ICSMS
Quality Control

Re-engineered version

2014 update

ICSMS – Quality Control

- Quality control guidance was circulated by the EU Commission at last years meeting
- The suggested method was for “managers etc” to sample entries made by their staff and to highlight key missing, incorrect or poor data
- It was hoped this could help to identify where extra training or coaching was needed

ICSMS – Quality Control

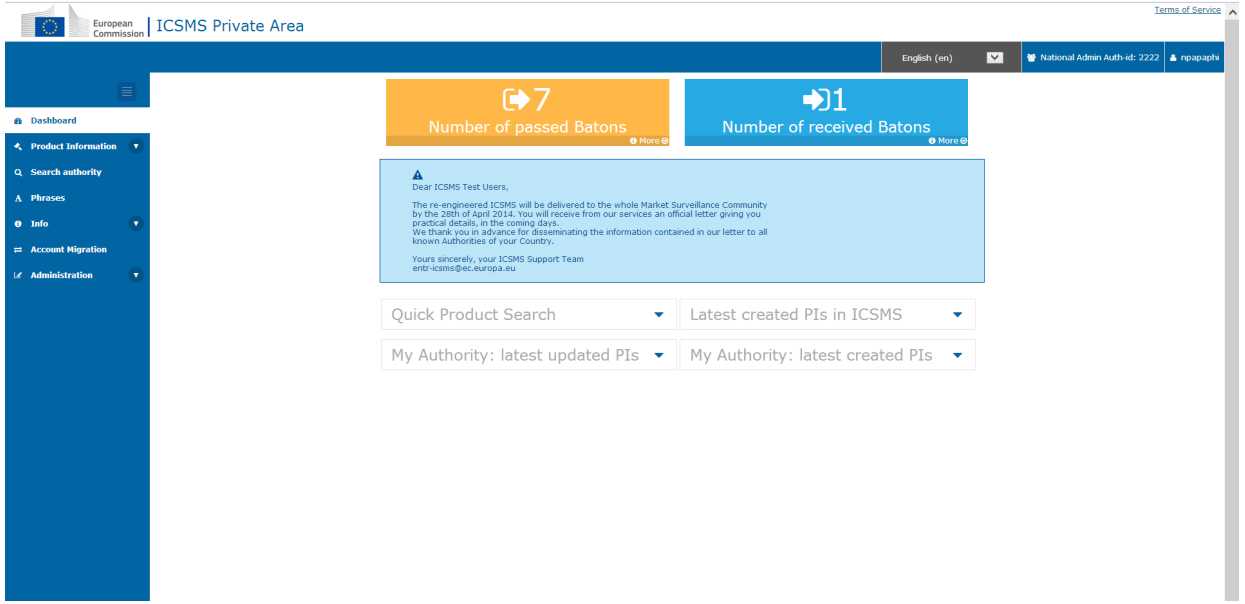
- **This presentation and paper are updates and includes sample outputs that indicate improvements to key area's data quality is needed**
- **The quality of the data in ICSMS is important to ensure:**
  - a search for PIs identifies them correctly and thus stops duplicate work
  - effective targeting of products for surveillance based on analyses of the database
  - accurate outputs for reports that may inform policy development

ICSMS – Quality Control

- Both the old and re-engineered version of ICSMS use the single entry approach for all legislation
- Field names and meanings may not match the needs of many Directives
- The Directive Related Product Information (DRPI) version should help to improve input quality
- Until then attention is needed to ensure certain fields are completed as information becomes available and key fields are filled when the PI is complete
- Guidance on the meaning of particular fields is available in the “user guide”. To make this more accessible in the revised DRPI version “pop up” guides for each field will be implemented

Re-engineered ICSMS - sample analysis

- Ø Baton passing - the “re-engineered” ICSMS makes it much easier to keep track of Batons as numbers are shown when the user log on to the internal system.
- Ø This should help avoid delays



Sample analysis (mainly April 2014)– key observations

- **Search criteria (product key words) – Field 11**
  - field is being used, but in most cases it is a repeat of Field 12 – it should have alternative “names” for the product e.g. in Dummy” “Pacifier” and “Soother”
- **Product designation (English) – Field 12**
  - 19% of PIs had this field blank in April 2014
- **Brand – Field 14**
  - 45% of PIs had this field blank. This is an critical field also used by RAPEX (Manufacturer/supplier not shown on RAPEX) and also the best field to search on usually the prominent on product
- **Type / Model - Field 15**
  - 29% of completed Machines and LVD PIs had this field blank. Usually different models - critical to which was tested.

Sample analysis (mainly April 2014)– key observations

- **Country of Origin - Field 23**
  - 60% of completed PIs had this field blank. Field is important for proactive work, e.g. on border control.
- **Directives / Regulations - Field 31**
  - For Completed PIs only 5% found blank. This should not occur because if no Directive applies then “no Directive applies” should be used.

    Note, only Directives that are the subject to examination should be listed. If others are listed it suggests a product has been tested for these also - will be resolved under DRPI
- **CE marking - Field 33**
  - Well completed with only 3% blank for Completed PIs.

Sample analysis (mainly April 2014)– key observations

- **Testing and Examination – Fields 48 to 52**
  - These reports should be only what the Authority have done or commissioned, and not any that the manufacturer has produced or had completed.
  - Any manufacturer's reports can be uploaded in Field 74

Sample analysis (mainly April 2014)– key observations

Ø Defect risks classification – Field 55

- Ø 32 % of Machinery Completed PIs had this field blank in 2014! Classification is critical both for RAPEX notification but also to judge the priority for action. Also people with Subscriptions often restrict these to type 3 & 4 risks, so they will not see this 32%

- Ø Note, if no risk identified category “0” can be used. For “non-safety” type Directives/Regulations this classification is problematic. This issue will be considered and suggestions to improve guidance and possibly modifications made.

Sample analysis (mainly April 2014)– key observations

- **Description of defects – Field 56**
  - 44 % of all Machinery completed PIs in 2014 had this field blank. Many were low risks (1) but 9% were for high risks (3). This is vital information needing to look at engineer's reports is not a solution.
- **Status – Field 65**
  - 12% of all PIs up to 28 April 2013 were shown as "not complete". Are these investigations ongoing?
- **Visibility of information for EU/EFTA authorities – Field 73**
  - Most PIs were open for EU/EFTA authorities, only a small number of older PIs were "internal only". This category should only be used, if at all, at initial stages e.g. when trainees have input the data and it is yet to be checked

Guidance on Quality Checking – updated for the re-engineered version of ICSMS

- **No fundamental change in approach from that issued last year** – the ICSMS screens look different but the fields numbers and in most cases the names are the same.
- **The approach continues to be: taking a sample of the entries and to manually check for key missing or incorrect data, and that completed investigations are not left "open". This may show a training need.**
- **Question 1**
  Have you found this approach useful and has it highlighted any particular problems or misunderstandings that are very common among your officers / authorities?

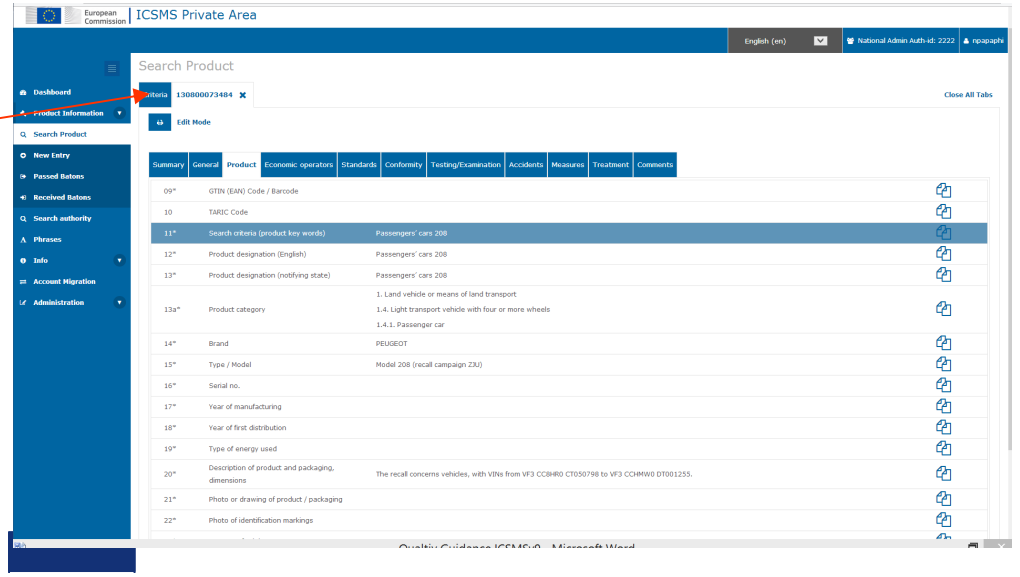
  This information will be useful to help improve guidance and also inform the structure of future improvements to the system

Quality checks – changes from 2013

- **09 GTIN (EAN) Code / Barcode & 11 Search criteria (Product Key Words)**
  - "Wild cards" are not supported in the new ICSMS (searches now bring up matches that contain the chosen criteria). This means it is no longer possible to search for all entries with something in a field by putting in a wild card (*). So the method of finding the number of blank field 09/11 by the above and taking this from the total number is not possible - manually check a sample.

Note when checking remember NOT to use the window back arrow from a PI to the list of PIs, but to use the Criteria button

If you try to look at more than 5 PIs, the system will not let you, until you have deleted the previous "links" from the top of the screen (see paper)



Quality checks – changes from 2013

- **32 Standards**
  - Covers two requirements: what the presumption of conformity has been claimed under and secondly what the Authority has used in the examination. It is suggested that only Standards used in the examination by the Authority are entered (we may need two fields in the future)

Question 2 to delegates

Do you agree with this suggestion of limited the listing of standards, which is a different approach to the one currently used in the ”ICSMS user guide”?

- **55 Defect risk classification**
  - Field is problematic for “non-safety” Directives / Regulations and consideration is being given if better guidance can be provided.

Question 3 to Delegates

Do you think it could be useful to have a “Seriousness of non-compliance” field?

Quality checks – changes from 2013

- **72 - Prohibition Order**
  - Changed from “Interdiction decree” as it was not understood, and each MS has its own legal approach. The meaning is: **a legal document that requires a person or firm to: stop the process; using the product; or stop selling the product**. If they fail to obey the Prohibition Order then they are liable for prosecution, as non compliance is considered a very serious offence
- **73 Visibility of information**
  - "National" should normally only be used at the initial stage. It is suggested that either this is not used at all or only used for a very limited period.

Question 4 to Delegates
Do you think the “National” visibility field is useful and if so when / where should it be used?