0.1%" (or larger). That is, we have statistical proof that "the true % disease is less than 0.1%". In other wording, we are "95% confident" that "the true % disease is less than 0.1%".

To solve the equation $0.999^x = 0.05$,

we take logs (to any base) of both sides, yielding $\log[0.999^x] = \log[0.05]$

which can be simplified to $x \log[0.999] = \log[0.05]$

and hence $x = \log[0.05] / \log[0.999]$

or, $\mathbf{x = \log[1 - 0.95] / \log[1 - 0.001]}$

where 0.95 corresponds to 95% confidence and 0.001 is the maximum allowable proportion of diseased plants (or off-type plants).

The answer, x, tells us the minimum sample size required for proving, with 95% certainty, that the true percentage of diseased plants is less than (or equal to) 0.1%. However, such proof exists only if NO diseased plants are found, out of the "x" plants sampled. If even

one diseased plant is found, with a sample size of “x”, then there is no statistical proof that the true percentage of diseased plants is less than (or equal to) 0.1%.

Clearly other confidence levels (such as 90% or 99%) can be substituted into the formula, and different tolerances can be substituted for 0.1% tolerance. When this is done, the results are as shown in Table 5 (which gives unrounded “x” values) or Table 6 (which gives rounded “x” values).

Table 1

Minimum sample size (along with NO disease in sampled plants) required for statistical proof that the true level of disease is less than the specified maximum, at confidence levels of 90%, 95% and 99%.

Specified maximum level of disease	**Minimum sample size (along with NO disease in sampled plants) required for statistical proof that the true level of disease is less than the specified maximum, at confidence levels**		
	90 %	95 %	99%
0%			
0.01%	23 025	29 956	46 049
0.1%	2 301	2 994	4 603
0.2%	1150	1 496	2 300
0.25%	02-	1 197	1 840
0.5%	459	598	919
0.8%	287	373	573
1%	229	298	458
1.5%	152	198	305
2%	114	148	228
6%	37	48	74

Table 2

***Rounded* minimum sample size (along with NO disease in sampled plants) required for statistical proof that the true level of disease is less than the specified maximum, at confidence levels of 90%, 95% and 99%.**

Specified maximum level of disease	**Minimum sample size (along with NO disease in sampled plants) required for statistical proof that the true level of disease is less than the specified maximum, at confidence levels**		
	90 %	95 %	99%
0%			
0.01%	23, 100	30 000	46 100
0.1%	2 310	3 000	4 610
0.2%	1 150	1 500	2 300
0.25%	920	1 200	1 840
0.5%	460	600	920
0.8%	290	380	580
1%	230	300	460
1.5%	160	200	310
2%	120	150	230
6%	40	50	75

2. "Larger than minimum" sample sizes

For 95% confidence that the true disease % in a field is ≤ 1%, for example, and for a sample of 300 independently sampled plants, there must be NO disease observed in the sample (Table 6).

However, if a larger sample is taken, then the allowable number of diseased plants may be greater than zero. For example, if the sample size is 1,000, then for 95% confidence that the true disease % in a field is ≤ 1%, there can be up to 4 diseased plants observed (or ≤ 0.4%).

As a second example, if the sample size is 10,000, then for 95% confidence that the true disease % in a field is ≤ 1%, there can be up to 83 diseased plants observed (or ≤ 0.83%).

3. Survey or census?

The above calculations assume the field is reasonably large; in such cases the statistical accuracy depends on the *number of plants sampled*, not the percentage of plants sampled. However, if a field has only 450 plants, for example, then the inspector may well inspect all plants, in which case results are exact, and not subject to statistical variation. This is called a census.

4. Lack of independence

In the above sample size calculations, independence of sampling is a basic assumption. If an inspector is observing disease in consecutive plants along two adjacent rows, this assumption is almost certainly violated. This means that the above sample sizes are likely to be gross under-estimates. Therefore higher levels of sampling are desirable.

Annex II

I. Background information - Sample sizes (discussion paper presented at 2015 meeting of the Bureau and Rapporteurs – Oulu, Finland)

At the Forty-second session of the Specialized Section on Standardization of Seed Potatoes (Geneva, 13-15 October 2014) it was agreed that it would be helpful to have guidance (e.g. an indicative table) in the Standard on the sample size that would ensure desired confidence levels for faults having different tolerance levels. The Specialized Section established a Working Group composed of the delegations of Finland, New Zealand (rapporteur), Sweden and the United States to propose, at the next meeting of the Bureau and the Rapporteurs, amendments to the Standard related to sample sizes for both field inspection and post-harvest testing.

A. Introduction

The Standard (Annex II) establishes the tolerances for faults that are not to be exceeded. However the Standard does not specify the number of plants that are required to be inspected or the level of confidence required when establishing a sample size. It is therefore probable that DAs have established sampling and inspection procedures that result in varying levels of confidence in the result of the inspection. This was explained further in the “Statistical Notes”.

There also appears to be a contradiction in the Standard. Annex II A of the Standard specifies the “minimum conditions to be satisfied by the crop” *as the proportion of growing plants* that shall not exceed a specified tolerance. For example the proportion of growing plants showing symptoms of virus diseases shall not exceed 0.1 per cent in the crop for production of Pre-basic class seed.

However Annex II B contradicts section A, in that section B states that “The number of plants affected by the diseases listed in Annex II, section A, points 2 and 3 and those not true to variety or of another variety (Annex II, section A, point 4) should be recorded separately in the field inspection report and each expressed *as a percentage of the total number of plants inspected in the crop*.”

Part B suggests that if 3 000 plants are inspected and there are 3 faults a tolerance of 0.1% has not been exceeded. However Part A states that the tolerance is *the tolerance for the crop*. This is different from the number of faults allowable in the sample. For example if 3000 plants are inspected in the crop and the tolerance is 0.1% the maximum number of allowable faults is zero in order to be 95% confident that the overall level of faults in the crop does not exceed 0.1% – not 3 in 3000 (or 0.1% of the inspection sample).

This is an important point for clarification.

B. Statistical considerations

Where tolerances are very small, e.g., 0.01%, a much larger number of plants need to be inspected (30 000 to be 95% confident). This number changes slightly depending on the number of plants in the crop, but over a certain number of plants makes no difference at all and can be ignored for the purposes of this paper.

Differing tolerances will apply to each crop. In a Certified Class II crop the tolerance for blackleg is 2%, virus 6%, and off types 0.5%. To be 95% confident that the tolerance for off types is not exceeded 600 plants need to be inspected but for virus only 50 plants need to be inspected with no virus detected. As a minimum of 600 plants will be inspected to allow the off type tolerance to be verified the number of virus and blackleg faults in the 600 inspection sample is adjusted to provide an acceptance number. The paper establishes the minimum number of plants that can be inspected with no faults found in order to verify that the tolerance is not exceeded. A larger number of plants can be inspected and an acceptance number <0 can be applied.

The paper presents minimum sample sizes for 90%, 95%, and 99% confidence that the tolerances specified in the Standard will not be exceeded. Depending on the selected confidence level it can be expected that true level of faults in the crop may exceed the specified tolerance once every 10, 20, or 100 crop inspections respectively.

The Standard specifies a zero tolerance for several diseases. This is problematic in that to verify that there is no disease in a crop every plant would have to be inspected. Even if a tolerance of 1/100,000 plants (rather than zero) was established this would require inspection of 300,000 plants in order to be 95% confident. For other faults the number of plants inspected will vary depending on the class of seed crop being inspected but is considerable lower – this could range from 50 to 30,000 plants. So the level of confidence of detecting “zero tolerance” diseases even at a rate of 1/100,000 is very low (<5% if 50 plants are inspected).

C. Practical considerations

Classes to which very low tolerances are applied (e.g., 0.01% for off-types in Pre-basic) are usually planted in small areas so the very large number of plants required to be inspected to achieve 95% or 99% confidence would normally exceed the number of plants in the crop, so all of the plants would be inspected. In practice the number of plants to be inspected in a crop to achieve 95% confidence that a 0.01% tolerance is not exceeded will not be 30,000 plants it will be the actual number of plants and will be far lower than this number. For higher tolerances the number of plants will be an achievable number – perhaps even considered unrealistically low.

D. Recommendations

In order to encourage standardization in field and post-harvest evaluations it is recommended that the Specialized Section agrees on an appropriate level of confidence that should be achieved in field inspections. Ideally this will reflect current practices of DAs.

It is recommended that Annex II B is modified to confirm that the tolerances specified in the Standard are the maximum allowable proportions of faults in the crop. Section 2 of Annex II B could be re-written by modifying the second paragraph as follows:

The DA shall specify the inspection procedures. In general, the procedures should allow the inspector to inspect at random a representative sample of plants from a crop. The number of plants inspected should be sufficient to ensure that, with XX% confidence, the tolerances given in Annex II A are not exceeded. Table YY provides guidance on the number of plants to sample and maximum allowable number of each fault in each sample size.

The number of plants affected by the diseases listed in Annex II, section A, points 2 and 3 and those not true to variety or of another variety (Annex II, section A, point 4) should be recorded separately in the field inspection report ~~and each expressed as a percentage of the~~

~~total number of plants inspected in the crop~~ compared to the acceptance number for each fault in Table YY for the sample size.

XX% will be the confidence level agreed as above.

Table YY will be developed if this approach is accepted by the working group.

The Specialized section should also revise its position on zero tolerance diseases. It may be more appropriate to express these as zero faults observed in the inspection sample and any other part of the crop viewed by the inspector (this is in line with the Field Inspection Guide). However in doing so it must be recognized that the level of confidence in detecting these diseases will be very low. It may be necessary to determine a minimum number of plants to be inspected in any class that provides an acceptable level of confidence that "zero tolerance" diseases will not be detected and provide a table of acceptance numbers for faults with higher tolerances in the same class. Annex II B could be modified by adding a paragraph, following those modified above, to read:

No symptoms of the diseases specified in Annex II A 5 shall be detected in the inspection sample of any other part of the crop viewed by the inspector during the course of field inspections.

Annex IV specifies that the sample size for post-harvest visual evaluations is 100 tubers. To achieve 95% confidence that the tolerances referred to in the Annex would require a much larger sample size (e.g., 0.01 per cent for Pre-basic class). Table 1 of Annex IX reflects this by indicating that for a tolerance of 0.5% with no faults detected the true number of faults lies between 0 and 2.95 (the confidence interval). Put another way, the confidence level in this example is 39%. It is recommended that this section is revised to reflect the detection limits imposed by a sample size of 100 tubers.