TECHNICAL REPORT

Sample size calculation tool for monitoring stunning at slaughter[1] [2]

European Food Safety Authority[3, 4]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Article 16 of Council Regulation (EC) No 1099/2009 on the protection of animals at the time of killing requires slaughterhouse operators to carry out regular checks to ensure that animals do not present any sign of consciousness following stunning. The Commission therefore considered it opportune to request EFSA to provide an independent view on the indicators and elements for putting in place monitoring procedures, including sampling protocols, at slaughterhouses for different methods of stunning and slaughtering. In order to provide food business operators with an indication on the sample size and frequency of sampling, a mathematical model was developed to calculate the number of animals that need to be checked to fulfil the above mentioned requirements. The model also allows to estimate the potential failure rate given a certain sample size. The model was implemented in a tool with a user friendly interface. This technical report presents this tool and explains its theoretical basis. A user manual is also provided where detailed instructions can be found.

KEY WORDS

stunning, slaughter, welfare indicators, monitoring procedures, sample size

---

[1] On request from EFSA, Question No EFSA-Q-2013-00584, approved on 19 December 2013.

[2]. Please note that this document has been established for information and consultation purposes only and does not necessarily constitute the views of the Commission as it has not been adopted or in any way approved by the European Commission. The European Commission does not guarantee the accuracy of the information provided, nor does it accept responsibility for any use made thereof. EFSA has taken precautions in creating the *EFSA SStun* application interface, version 1.0 and the documentation accompanying it. However, EFSA is not responsible for errors, omissions or deficiencies regarding the system and the accompanying documentation. The application interface and the accompanying documentation were developed in the context of the Mandate number M-2012-0281, and are being made available as such without any warranty either expressed or implied, including, but not limited to, warranties of performance, merchantability, and fitness for a particular purpose. EFSA is not regularly updating the *SStun* application interface and the accompanying documentation. However, EFSA will inform the users in case an update of the application interface is available. In no event shall EFSA be liable for direct, indirect, special, incidental, or consequential damages resulting from the use, misuse, or inability to use the application interface and the accompanying documentation.

[3] Correspondence: SAS@efsa.europa.eu

[4] Acknowledgement: EFSA wishes to thank the WG on monitoring procedures at slaughterhouses for the preparatory work on this output and EFSA staff: Gabriele Zancanaro, José Cortiñas Abrahantes and Denise Candiani for the support provided to this output.

Suggested citation: European Food Safety Authority, 2013; Sample size calculation tool for monitoring at slaughterhouse. EFSA supporting publication 2013:EN-541. 18 pp.

Available online: www.efsa.europa.eu/publications

SUMMARY

Article 16 of Council Regulation (EC) No 1099/2009[5] on the protection of animals at the time of killing[6] requires slaughterhouse operators to put in place and implement monitoring procedures in order to check the stunning process. In particular, FBO's (Food Business Operators) should carry out regular checks to ensure that animals do not present any sign of consciousness or sensibility in the period between the end of the stunning process and death. Those checks shall be carried out on a sufficiently representative sample of animals and their frequency shall be established taking into account the outcomes of previous checks and any factors which may affect the efficiency of the stunning process.

The Commission considered as opportune to request EFSA to provide an independent view on the indicators and elements for putting in place monitoring procedures at slaughterhouses for different methods of stunning and slaughtering, in light of the most recent scientific developments. In particular, the following groups of methods and species are covered: i) penetrative captive bolt for bovine animals, ii) head-only electrical stunning for pigs, iii) head-only electrical stunning for sheep and goats, iv) electrical waterbath for poultry (chickens and turkeys), v) carbon dioxide at high concentration for pigs, vi) all authorised gas methods to slaughter chickens and turkeys (carbon dioxide in two phases, carbon dioxide associated with inert gases and inert gases alone), vii) slaughter without stunning for bovine animals, viii) slaughter without stunning for sheep and goats, ix) slaughter without stunning for chickens and turkeys. It is worth noticing that, according to Regulation (EC) No 1099/2009, in case of slaughter without stunning the checks must be systematic and therefore sampling procedures only apply to the situation in which animals are slaughtered with prior stunning. This report will therefore focus only on slaughter procedures with stunning.

A mathematical model was developed to calculate the number of animals that need to be checked to fulfil the above mentioned requirements. The model should also allow to estimate the potential failure rate given a certain sample size.

Independently of the species and methods, a tool was developed to provide all relevant stakeholders, including FBO's, with a simple and user-friendly software application to enable them to have an estimation about: i) sample size needed, given a fixed failure rate considered acceptable; ii) expected failure rate, given the sample size.

This technical report presents this tool and explains its theoretical basis. A user manual is also provided where detailed instructions can be found.

5 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri = OJ:L:2009:303:0001:0030:EN:PDF
6 OJ L 303, 18.11.2009, p. 1.

TABLE OF CONTENTS

Abstract 1
Summary 2
Table of contents 3
Background as provided by the European Commission 4
Terms of reference 5
Assessment 5
1. Introduction 5
2. Materials and methods 6
 2.1. Development of a sampling protocol 6
  2.1.1. Technical specification 7
   2.1.1.1. Estimation of the sample size 8
   2.1.1.2. Estimation of the potential failure rate 8
3. Results 9
 3.1. The resulting model for the sampling protocol 9
4. The development of a tool for calculation of sample size 11
 4.1. Software 11
 4.2. Tool availability 11
Recommendations 12
References 12
Appendices 13
Appendix A. User Manual 13
- Estimation of the sample size 13
- Estimation of the potential failure rate 15
Appendix B. Declaration 17
Declaration regarding use of the EFSA SStun model, version 1.0 17
Glossary 18

BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

Article 16 of Council Regulation (EC) No 1099/2009[7] on the protection of animals at the time of killing[8] requires slaughterhouse operators to put in place and implement monitoring procedures in order to check that their stunning processes deliver the expected results in a reliable way.

Article 16 refers to Article 5 which requires operators to carry out regular checks to ensure that animals do not present any signs of consciousness or sensibility in the period between the end of the stunning process and death.

Those checks shall be carried out on a sufficiently representative sample of animals and their frequency shall be established taking into account the outcomes of previous checks and any factors which may affect the efficiency of the stunning process.

Article 5 also requires operators, when animals are slaughtered without stunning, to carry out systematic checks to ensure that the animals do not present any signs of consciousness or sensibility before being released from restraint and do not present any sign of life before undergoing dressing or scalding.

According to Article 16(2), a monitoring procedure shall include in particular the following:

(a) indicators designed to detect signs of unconsciousness and consciousness or sensibility in the animals (before death or release from restraint, in case of slaughter without stunning, = indicators A); or indicators designed to detect the absence of signs of life in the animals slaughtered without stunning (before undergoing dressing or scalding = indicators B);

(b) criteria for determining whether the results shown by the indicators previously mentioned are satisfactory;

(c) the circumstances and/or the time when the monitoring must take place

(d) the number of animals in each sample to be checked during the monitoring.

Furthermore, Article 16 (4) specifies that: "*The frequency of the checks shall take into account the main risk factors, such as changes regarding the types or the size of animals slaughtered or personnel working patterns and shall be established so as to ensure results with a high level of confidence*."

The Commission plans to establish EU guidelines concerning monitoring procedures at slaughterhouses.

The purpose of the Commission is to provide a sort of "toolbox" for establishing monitoring procedures so that slaughterhouse operators can use scientifically based procedures which will provide them proper information on their stunning processes. The guidelines will also be used by the competent authorities in order to check that slaughterhouse operators are not using unreliable monitoring procedures.

In order to prepare these guidelines, a sound basis for checks on stunning as laid down in Articles 5 and 16 of the above-mentioned regulation is needed.

[7] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri = OJ:L:2009:303:0001:0030:EN:PDF
[8] OJ L 303, 18.11.2009, p. 1.

TERMS OF REFERENCE

The Commission considered opportune to request EFSA to provide an independent view on the indicators and elements for putting in place monitoring procedures at slaughterhouses for different methods of stunning and slaughtering, in light of the most recent scientific developments. In particular, the following groups of methods and species are covered: i) penetrative captive bolt for bovine animals, ii) head-only electrical stunning for pigs, iii) head-only electrical stunning for sheep and goats, iv) electrical waterbath for poultry (chickens and turkeys), v) carbon dioxide at high concentration for pigs, vi) all authorised gas methods to slaughter chickens and turkeys (carbon dioxide in two phases, carbon dioxide associated with inert gases and inert gases alone), vii) slaughter without stunning for bovine animals, viii) slaughter without stunning for sheep and goats, ix) slaughter without stunning for chickens and turkeys.

It is worth noticing that, according to Regulation (EC) No 1099/2009, in case of slaughter without stunning the checks must be systematic and therefore sampling procedures only apply to the situation in which animals are slaughtered with prior stunning. This report therefore focuses only on slaughter procedures with stunning.

For each group of slaughtering procedures with prior stunning, the EFSA, based on the relevant scientific basis and on indicators' performances, will provide welfare indicators as well as the other elements of the monitoring procedure (criteria for satisfactory results in terms of animal welfare, circumstances and sampling procedure, including minimum sampling and frequency).

The mandate was accepted by EFSA and assigned to the AHAW Unit. The SAS Unit is requested to develop a mathematical model to calculate the number of animals that need to be checked to fulfil the above mentioned requirements. The model should also allow to estimate the potential failure rate given a certain sample size.

ASSESSMENT

1. Introduction

In order to develop a monitoring procedure for slaughter with stunning, the animals should be checked for signs of consciousness based on a series of selected welfare indicators as defined in the scientific opinions of the AHAW Panel on "Monitoring procedures at slaughterhouses for bovines", "Monitoring procedures at slaughterhouses for sheep and goats", "Monitoring procedures at slaughterhouses for pigs" and "Monitoring procedures at slaughterhouses for poultry" (EFSA, 2013a, b, c and d). As explained in such opinions, the suitability for inclusion of an indicator into the monitoring system was determined based on the indicator sensitivity and specificity, and its feasibility for use at different key stages of the slaughter process. The indicators that should be used for the monitoring of each species/method combination and their values for sensitivity (Se), specificity (Sp) and feasibility are detailed in the above mentioned scientific opinions; more precisely:

- penetrative captive bolt for bovine animals: EFSA, 2013a - indicators to be used are found in section 4.2; their values for Se, Sp and feasibility can be found in section 3.4 and in Table 7.

- head-only electrical stunning for pigs: EFSA, 2013a - indicators to be used are found in chapter 4.2.; their values for Se, Sp and feasibility can be found in chapter 3.6 and in Table 5.

- carbon dioxide at high concentration for pigs: EFSA, 2013a - indicators to be used are found in chapter 4.2.3; their values for Se, Sp and feasibility can be found in chapter 3.4 and in Table 6.

- electrical waterbath for poultry: EFSA, 2013a - indicators to be used are found in chapter 4.2; their values for Se, Sp and feasibility can be found in chapter 3.7 and in Table 6.

- all authorised gas methods to slaughter chickens and turkeys: EFSA, 2013a - indicators to be used are found in chapter 4.3; their values for Se, Sp and feasibility can be found in chapter 3.8 and in Table 7.

- head-only electrical stunning for sheep and goats: EFSA, 2013a - indicators to be used are found in chapter 4.2; their values for Se, Sp and feasibility can be found in chapter 3.4 and in Table 7.

2. Materials and methods

2.1. Development of a sampling protocol

The mandate from the Commission requests EFSA to estimate the optimal frequency with which animals should be monitored to assess the efficacy of stunning. Such assessment is done by checking some indicators in order to exclude signs of consciousness following stunning.

As explained in section 2.1 of the scientific opinions on monitoring slaughter (EFSA 2013 a, b, c and d), when monitoring the effectiveness of the stunning, in order to safeguard animal welfare, it is of major interest to detect those animals that are not properly stunned or recover consciousness after stunning. The sensitivity of an indicator, i.e. the probability of such an indicator of detecting any truly conscious animal, is therefore the most relevant parameter related to the indicator itself to be included in the sample size calculation.

On the other hand, it must be noted that specificity is not considered for the purposes of this model, as it is not related to the risks associated with reduced welfare.[9] In facts, a lack of specificity will lead to classify an animal as conscious (i.e. a welfare problem) while in reality the animal is unconscious. However, these misclassified animals would all be re-stunned and will therefore not represent anymore a welfare problem. In such a framework, from a probabilistic point of view and for the calculation of the sample size as defined in this report, the indicator specificity can be assumed to be 100% (see also Martin et al., 2007).

The sampling frequency is determined based on the indicator sensitivity and other parameters (see section 3.1 and following). To calculate the optimal sampling fraction (or sampling frequency), at least two parameters need to be quantified: first, the highest proportion of insufficiently stunned animals that may be considered acceptable (i.e. the Failure Rate); and, second, the effects of the risk factors (individually or in combination) on the performance of the indicator (i.e. the Indicator Sensitivity).

Regarding the level of acceptability, the legislation specifies that no animals should show signs of consciousness following stunning. All animals should be stunned properly, and therefore the threshold level for the acceptability of ineffective stunning is zero. The second component requires a large number of data on the interactive effects of risk factors on the frequency at which a test correctly classifies a truly mis-stunned animal, given a wide range of circumstances under which animals are slaughtered in EU abattoirs. These data are not available. An estimation of this latter parameter has been performed by means of a questionnaire (see EFSA 2013 a, b, c and d).

However, it is possible to model the relationship between the fraction of slaughtered animals sampled and the minimum proportion of ineffectively stunned animals that will be detectable using a certain sampling protocol. Understanding this relationship allows risk managers (and others concerned) to

[9] It should be noted that an indicator of low specificity, although not representing an animal welfare issue, definitely represents an issue from a food business operator (FBO) perspective. An indicator with low specificity would more often misclassify unconscious animals as conscious. Obviously, this represents a problem from a FBO perspective as an unnecessary corrective action must be taken, entailing a waste of money and time.

relate the economic and other costs associated with a particular sample size to the benefits associated with improved detection levels (i.e. improved animal welfare).

It is important to notice that the tool does not depend directly on the animal species itself: all the differences are actually reflected in the relevant parameters of the model. As an example, the “slaughter population” (i.e. an homogeneous group of animals, with analogous individual characteristics and slaughtered under the same conditions) varies across species. This is particularly evident comparing bovines and poultry, where the parameter “slaughter population” differs substantially, as the number of animals that compose a single batch is much greater in poultry than in bovines. Therefore, inputting the “slaughter population” parameter in the software application will indirectly capture the specific species characteristics or, from another perspective, there is no need to design the model differently according to the species.

Another example is given by the indicators: some indicators are relevant only for certain species and stunning methods. However, each indicator is characterised by a specific sensitivity value. Therefore, inputting in the model the “indicator sensitivity” parameter will reflect, in probabilistic terms, the different characteristics of the different species and stunning methods.

2.1.1. Technical specification

The relationship between the fraction of slaughtered animals sampled and the minimum proportion of ineffectively stunned animals that will be detectable using a certain sampling protocol can be modelled using existing approaches for process monitoring (e.g. continuous quality assurance regarding threshold failure rate in computer chip production). Although the statistical relationship is identical to those applied in planning disease surveillance, the related terminology (e.g. design prevalence) was considered less appropriate for addressing the issue of mis-stunned animals and therefore this text adheres to the terminology of failure management. For the statistical model, we used the following parameters:

1. **Threshold failure rate**: for proportion of mis-stunned animals. This specifies the minimum proportion of animals that are ineffectively stunned which will still be detected by the sampling protocol.

2. **Sensitivity of the indicators**. The percentage of truly conscious animals detected as conscious by the indicator.

3. **Slaughter population**. This is the total number of animals slaughtered under the same circumstances as determined by risk factors (EFSA 2013 a, b, c and d). Note that the slaughter population is independent of the line speed, and can cover a period of minutes, hours or even days.

4. **Sampling fraction**. This is the proportion of the slaughter population which is assessed in the sampling protocol.

5. **Accuracy** of the sampling protocol. This is the percentage of situations in which the sampling protocol was applied and served its purpose, i.e. raising an alarm if the number of ineffectively stunned animals was higher than the prescribed threshold failure rate would allow.

Given these parameters, the details of the monitoring protocol can be calculated from Equation 1 (Cannon, 2001).

$$SF = \frac{n}{SP} \cong \frac{\left(1-(1-A)^{1/(SP\cdot FR)}\right)\cdot\left(SP-0.5(A(SP\cdot FR)-1\right)}{ISe}$$ **Equation (1)**

Where:

- A = requested accuracy of the sampling protocol
- FR = standard threshold failure rate
- ISe = indicator sensitivity
- *n* = number of animals tested
- SF = sample size or sampling fraction
- SP = slaughter population

2.1.1.1. Estimation of the sample size

The first objective for the tool was to enable the calculation of the required sample size, given the following known parameters; i) Indicator Sensitivity; ii) desired accuracy; iii) acceptable failure rate. Dividing the result by the slaughter population, it is then possible to estimate the sampling fraction.

Equation 1 affords this calculation in a straightforward way.

2.1.1.2. Estimation of the potential failure rate

It was considered useful to estimate the potential failure rate, given a certain number of animals checked. Of course, also in this case, other parameters need to be known, i.e.: i) Slaughter population; ii) Indicator Sensitivity; iii) desired accuracy.

However, Equation 1 cannot be solved for the FR in an algebraic way. For this reason, it was necessary to solve the equation numerically. For the purpose, the Microsoft Office Excel function VLOOKUP was used.

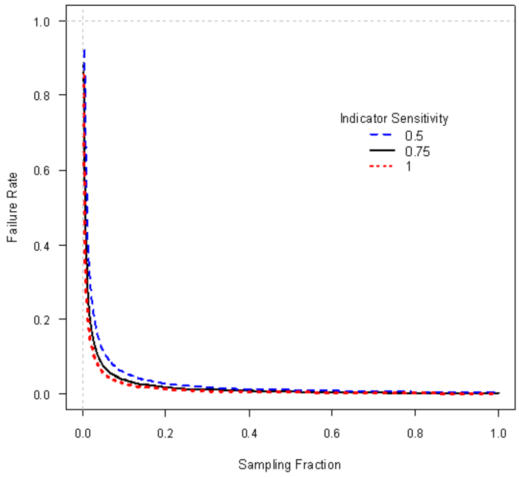
Briefly: once the slaughter population, the desired accuracy and the indicator sensitivity are known, it is possible to calculate the required sample size for different failure rate values. This sample size calculation was then performed for many failure rate values (going from 0.001 to 1, by a 0.001 step, for a total of 1000 values). At the end of the process, the tool calculated 1000 different sample size values. The VLOOKUP Excel function actually looks for the failure rate value which gave a calculated sample size equal to the one set by the user.

Appendix A. gives all details on how to use the tool and interpret the results.

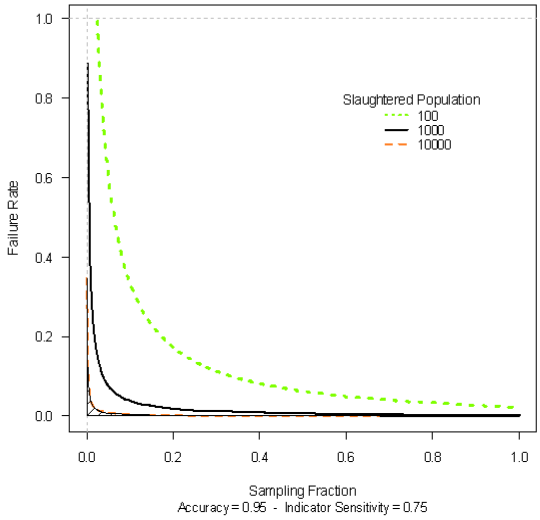
3. Results

3.1. The resulting model for the sampling protocol

Using the five parameters of the model presented in Equation 1 (see page 8), it is possible to calculate each of them if the other four are specified. To illustrate the influence of the different parameters, the full range for Failure Rate and Sampling Fraction values (both going from 0 to 1) were combined with (a) the sensitivity of the indicator, (b) the slaughter population of the slaughterhouse[10] and (c) the desired accuracy of the sampling protocol[11] whilst keeping the other two parameters constant in each case. The impacts of different indicator sensitivity, slaughter population and accuracy values are presented in Figure 2a, 2b and 2c.



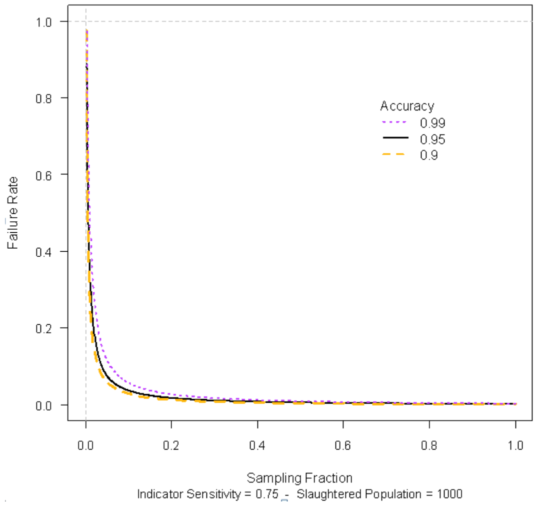
(a) The effect of SF on threshold FR for three levels of indicator sensitivity (0.5, 0,75 and 1), given a slaughter population of 1000 animals and an accuracy of 0.95.



(b) The effect of SF on threshold FR for three levels of slaughter population (100, 1000 and 10000), given an accuracy of 0.95 and indicator sensitivity of 0.75.

[10] The total number of animals being stunned during a given period according to the type of the slaughterhouse and the species slaughtered (see Section 2.3.1).

[11] Percentage of situations in which the sampling protocol was applied and served its purpose, i.e. raising an alarm if there were more ineffectively stunned animals than the prescribed failure rate would allow (see Section 2.3.1).



(c) The effect of SF on threshold FR for three levels of accuracy (0.9, 0.95 and 0.99), given a slaughter population of 1 000 animals and indicator sensitivity of 0.75.

Figure 1: Effect of SF on threshold FR for three levels of indicator sensitivity (a), slaughter population (b) and accuracy (c), given a slaughter population of 1 000 animals (a, c), an accuracy of 0.95 (a, b) and indicator sensitivity of 0.75 (b, c)
Each *x*–*y*-coordinate in the diagrams represents a single possible sampling protocol.

Those sampling protocols that fall below the line describing that combination of parameters will not be able to meet the purpose of detecting if FR is exceeded; those protocols above the line will meet the required purpose and raise an alarm.

Table 1a, 1b and 1c show numerical examples of FR's for three levels of indicator sensitivity, SF and sampling protocol accuracy.

Table 1: Effect of SF on threshold FR for three levels of (a) indicator sensitivity, given a slaughter population of 1 000 animals and accuracy of 0.95; (b) slaughter population, given an accuracy of 0.95 and indicator sensitivity of 0.75; and (c) accuracy, given a slaughter population of 1000 animals and indicator sensitivity of 0.75

(a) Effect of SF on threshold FR for three levels of indicator sensitivity (0.5, 0,75 and 1), given a slaughter population of 1 000 animals and accuracy of 0.95

Sampling fraction	**Threshold failure rate**		
	Indicator sensitivity = 0.5	**Indicator sensitivity = 0.75**	**Indicator sensitivity = 1**
0.1	0.058	0.038	0.028
0.2	0.028	0.018	0.013
0.3	0.018	0.012	0.008
0.4	0.013	0.008	0.006
0.5	0.01	0.006	0.004
0.6	0.008	0.005	0.003
0.7	0.007	0.004	0.002
0.8	0.006	0.003	0.002
0.9	0.005	0.003	0.001
1	0.004	0.002	NA

(b) Effect of SF on threshold FR for three levels of slaughter population (100, 1 000 and 10 000 animals), given an accuracy of 0.95 and indicator sensitivity of 0.75.

Sampling fraction	**Threshold failure rate**		
	***n* = 100**	***n* = 1 000**	***n* = 10 000**
0.1	0.34	0.04	0
0.2	0.17	0.02	0
0.3	0.11	0.01	0
0.4	0.08	0.01	0
0.5	0.06	0.01	0
0.6	0.05	0.01	0
0.7	0.04	0	0
0.8	0.03	0	0
0.9	0.03	0	0
1	0.02	0	0

(c) Effect of SF on threshold FR for three levels of accuracy (0.9, 0.95 and 0.99), given a slaughter population of 1 000 animals and indicator sensitivity of 0.75.

Sampling fraction	**Threshold failure rate**		
	Accuracy = 0.9	**Accuracy = 0.95**	**Accuracy = 0.99**
0.1	0.029	0.038	0.058
0.2	0.014	0.018	0.028
0.3	0.009	0.012	0.018
0.4	0.006	0.008	0.013
0.5	0.005	0.006	0.01
0.6	0.004	0.005	0.008
0.7	0.003	0.004	0.006
0.8	0.003	0.003	0.005
0.9	0.002	0.003	0.004
1	0.002	0.002	0.003

4. The development of a tool for calculation of sample size

Independently of the species and methods, a tool was developed to provide all relevant stakeholders, including Food Business Operators, with a simple and user-friendly software application to enable them to have an estimation about: i) sample size needed, given a fixed failure rate considered acceptable; ii) expected failure rate, given the sample size.

4.1. Software

Considering the potential customers of the tool, it was agreed that this latter should not be developed using tools that would require a licence, nor using tools that require particular skills on computer programming or statistical softwares.

For these reasons, the choice for the development of the tool fell on Microsoft Excel[12].

4.2. Tool availability

The tool is available upon request to the EFSA SAS unit by filling in the form in Appendix B. and sending it, after scanning, to SAS@efsa.europa.eu.

[12] Microsoft. Microsoft Office Excel. Redmond, Washington: Microsoft, 2007. Computer Software.

RECOMMENDATIONS

The tool has been tested in EFSA by simulating realistic situations where different stakeholders could question the tool to obtain relevant information on the performance of the stunning procedures. The tool fitted the expected requirements.

However, it has to be highlighted that the choice of the parameters to be inputted in the tool (and therefore in the underpinning model) is crucial: all values have to be carefully determined beforehand and based on the thorough assessment and criteria developed in the scientific opinions of the AHAW Panel on "Monitoring procedures at slaughterhouses for bovines", "Monitoring procedures at slaughterhouses for sheep and goats", "Monitoring procedures at slaughterhouses for pigs" and "Monitoring procedures at slaughterhouses for poultry" (EFSA, 2013a, b, c and d).

REFERENCES

Cannon RM, 2001. Sense and sensitivity – designing surveys based on an imperfect test. Preventive Veterinary Medicine, 49(2001) 141-163

EFSA AHAW Panel (EFSA Panel on Animal Health and Welfare), 2013a. Scientific Opinion on monitoring procedures at slaughterhouses for bovines. EFSA Journal 2013;11(12):3460, 18 pp. doi:10.2903/j.efsa.2013.3460

EFSA AHAW Panel (EFSA Panel on Animal Health and Welfare), 2013b. Scientific Opinion on monitoring procedures at slaughterhouses for pigs. EFSA Journal 2013;11(12):3523, 18 pp. doi:10.2903/j.efsa.2013.3523

EFSA AHAW Panel (EFSA Panel on Animal Health and Welfare), 2013c. Scientific Opinion on monitoring procedures at slaughterhouses for poultry. EFSA Journal 2013;11(12):3521, 18 pp. doi:10.2903/j.efsa.2013.3521

EFSA AHAW Panel (EFSA Panel on Animal Health and Welfare), 2013d. Scientific Opinion on monitoring procedures at slaughterhouses for sheep and goats. EFSA Journal 2013;11(12):3522, 18 pp. doi:10.2903/j.efsa.2013.3522

Martin PAJ, Cameron AR and Greiner M, 2007. Demonstrating freedom from disease using multiple complex data sources – 1: A new methodology based on scenario trees. Preventive Veterinary Medicine, 79(2007) 71-97

APPENDICES

Appendix A. USER MANUAL

- **ESTIMATION OF THE SAMPLE SIZE**

Figure 1 shows the screenshot of spreadsheet "from FR to ss". This calculation sheet allows to calculate the required sample size according to the parameters set.

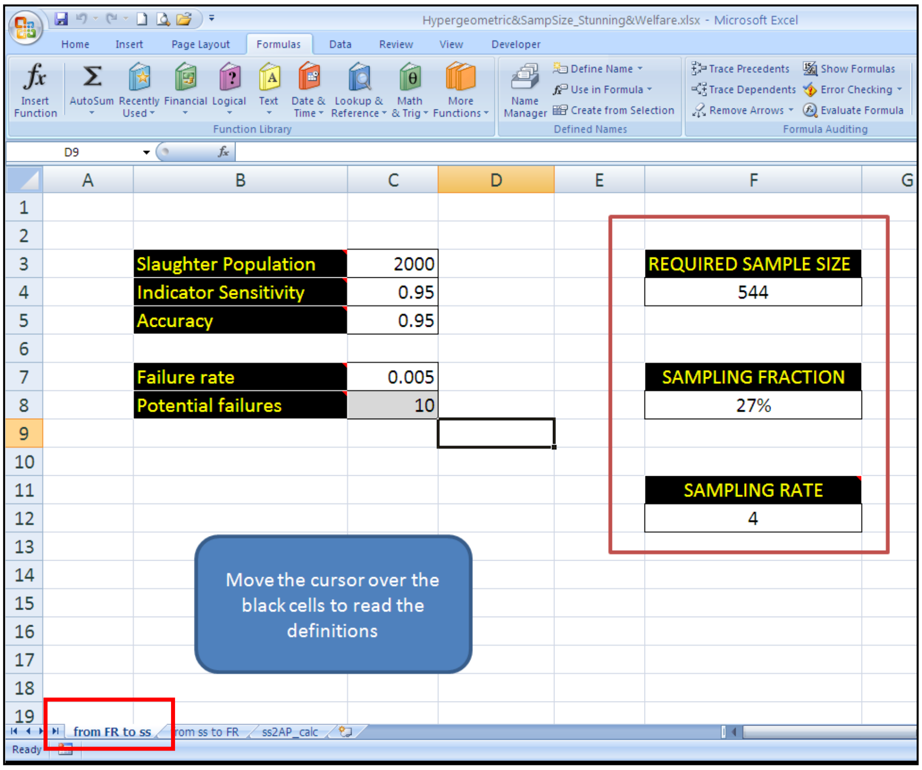


Figure 1: Screenshot of spreadsheet "from FR to ss".

The data have to be inputted in the white cells on the left of the calculation sheet (see Figure 2). The gray cells are calculated values. Both workbooks and spreadsheets are protected, so there is no risk of modifying hidden equations and functions.

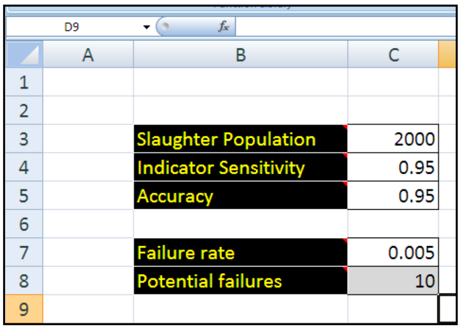


Figure 2: input values

The tool provides the user with pop-up definitions of the variables: moving the cursor over the black cells (the ones with the name of the variable inside) it is possible to automatically visualise the description of the value that needs to be inputted (see Figure 3).

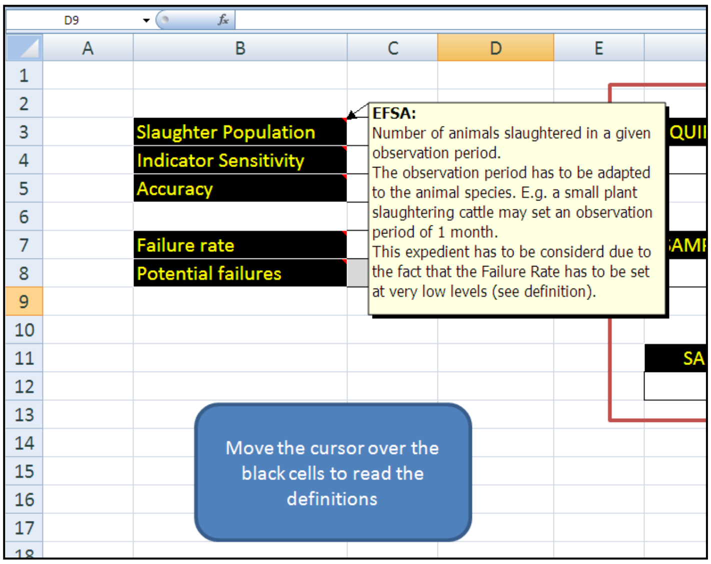


Figure 3: pop-up definitions

The values appearing on the right of the screen, surrounded by a red square, are the output of the calculation (see Figure 4).

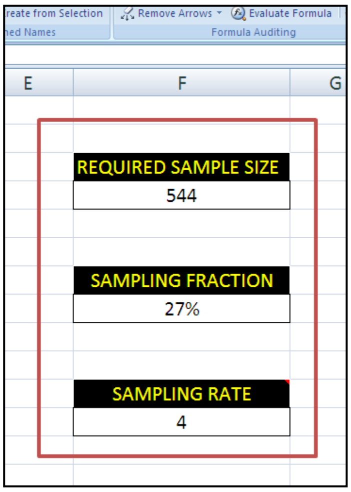


Figure 4: results of the calculation

- **ESTIMATION OF THE POTENTIAL FAILURE RATE**

Figure 5 shows the screenshot of spreadsheet "from FR to ss". This calculation sheet allows to calculate the potential failure rate according to the parameters set, particularly the sample size.

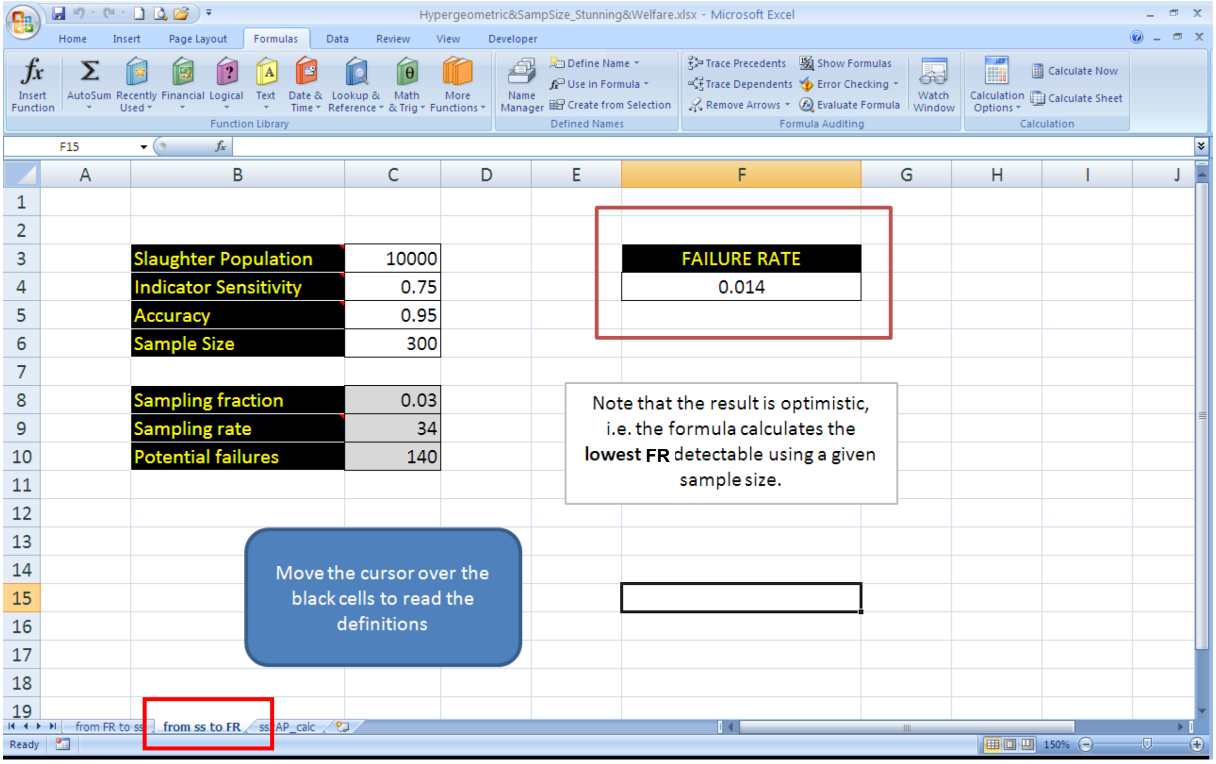
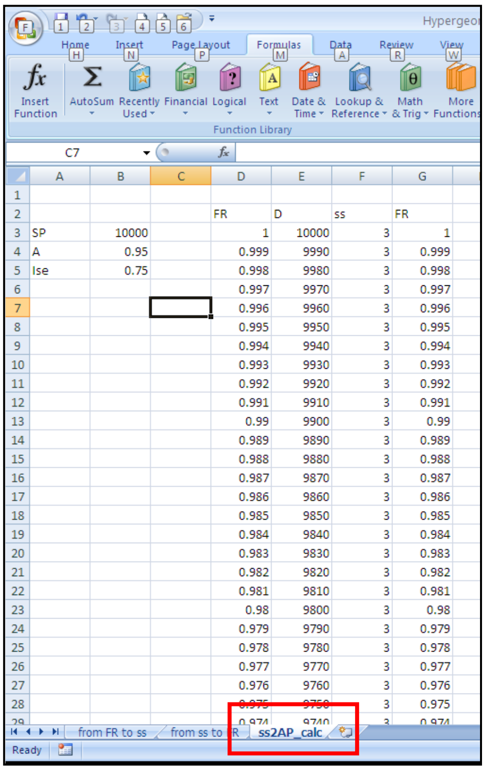


Figure 5: Screenshot of spreadsheet "from ss to FR".

As for the "from FR to ss "spreadsheet, the data have to be inputted in the white cells on the left of the calculation sheet. The gray cells are calculated values. Both workbooks and spreadsheets are protected, so there is no risk of modifying hidden equations and functions.

Also in this case, pop-up definitions of the variables are available: moving the cursor over the black cells (the ones with the name of the variable inside) it is possible to automatically visualise the description of the value that needs to be inputted.
The value appearing on the right of the screen, surrounded by a red square, is the output of the calculation.

The last spreadsheet (ss2AP_calc), showed in Figure 6, is just a calculation sheet needed in order to obtain the desired parameter to be estimated. This sheet is necessary as Equation 1 is not analytically solvable fro the FR. The user will not be able to see this spreadsheet.



	A	B	C	D	E	F	G
1							
2				FR	D	ss	FR
3	SP	10000		1	10000	3	1
4	A	0.95		0.999	9990	3	0.999
5	lse	0.75		0.998	9980	3	0.998
6				0.997	9970	3	0.997
7				0.996	9960	3	0.996
8				0.995	9950	3	0.995
9				0.994	9940	3	0.994
10				0.993	9930	3	0.993
11				0.992	9920	3	0.992
12				0.991	9910	3	0.991
13				0.99	9900	3	0.99
14				0.989	9890	3	0.989
15				0.988	9880	3	0.988
16				0.987	9870	3	0.987
17				0.986	9860	3	0.986
18				0.985	9850	3	0.985
19				0.984	9840	3	0.984
20				0.983	9830	3	0.983
21				0.982	9820	3	0.982
22				0.981	9810	3	0.981
23				0.98	9800	3	0.98
24				0.979	9790	3	0.979
25				0.978	9780	3	0.978
26				0.977	9770	3	0.977
27				0.976	9760	3	0.976
28				0.975	9750	3	0.975
29				0.974	9740	3	0.974

Figure 6: calculation sheet for the "from ss to FR" spreadsheet

Appendix B. DECLARATION

DECLARATION REGARDING USE OF THE EFSA SSTUN MODEL, VERSION 1.0

SURNAME:____
FIRST NAME:____
TITLE/FUNCTION:_______________________________________
AFFILIATION:____
USE OF THE *SStun* APPLICATION INTERFACE (Please explain with detail):
____
____

I hereby declare that I am aware that the European Food Safety Authority (EFSA) is the owner of the SStun application interface I am receiving and therefore I am allowed to make limited use of it under conditions hereunder detailed, but not limited to them:

I fully commit to the following:

- Not to transfer the EFSA SStun application interface to any natural or legal person or institution.
- Not to make commercial use of the SStun application interface or further develop the model or use it to create another model.
- I am responsible for the interpretation and use I am doing of the SStun application interface and the accompanying documentation.
- Any distribution or publication of information (e.g. publications, reports, posters) arising from the use of the EFSA SStun application interface shall require prior written authorisation from the Authority.
- I shall provide EFSA with a copy of any report and publication that would have been produced using the SStun application interface received.
- Where the EFSA SStun application interface has been used, reference to the model should be made as following: EFSA, 2013. EFSA Sample Size and Stunning (EFSA *SStun* model), version 1.0 – application interface developed by EFSA. This application interface can be made available upon request to sas@efsa.europa.eu.
- The use I do of the SStun application interface and its accompanying documentation shall include the suggested citation and I shall always indicate that all statements made by me exclusively expresses my opinion and does not in any way represent EFSA's official position.
- I shall add a disclaimer in all communications I make referring to the EFSA SStun application interface: "The present document has been produced and adopted by the bodies identified above as author(s). The views and findings in this article are solely those of the author and do not necessarily reflect the views or position of the European Food Safety Authority."

I acknowledge that EFSA has taken precautions in creating the EFSA SStun application interface, version 1.0 and the documentation accompanying it. However, EFSA is not responsible for errors, omissions or deficiencies regarding the system and the accompanying documentation. The application interface and the accompanying documentation were developed in the context of the Mandate number M-2012-0281, and are being made available as such without any warranty either expressed or implied, including, but not limited to, warranties of performance, merchantability, and fitness for a particular purpose.

EFSA is not regularly updating the SStun application interface and the accompanying documentation. However, EFSA will inform the users in case an update of the application interface is available.

In no event shall EFSA be liable for direct, indirect, special, incidental, or consequential damages resulting from the use, misuse, or inability to use the application interface and the accompanying documentation.

Done at   on

Signature

GLOSSARY

Accuracy of the sampling protocol: percentage of situations in which the sampling protocol was applied and served its purpose, i.e. raising an alarm if there were more ineffectively stunned animals than the prescribed threshold failure rate would allow. This corresponds to confidence level in freedom from disease methodologies.

Feasibility of an indicator: considered in relation to physical aspects of its implementation. These include, for example, the position of the animal relative to the assessor, the assessor's access to the animal and the line speed. Feasibility for the purpose of this opinion does not include economic aspects.

Sampling fraction: proportion of the slaughter population which has to be tested (i.e. on which the consciousness has to be assessed) in order to achieve the desired accuracy when stating that the failure rate is below the set threshold.

Sensitivity of the indicators: probability that a truly conscious animal is correctly classified as conscious. This probability can also be interpreted as the percentage of truly conscious animals detected as conscious by the indicator. This corresponds to diagnostic test sensitivity in freedom from disease methodologies.

Slaughter population: a group of animals with homogeneous individual characteristics and being slaughtered under the same circumstances as determined by risk factors (see EFSA, 2013a, b, c and d).

Specificity of the indicators: probability that a truly unconscious animal is correctly classified as unconscious. This probability can also be interpreted as the percentage of truly unconscious animals classified as unconscious by the indicator. This corresponds to diagnostic test specificity in freedom from disease methodologies. Note that in this particular framework the specificity of the indicator is assumed to be 100% (see Section 2.1).

Threshold failure rate for proportion of mis-stunned animals: minimum proportion of animals that are ineffectively stunned, but which will still be detected by the sampling protocol. This corresponds to design prevalence in freedom from disease methodologies.