US EPA ARCHIVE DOCUMENT

E-Submission Preparation and Quality Checks

PPDC PRIA Process Improvement Workgroup Meeting

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Chair, CLA E-Submissions Working Group

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E-Submission Preparation & Quality Checks

- **Topics**
  - History
  - BASF 'XML Builder'
  - Quality Checks – Pre/Post Electronic
  - Questions

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E-Submission Preparation & Quality Checks

- **History**
  - First e-Submission: picolinafen (BAS 700 H) in 2000 (Cyanamid) to PMRA
  - First EPA e-Submission: boscalid (BAS 510 F) in 2001 (BASF)
  - From 2001-2007, ca. 55 paper/e-Subs completed. Compiled in MRID folder hierarchy format with 'smart' PDFs.
  - From 2008 – present, ca. 125 paper/e-Subs completed. (MRID folder hierarchy format)

    ca. 175 e-subs in XML/PDF format only!

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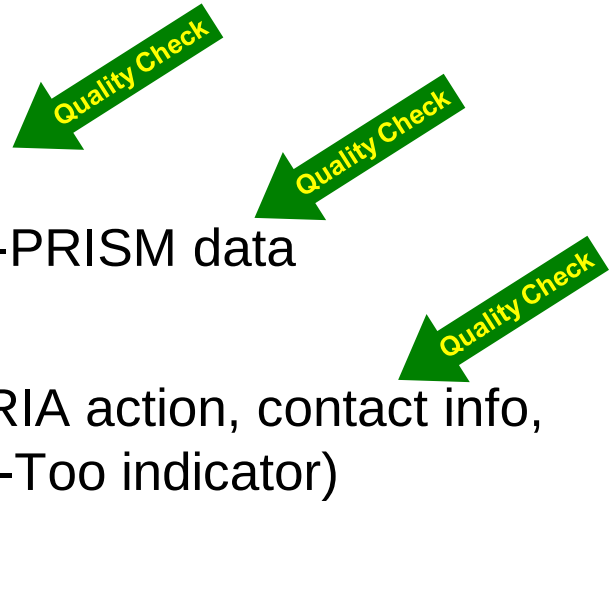
e-Sub Categories

- Currently, e-Subs can only be sent in for…
  - Section 3's
  - EUP's
  - Tolerance petitions
  - Distributor products
- 6(a)(2) 8ee – can be handled as well provided it refers to an existing Sec. 3 registration
- Others under consideration *(which are also PRIA actions)*
  - "Pre-Application" applications
  - Inert Ingredient clearances
- Data call-ins – tracked differently and would not interface with current e-Sub system. Changes may be made to accommodate these.

E-Submission Preparation & Quality Checks

- **BASF 'XML Builder'**
  - Java-based web application front-end that contains all elements of the E-PRISM data dictionary and interfaces directly to our Documentum study report system (REGY)
    - Allows input of BASF Reg. Doc. #s
    - Extracts metadata from Documentum
    - Pre-selected and enduser-selected E-PRISM data *(e.g CBI designation)*
    - Handles ALL mandatory fields (e.g PRIA action, contact info, registration type, application type, Me-Too indicator)
    - Compiles final XML file



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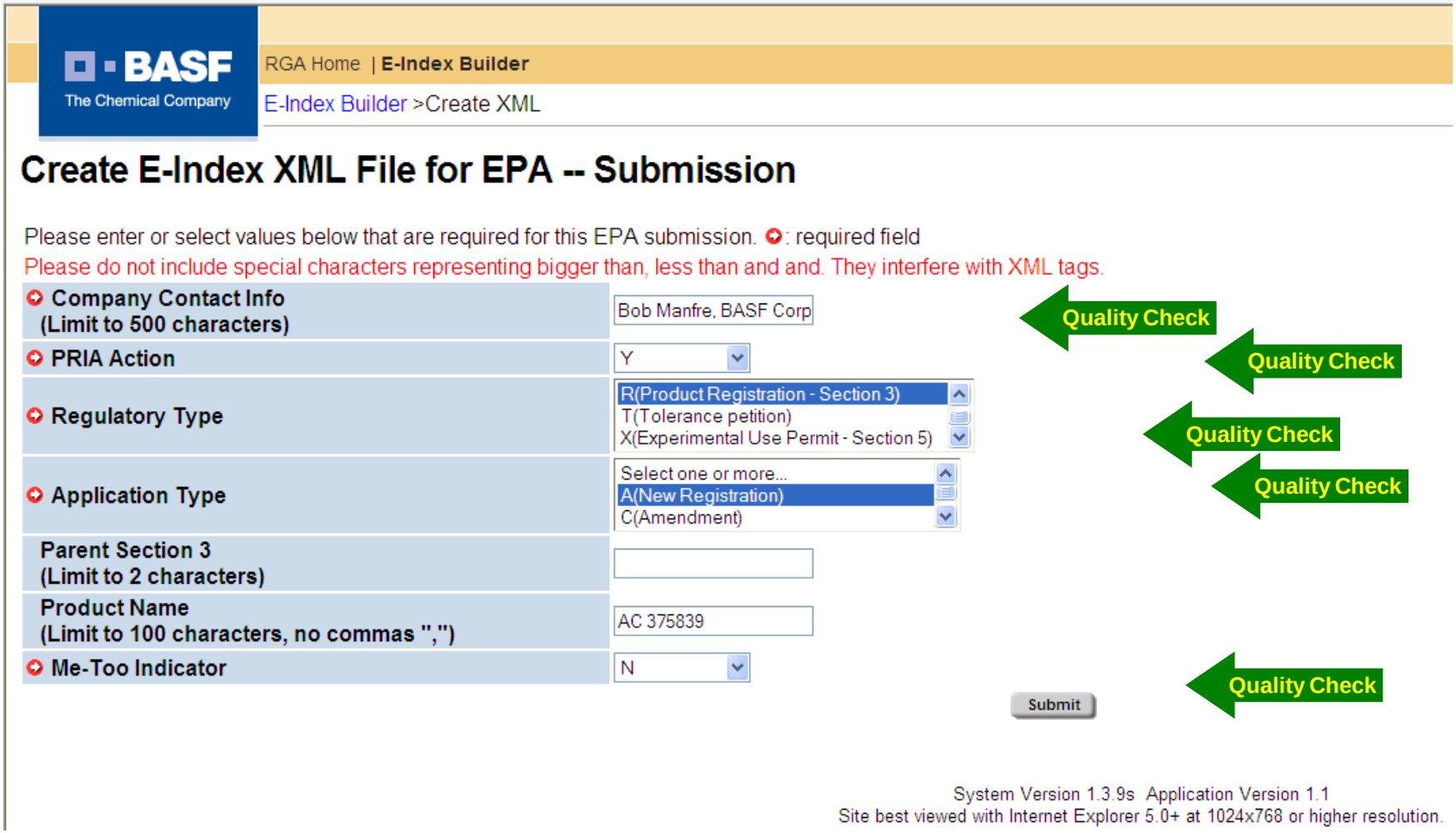

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REGY Metadata

Report No.:	2000/7000144
Title:	AC 375839 (CL 375839): Storage stability of AC 375839 residues at less than -18°C in grapes and wine
Author(s)	Class, T.
Completion Date	2000-10-27
MRID	
Lab Report No	US-P 384 G, US-CFS DER 138
Published	N
EPA Guidelines	EPA 860.1000 EPA 860.1380

XML File Record

Note:
All enduser-selected data is stored back in REGY for potential re-use

OECD Data Point(Cannot have commas, please use semi-colon or other delimiters)	IIA 6.1.1		
Document Type	ST(Study)		
Product Name(Limit to 100 characters, no commas ",")	AC 375839		
Document Group	Metabolism and Residue		
Admin Number Type	Select one...	Admin Number	
Admin Number Type	Select one...	Admin Number	
Admin Number Type	Select one...	Admin Number	
CBI Status (EPA)	0(No CBI)		
Content Category	01(Complete primary report -- experimental research)		
Guideline Number	860.1340 Residue analytical method 860.1360 Multiresidue method 860.1380 Storage stability data 860.1400 Water, fish, and irrigated crops 860.1460 Food handling 860.1480 Meat/milk/poultry/eggs		
Number of Pages (Required by EPA for Studies only, must be a number)	110		
Select a File (file name cannot have commas ",")	C:\Documents and Settings\manfrer\My Documents\My Docume	Browse...	

Quality Check

Quality Check

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- XML file is combined with all PDFs and zipped
- Prior to zipping, we run a small Visual Basic app "E-PRISM Validator" to check if any PDFs are duplicated *(not allowed)* **Quality Check**
- Zip file is burned to CD
- CD is checked by re-opening all files **Quality Check**
- CD + copy of CD label are sent with request to pin-punch copy of CD label and return as proof of receipt. **Quality Check**
  (If paper sub only, 1st page of cover letter is requested for pin-punching.)

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E-Submission Preparation & Quality Checks

- **Items checked during proofing documents for an EPA submission**
  - No shading
  - No skewed pages
  - Legibility
  - All pages printed
  - No foreign language without translation
  - Signatures on pages 2 and 3
  - Page 2 = Company agent signature
  - Page 3 = Study Director, Sponsor & Submitter signatures
  - If page 3 refers to another page for the Study Director's signature, that page number is correct
  - Paginated with unique number (usually the Reg. Doc #) and page x of y
  - Confidential Appendices must be paginated separately from the study
  - No holes punched in data tables or report. This includes blank spaces from copying
  - Correct table / figure / appendix numbering

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