

# **A Batch Record Emission Calculation System**

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## **ABSTRACT**

The Batch Record Emission Calculation System (BR-Calc) is a Windows-based system to calculate, track and report VOC and HAP emissions in the batch production of pharmaceutical and specialty chemical products.

BR-Calc is a system that has been developed over the last six years at the Pfizer facility in Groton Connecticut. BR-Calc is based on US EPA Office of Quality Planning and Standards (OAQPS) calculation methods and has been utilized as a compliance tool for Title V and MACT applications.

BR-Calc maintains all individual unit operations by campaign/batch for each product in the system. Control devices are also tracked in the system to calculate pre- and post-control emissions. To verify the calculations, a detailed step-by-step printout of each unit operation's calculations is available with references in the calculations to the appropriate US EPA equation. The reports in the system are used to meet state, federal and internal reporting requirements.

BR-Calc has streamlined and significantly improved batch emission calculation and reporting capabilities at Pfizer to compile and report SARA, Title V and MACT data.

## **INTRODUCTION**

The Pfizer Plant, located in Groton, Connecticut, manufactures batch pharmaceutical products. Across the facility, different departments run campaigns producing various pharmaceutical products. The batch production operations taking place daily include hundreds of chemical processing steps and utilize various types of production equipment and control devices. In order to track and manage the environmental issues related to the manufacturing of batch pharmaceutical products, Pfizer created the Batch Emission Calculation and Reporting System (BR-Calc).

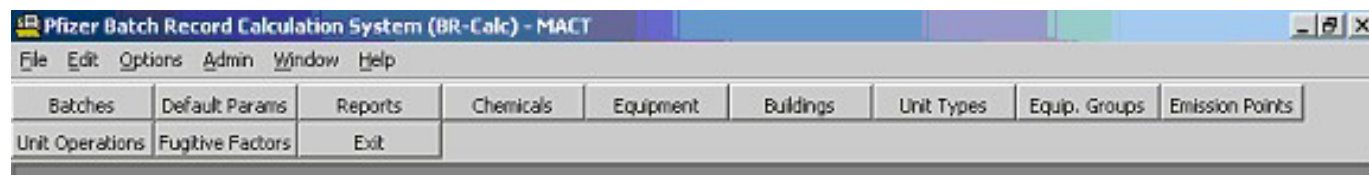
The Batch Record Emission Calculation System (BR-Calc) is a Windows-based system to calculate, track and report VOC and HAP emissions in the batch production of pharmaceutical and specialty chemical products. BR-Calc is based on US EPA Office of Quality Planning and Standards (OAQPS) calculation methods and has been utilized as a compliance tool for SARA, Title V and Maximum Achievable Control Technology (MACT) applications.

BR-Calc maintains all individual unit operations by campaign/batch for each product in the system. Control devices are also tracked in the system to calculate pre- and post-control emissions. To verify the calculations, a detailed step-by-step printout of each unit operation's calculations is available with references in the calculations to the appropriate US EPA equation. The reports in the system are used to meet state, federal and internal reporting requirements.

## BR-Calc SYSTEM

The BR-Calc system is a Windows-based program written in Microsoft's Visual Basic. The modules in the system consist of data entry for batch product information, reports and support databases. Figure 1 shows the main toolbar in BR-Calc.

Figure 1. BR-Calc main screen toolbar.

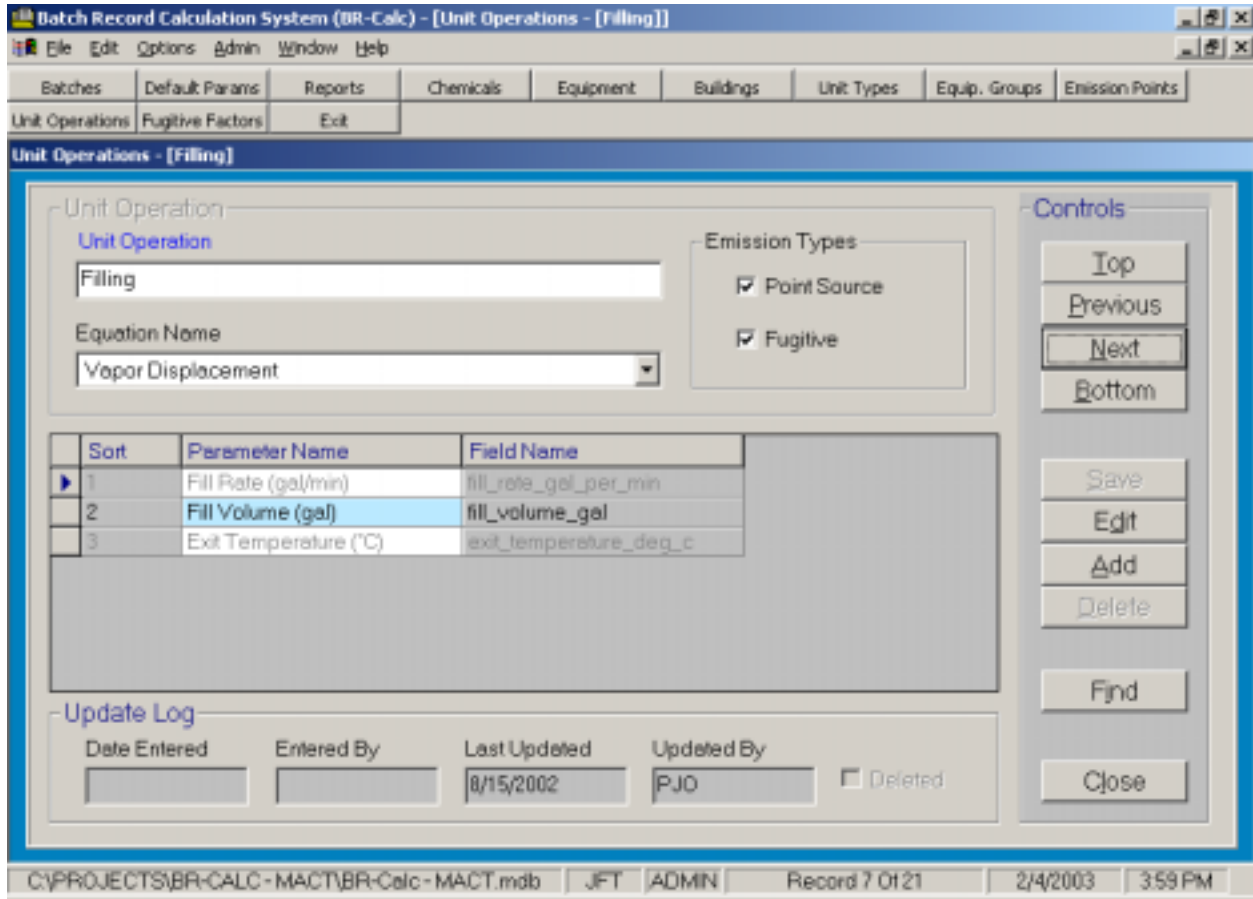


In BR-Calc users enter batch product information, produce reports or maintain support databases. The support tables contain information that is used throughout the system. BR-Calc's support tables are as follows:

- Chemicals
- Equipment
- Buildings
- Unit Types
- Equipment Groups
- Emission Points
- Unit Operations
- Fugitive Factors
- Default Parameters

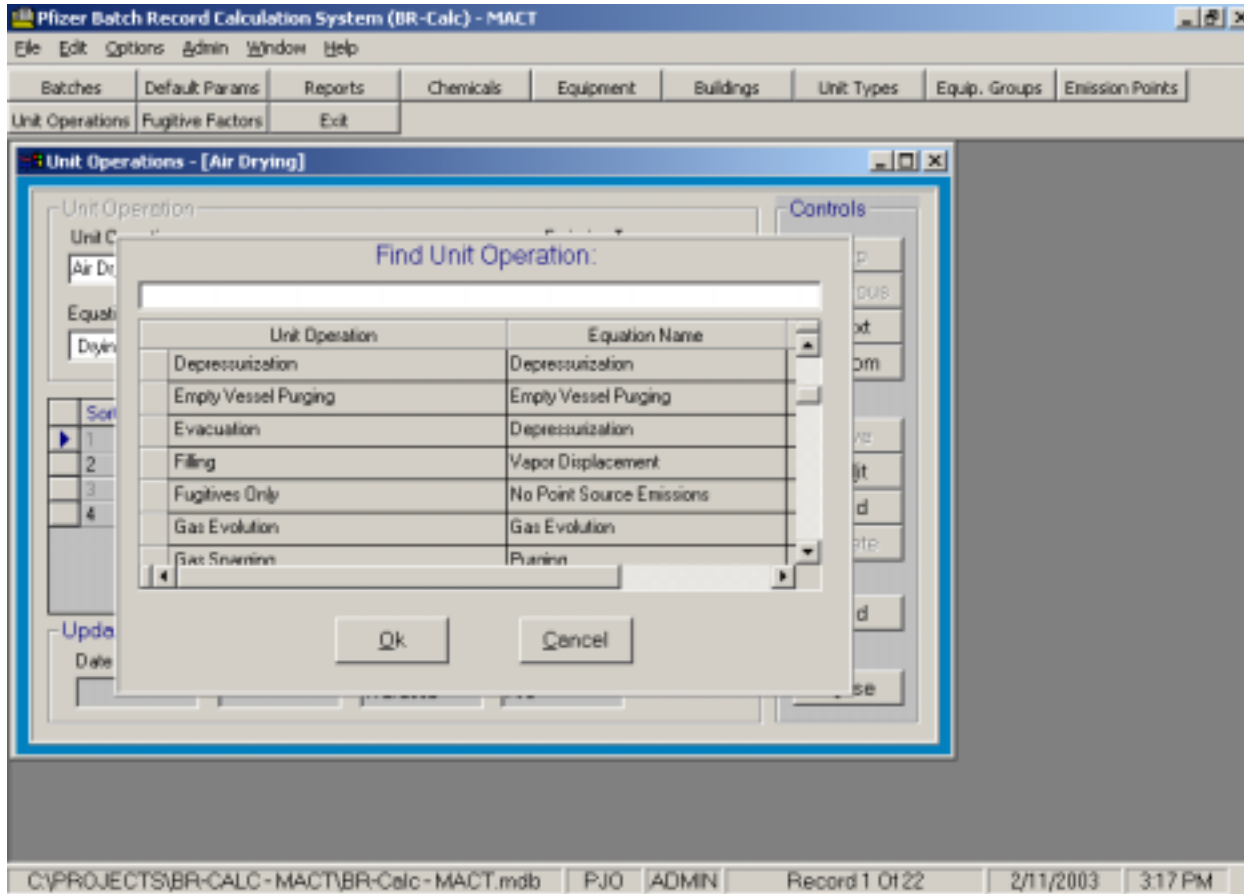
Each support table is a separate button in the BR-Calc toolbar. One example of the Support Tables for Unit Operations is shown in Figure 2. The Unit Operations table includes information on the operation type, equation type, required input parameters and the type of emission. Each record entry into BR-Calc also records an audit trail of who and when the record was created and last updated.

Figure 2. Support Table – Unit Operations



The maneuvering controls in Figure 2 are similar to those used throughout BR-Calc. The user can move through the records in the database with the Top, Previous, Next or Bottom button or use the Find button to display a grid of all records in the database (Figure 3).

Figure 3. Unit Operations support table find screen.

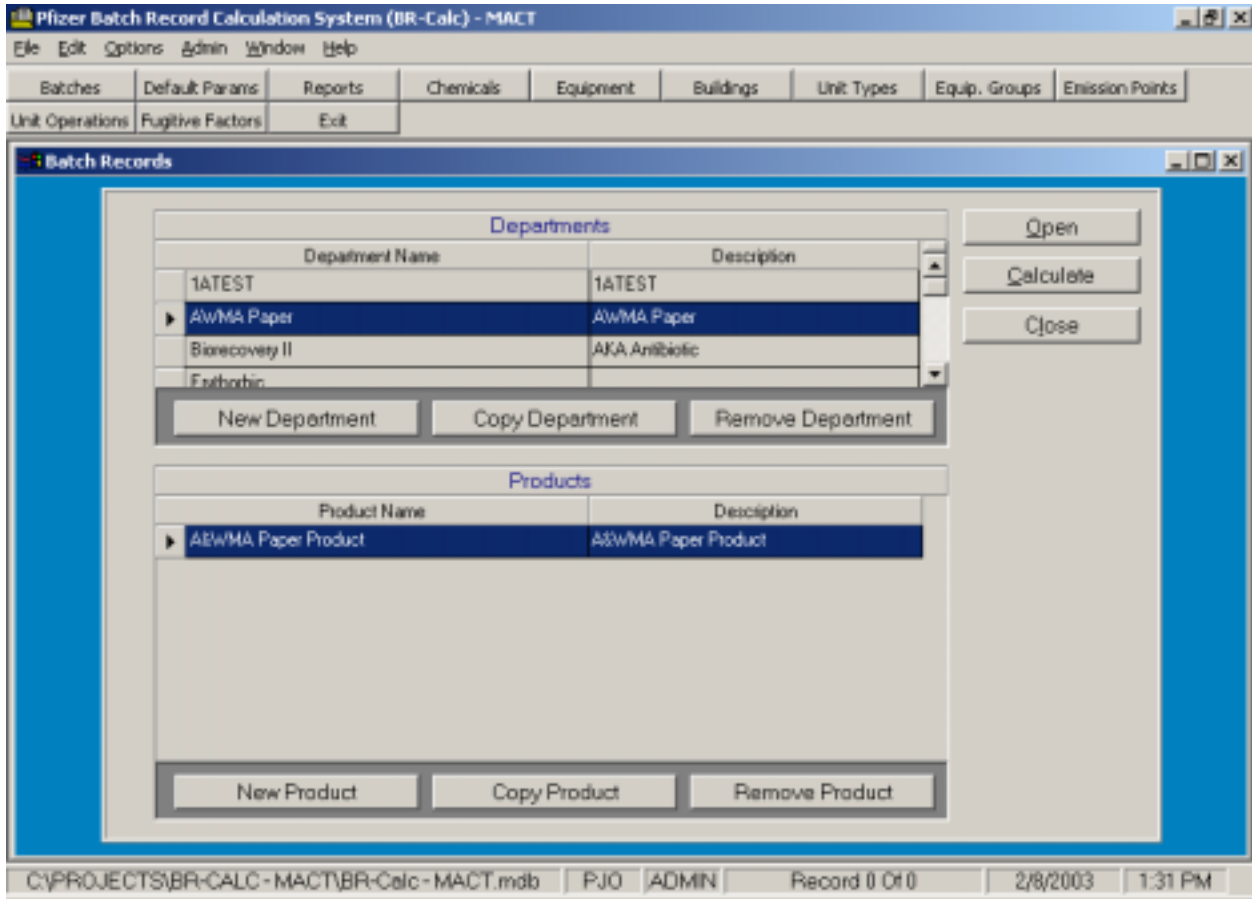


To modify existing data the user selects the Edit button. The Add button allows the user to enter a new unit operation type. After editing or adding new information, the user would press the Save button to save all of the new information.

The Delete button allows the user to remove records. BR-Calc also includes a restore function that will allow a user to “un-delete” a record that has been accidentally removed.

The entry of batch product information is in the Batches module. Pressing the Batches button displays the screen shown in Figure 4. This screen allows the user to select an existing department or create/remove a department. When a department is selected (highlighted), all of the existing products in the selected department are displayed in the bottom grid. In the products grid, the user can select a product to work with or add/remove products.

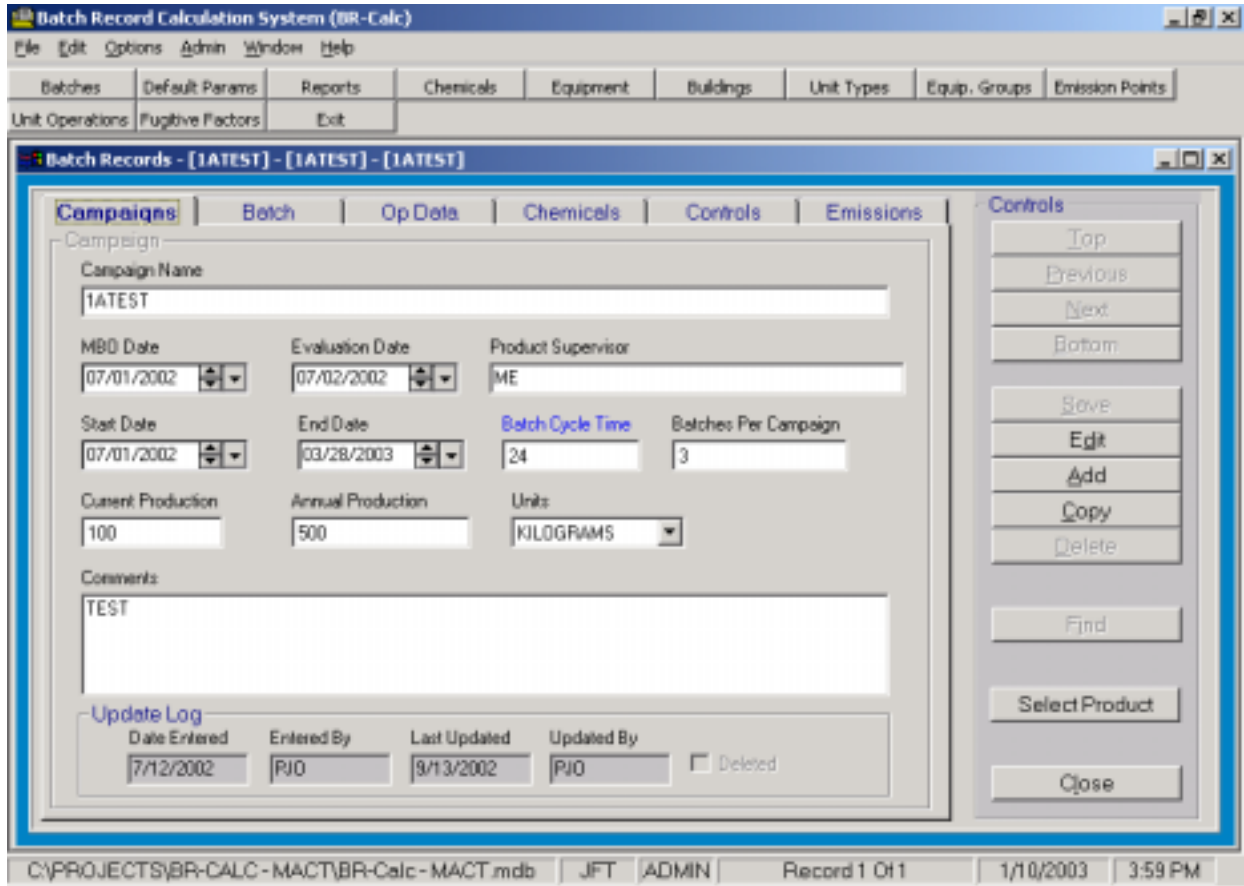
Figure 4. Batch Records Department / Product selection screen.



After selecting a product to work with, the user presses the Open button. Opening a product (Figure 5) displays the campaign screen for this product. Since this product can be run more than once, an individual record is stored detailing the start and stop date of each campaign as well as campaign production data, such as campaign identification number, number of batches, etc.

The campaign screen consists of a flip card that supplies detailed information on the individual batch operations, chemicals used in the process, control devices and emissions information at the batch record level.

Figure 5. Campaign Screen for a selected product.

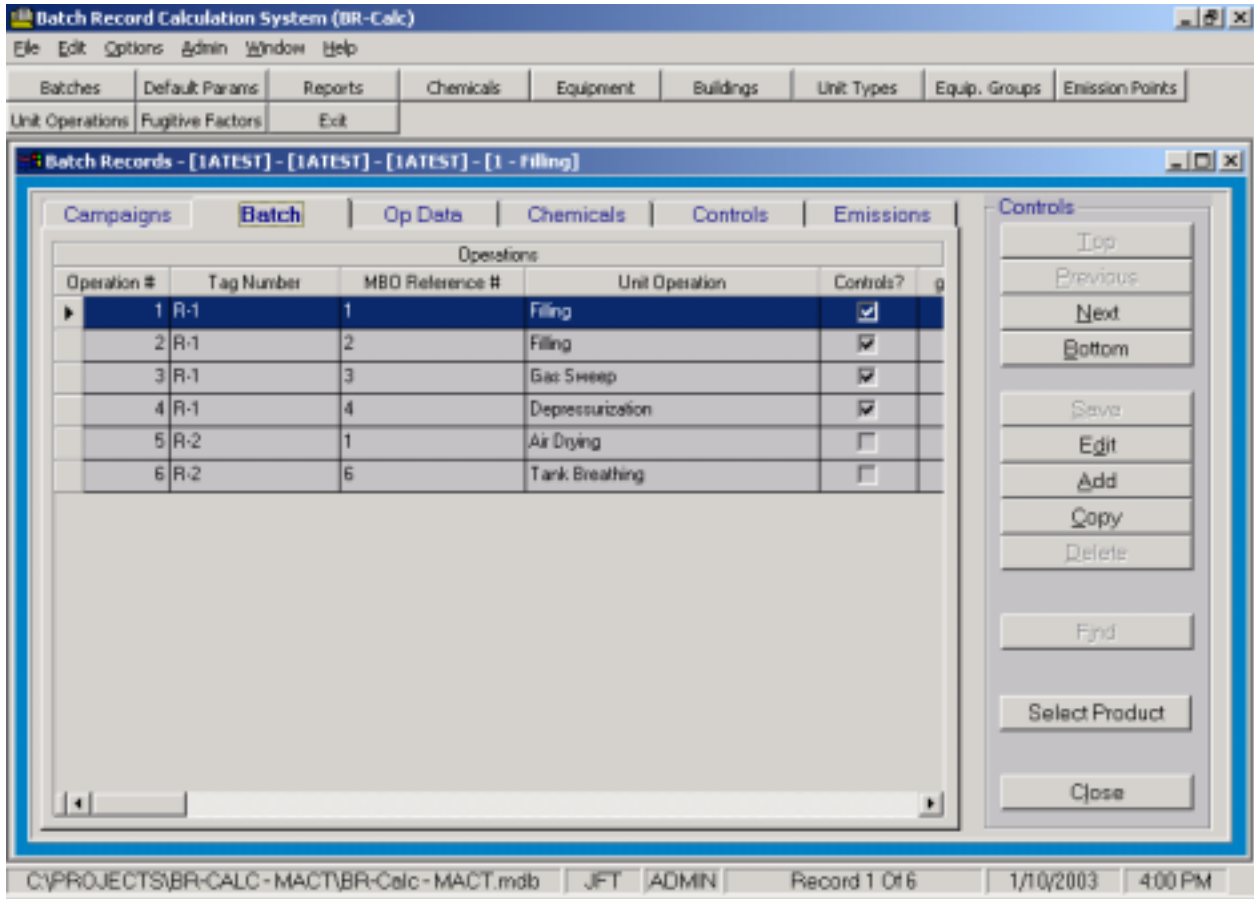


The Copy button at the campaign level allows the user to make a complete copy of the selected campaign including all batch record steps, chemicals and control devices.

Selecting the Batch tab (Figure 6) displays a grid of the individual unit operations that make up the entire batch record cycle. To add a new step to this batch record, the user presses the Add button. An option also exists to copy an existing batch record with all of its information and add it as a new record.

To look at the detailed information about an individual unit operation in the batch record the user clicks on a record in the grid. The selected record then becomes highlighted. Once a record is highlighted, the user can look at detailed input and emissions information for that unit operation.

Figure 6. Batch Record Grid



Selecting the Op Data tab on the flipcard (Figure 7) displays the input data for the selected individual unit operation. The unit operation input data fields will vary depending on the required information for a particular unit operation. Figure 7 displays an example for a vessel Filling operation. The required input fields are vessel fill rate, total fill volume, and exit temperature of gasses from the vessel. The user is also able to add on this screen any unit operation specific comments.

Figure 7. Unit operation Op Data input screen.

The screenshot displays the 'Batch Record Calculation System (BR-Calc)' software interface. The main window is titled 'Batch Records - [IATEST] - [IATEST] - [IATEST] - [1 - Filling]'. The interface is divided into several sections:

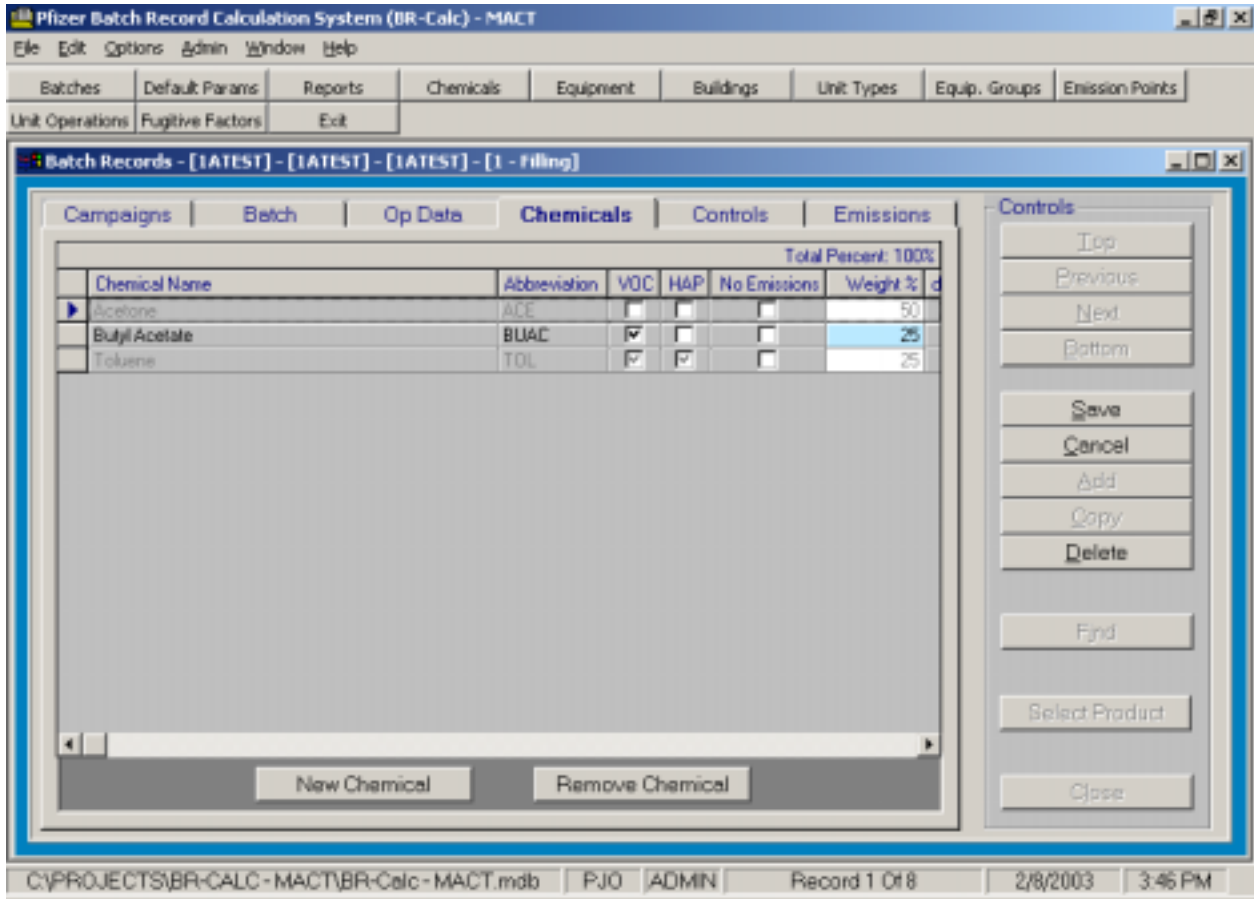
- Top Menu:** File, Edit, Options, Admin, Window, Help.
- Navigation Tabs:** Batches, Default Params, Reports, Chemicals, Equipment, Buildings, Unit Types, Equip. Groups, Emission Points, Unit Operations, Fugitive Factors, Exit.
- Sub-Menu:** Campaigns, Batch, Op Data (selected), Chemicals, Controls, Emissions.
- Operation Data Section:**
  - Operation Number: 1
  - Tag Number: R-1
  - MBD Reference Number: 1
  - Unit Operation: Filling
  - Equipment Group: 103-A
  - Unit Type: Reactor
  - Emission Point: EOL-1
  - Equation: Vapor Displacement
  - Ops Per Day: 1
  - Ops Per Batch: 2
  - Ops Per Campaign: 6
  - Comments: test
  - Fill Rate (gal/min): 10
  - Fill Volume (gal): 60
  - Exit Temperature (°C): 25
- Update Log Section:**

Date Entered	Entered By	Last Updated	Updated By	Deleted
7/12/2002	PJO	8/15/2002	PJO	<input type="checkbox"/>
- Controls Panel:** Top, Previous, Next, Bottom, Save, Edit, Add, Copy, Delete, Find, Select Product, Close.
- Status Bar:** C:\PROJECTS\BR-CALC - MACT\BR-Calc - MACT.mdb | JFT ADMIN | Record 6 Of 6 | 1/10/2003 4:00 PM

Selecting the Chemicals flipcard (Figure 8) displays the screen that shows chemicals used in the selected unit operation. The user can add or remove chemicals from the unit operation and set the weight percent of the chemicals in the mixture. The BR-Calc system requires that 100 percent (based on weight) of all chemicals used be accounted for in the unit operation. If the chemical weight percent is less than 100 percent, the system will generate a warning message. This requires the user to adjust the weight percent of the chemicals so that the total equals 100 percent.

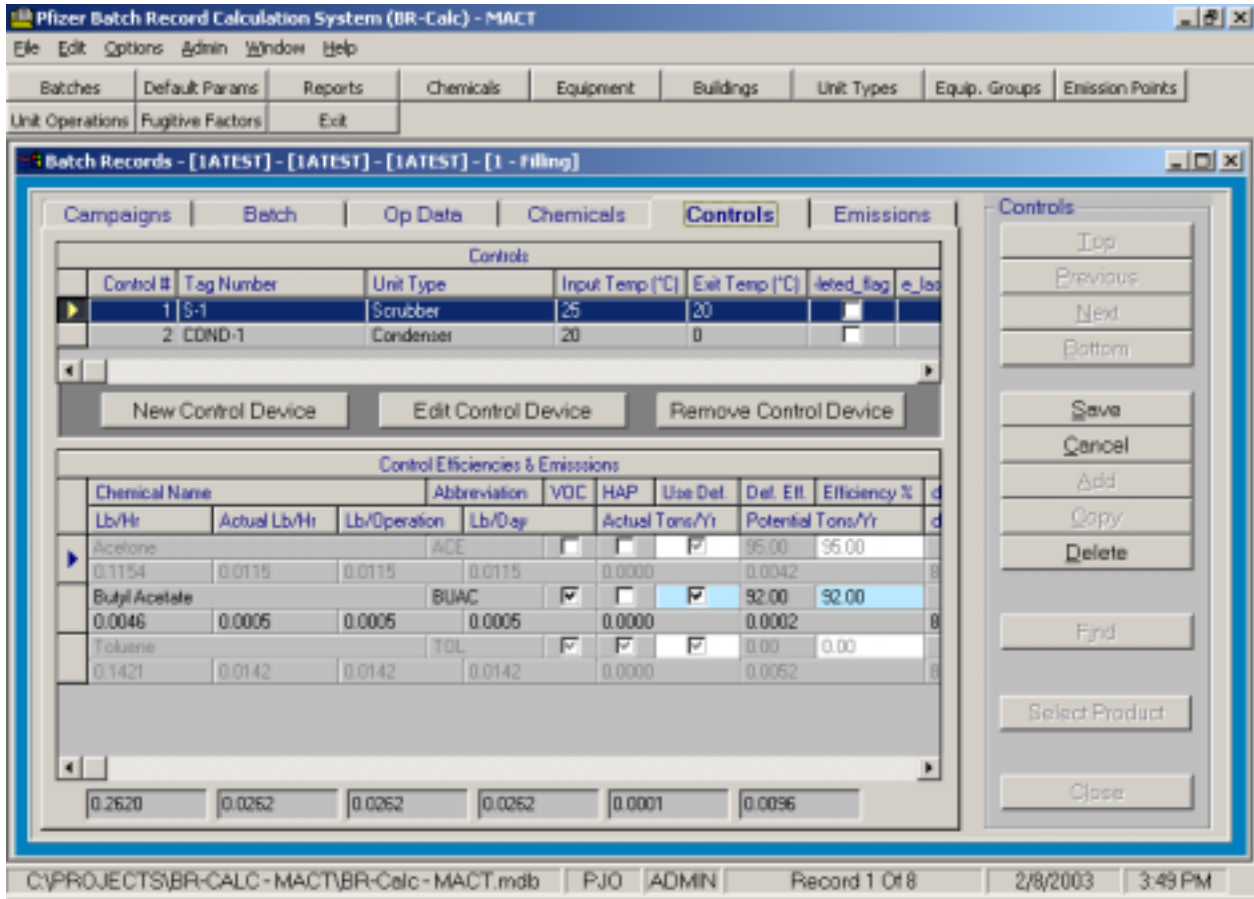


Figure 8. Unit Operation Chemical usage screen.



Selecting the Controls tab (Figure 9) displays the control devices that may be attached to the vessel in this unit operation. The user can add as many control devices as required. Selecting a control device (highlighted) in the top grid will display the after control emissions for each chemical in the unit operation in the grid at the bottom half of the screen. At the very bottom of the screen the total emissions over all chemicals after control for the selected control device is displayed.

Figure 9. Unit Operation Control Device screen.



Selecting the Emissions tab (Figure 10) displays the uncontrolled and final emissions after all control devices for each chemical in the unit operation. At the bottom of the screen, the total over all chemicals uncontrolled emissions and the after controls emissions are displayed.

Figure 10. Unit Operation Emissions screen.

The screenshot shows the 'Unit Operation Emissions' screen in the Pfizer BR-Calc system. The interface includes a menu bar, a navigation bar with tabs like 'Campaigns', 'Batch', 'Op Data', 'Chemicals', 'Controls', and 'Emissions', and a main data table. The table lists chemical names and their associated emission metrics. A control panel on the right provides navigation and action buttons. The status bar at the bottom shows the file path, user information, and system date/time.

Chemical Name		Abbreviation	VOC	HAP
Lb/Hour	Act. Lb/Hour	Lb/Operation	Lb/Day	Act. Tons/Yr
Lb/Hour	Act. Lb/Hour	Lb/Operation	Lb/Day	Act. Tons/Yr
<b>Acetone</b>				
2.3071	0.2307	0.2307	0.2307	0.0007
0.0436	0.0044	0.0044	0.0044	0.0000
<b>Butyl Acetate</b>				
0.0573	0.0057	0.0057	0.0057	0.0000
0.0012	0.0001	0.0001	0.0001	0.0000
<b>Toluene</b>				
0.1421	0.0142	0.0142	0.0142	0.0000
0.0437	0.0044	0.0044	0.0044	0.0000
2.5065	0.2507	0.2507	0.2507	0.0008
0.3506	0.0351	0.0351	0.0351	0.0001

## REPORTS

The reports in the BR-Calc system are used to provide compliance information for the Title V permit, MACT compliance, State and internal reporting. The various reports in the BR-Calc system are listed in Figure 11. The reports in BR-Calc were developed using Crystal Decision's Crystal Reports.

Figure 11. BR-Calc report types.

**Department**  
1ATEST

**Products**

Product Name	Product Description
AW/MA Paper Product	Batch Record for A&W/MA Pa

**Campaigns**

Campaign Number	MBO Date
Batch 1	2/8/2003
Batch 2	2/8/2003
Batch 3	2/8/2003

Start Date: 02/08/2003      End Date: 02/08/2003

**Report Type**

Include Non-VOCs

Actual VOC Emissions       Potential Sum VOC Emissions       QAQPS Calculation Report  
 Actual Emissions per Control       RACT Report       Equipment List Report  
 Actual Sum VOC Emissions       Campaign Report       Chemical List Report  
 True Source Sum       Production Input Sheets       Fugitive Emissions By Product  
 Potential VOC Emisions       Input Sheet Columns       Fugitive Emissions By Departmer  
 Chemical / Vessel Highest Hour

The reports vary from emission reports of actual and potential emissions to hard copy output of batch record input data. Figure 12 shows an example of the Actual VOC Emissions report. This report displays individually each unit operation in the batch product. The emissions are reported by each chemical used in the unit operations. The report also gives the annual emissions over the entire batch record grouped by chemical.

Figure 12. Example of Actual VOC Emissions Report.

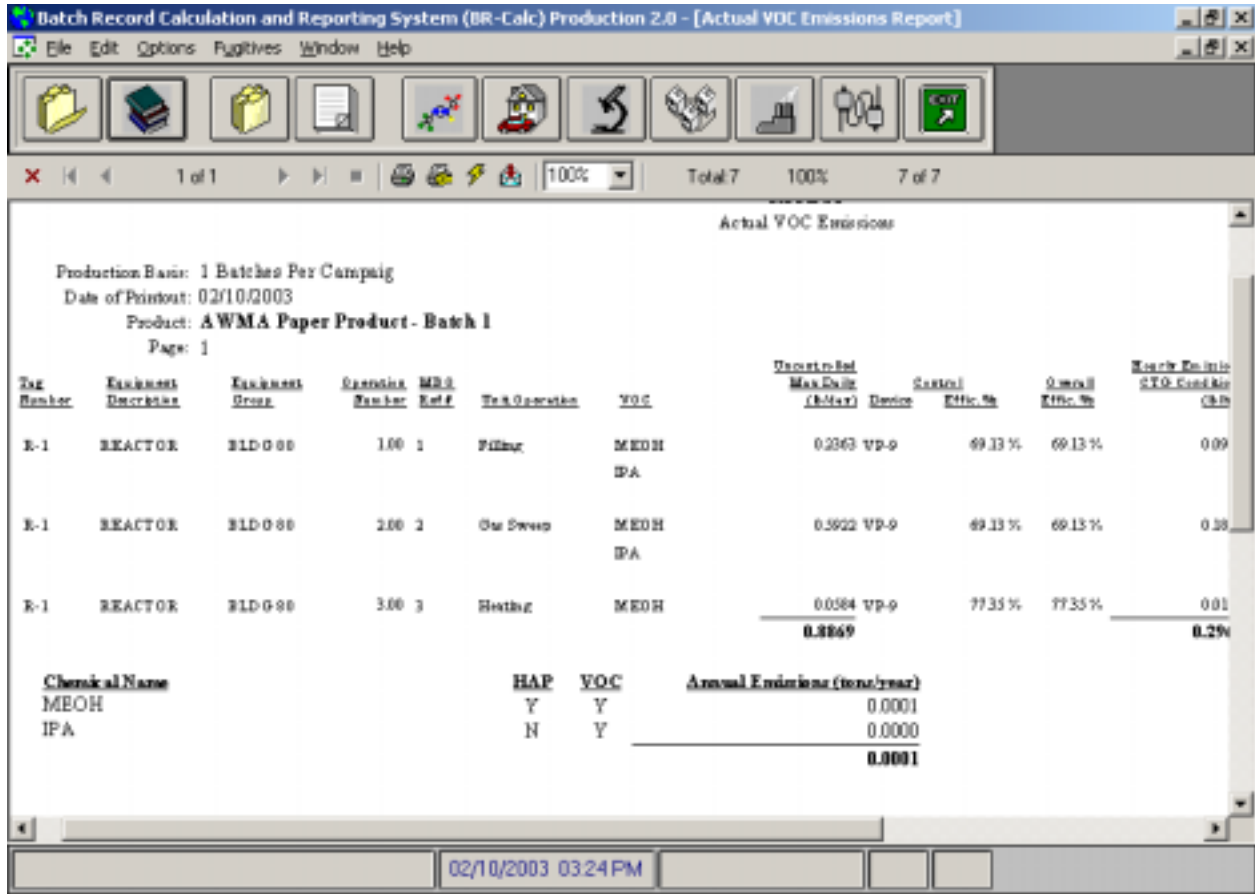
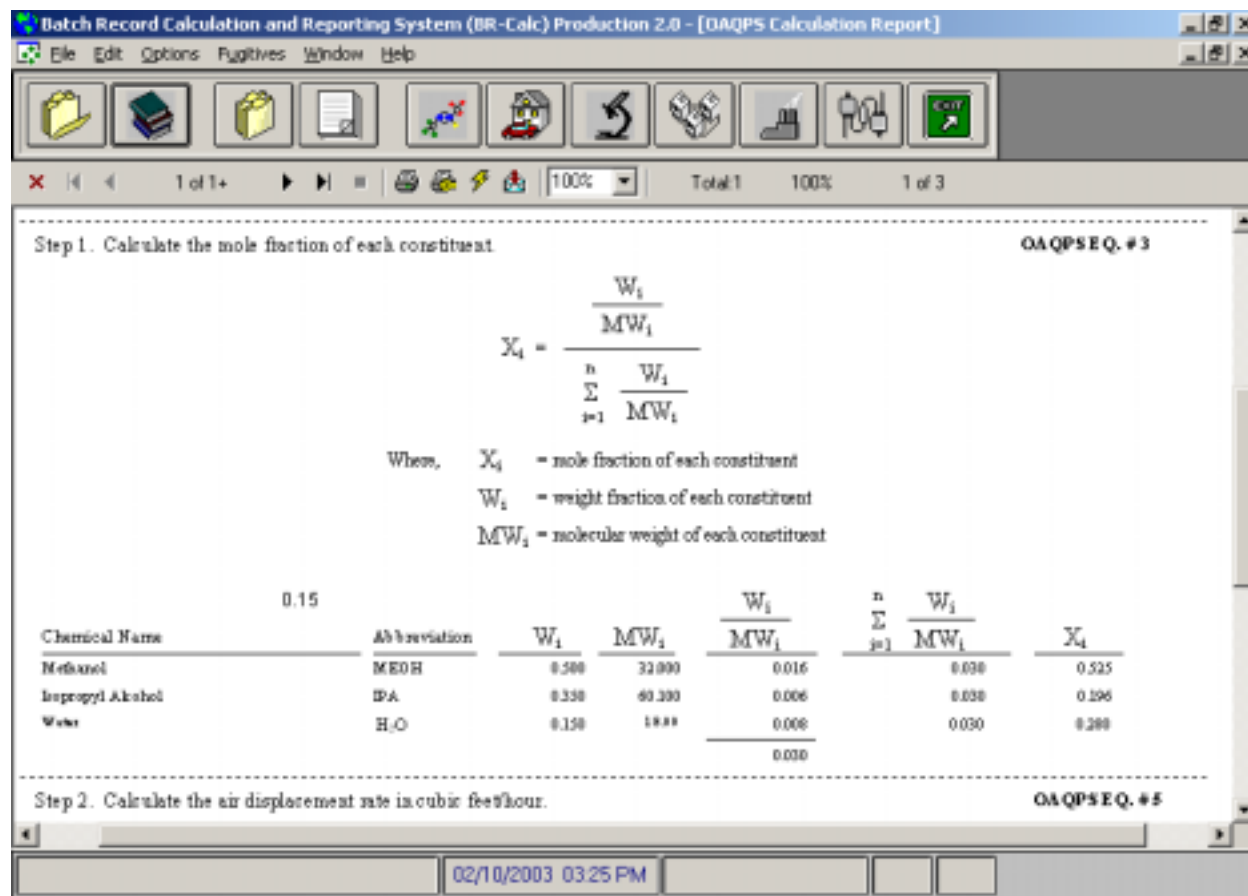


Figure 13 shows an example of the OAQPS report. This report, by specific unit operation in a batch product, presents the calculation methodologies used in the emission calculations. The report details the calculations and provides the specific EPA reference for the equations used.

Figure 13. Example of the OAQPS report detailing the unit operation calculations.



## CONCLUSION

Pfizer's Batch Record Emission Calculation System (BR-Calc) is used to track the air emissions for all of the manufacturing steps used in pharmaceutical batch production. The BR-Calc system is modular and easily modified as regulatory data tracking and reporting requirements change.

BR-Calc has streamlined and significantly improved batch emission calculation and reporting capabilities at Pfizer. The integration of this system has greatly shortened the time required to compile and report SARA, Title V and MACT data.

## KEY WORDS

Batch Emission Calculation, Emission Inventory, Environmental Data Management