#### SUPPORTING STATEMENT FOR

## UNITED STATES INTERNATIONAL TRADE COMMISSION QUESTIONNAIRE

# INDUSTRIAL BIOTECHNOLOGY: DEVELOPMENT AND ADOPTION BY THE U.S. CHEMICAL AND BIOFUEL INDUSTRIES

#### A. Justification

## 1. Request

On November 16, 2006, the U.S. International Trade Commission (Commission), at the request of the Chairman of Senate Finance Committee (attachment 1), instituted investigation number 332-481, Industrial Biotechnology: Development and Adoption by the U.S. Chemical and Biofuel Industries.

The Commission has the responsibility of providing reports on issues affecting trade under Section 332 of the Tariff Act of 1930. Section 333(a) of the Act authorizes the Commission to obtain information. Copies of the sections of the statute that authorize the provision of reports and the collection of information are attached to the supporting statement (attachments 2 and 3).

## 2. Purpose

The information collected will be consolidated by the Commission in a report and sent to the Senate Finance Committee by July 2, 2008. The information to be collected is critical to the Commission's task in addressing the request letter elements, as it will provide production, financial activity, investment, and research and development data for calendar years 2004 through 2007.

#### 3. Use of technology

All available information technology has been incorporated into the questionnaire design, including the use of the Microsoft Word form feature which will allow respondents to complete the questionnaire electronically. This interactive Word document will be available for download from the USITC website at www.usitc.gov/ind\_econ\_ana/research\_ana/biotech.htm.

#### 4. Non-duplication of available data

The Commission's investigation will also rely on existing publicly available data to the extent possible. After a thorough background search of data sources for this investigation, it has been determined that no other industry, government, or academic organizations collect or publish data which are duplicative of the data requested in the questionnaire.

Data from existing sources (such as the Department of Commerce, the Bureau of the Census, and the Department of Energy) which could be modified for use in the report are being used to the maximum extent possible. Data in other areas do not exist in a form or at a detailed level which could be modified to meet project needs.

#### 5. Impact on small businesses

Some of the companies that will receive a questionnaire are likely to be "small businesses," as specified under the Small Business Administration Rules (13 CFR Part 121). Many of the small producers are members of the Biotechnology Industry Organization, which is cooperating with the Commission on this investigation. To minimize the reporting burden, the producer questionnaires were designed to be as brief as possible, consistent with information requirements. Check-in type questions are used where appropriate to simplify questionnaire response. Also, the questionnaires indicate that carefully prepared estimates are acceptable; this should further reduce the potential burden on smaller firms that may not have the administrative resources or automated record systems of larger firms in the industry. Small business are typically involved in a limited number of activities, so large parts of the questionnaire will not be applicable to their operations.

## 6. Consequences of non-collection

Due to the lack of suitable data from other sources, without this information collection, the Commission would be unable to fulfill the request of the Senate Finance Committee, and therefore would not be able to satisfactorily discharge its responsibility under section 332 of the Tariff Act of 1930 (19 U.S.C. 1332(g)).

## 7. Frequency of data collection

This is a one-time, nonrecurring data collection.

#### 8a. Consistency with 5 CFR 1320.6 guidelines

No special circumstances exist that require the collection to be conducted in a manner inconsistent with the guidelines of 5 CFR 1320.6. If any respondents do not maintain information in the format requested by the questionnaires, they are permitted to submit carefully prepared estimates based upon available information and their best estimates.

## 8b. Consultations with affected public

The Commission's notice of submission to OMB requesting clearance under emergency approval provisions will be submitted to the Federal Register on August 23, 2007 and is expected to be published August 28, 2007. The notice will be posted on the Commission's Internet site (www.usitc.gov/ind\_econ\_ana/research\_ana/biotech.htm) by September 5, 2007.

From June-July 2007, the Commission field-tested the biotechnology liquid fuel and chemical industry questionnaire with regard to the availability of data, reporting burden, product coverage and definitions, clarity of instructions, disclosure, and reporting format. The following representatives of associations and companies were consulted on the content of the questionnaires and all received copies of the questionnaire.

- 1. Beth M. Holzman, ADM (202-572-0580)
- 2. Gregory A. Thies, BASF (202-904-2332)
- 3. Brent Erickson, BIO (202 962 9200)
- 4. Mike Brien, BP PLC (202-785-4888)
- 5. Marty Muenzmaier, Cargill (202-530-8165)
- 6. Rich Zalesky, Chevron (713-954-6102)
- 7. Alan Shaw, Codexis (650-980-5600)
- 8. Brad Shurdut, Dow (202-429-3434)
- 9. Colja Laana, DSM (colja.laane@dsm.com)
- 10. Michael Parr, DuPont (202-728-8900)
- 11. Dirk Carrez, EuropaBio (32-2-735-0313)
- 12. Alice Caddow, Genencor (650-846-7632)
- 13. Maurice Hladik, Iogen (613-293-2967)
- 14. Jay Kouba, Metabolix (617-492-0505)
- 15. Alan Weber, National Biodiesel Board (aweber@marciv.com)
- 16. Soren Lund, Novozymes (919-494-3000)
- 17. Hamish McArthur, Pfizer (917-679-3290)
- 18. Bob Dineen, Renewable Fuels Association (202-289-3835)

The following table provides comments from industry sources and actions taken during preparation of the questionnaire for producers of biofuels and biobased chemicals.

Page Number(s)	Comments/Suggestions	Adjustments to Questionnaire		
Kate LeStrange, Manager in the Australian Department of Industry Tel. 61-2-6276-1022				
Pages 26-28	Should have respondents identify which impediments caused them not to pursue R&D or commercialization.	Added question asking respondents to indicate the 3 most significant impediments for both R&D and commercialization.		
Pages 30-34	Level of detail needed to complete this section may be difficult unless respondents are permitted to provide estimates.	No change made. The instructions on page 7 explain that reasonable estimates are acceptable.		
Cassandra Ingram, C Tel. 202-482-0662	Office of Policy Development, U.S. Department	of Commerce		
Page 10	Give an example of downstream production activity.	Added "plastic fabrication" as an example.		
Pages 12-15	Clarify usage of terms shipments, sales, and net sales, and use consistently.	For "sales," made changes so that "net sales" is used in all cases		
Page 12	Not clear that "Operating income" applies to U.S. establishments or to all establishments.	Changed wording in question to clarify that operating income is associated with U.S. establishments.		
Page 13	Should request the value of net sales of exported products.	Did not make change. Increase in respondent burden to supply data not worthwhile because export sales are probably not significant in this industry.		
Page 25	Terms "Licensing income," "patent income," and "technology transfer income" not clearly distinguished.	Added clarifying wording, collapsing terms to licensing income.		
Matt Carr, Policy Di Tel. 202-962-9200	ector, Biotechnology Industry Organization			
Page 4	Agricultural feedstock definition should be expanded to include forestry biomass.	Did not make change. Forestry biomass not considered agricultural feedstocks according to many government and industry sources. But added explicit reference to biomass definition on page 5.		
Lucia Foster, Bureau Tel. 301-763-6444	ı of the Census			
Pages 15 and 20	Need to collect data on total labor costs, not just costs for production and related workers, so that value-added can be calculated.	Changed labor cost question to include all employees at production establishments, not just production and related workers.		
Page Number(s)	Comments/Suggestions	Adjustments to Questionnaire		
Anthony Arundel, O Tel. (33-14-524-941	organization of Economic Cooperation and Devel 2)	opment		
Page 12 and 16-17	Shorten question by requesting quantity or value production data, instead of both, and use industry averages to derive one figure from the other.	Did not make change. Industry averages are not available.		
General	There is little instruction indicating correct	Explicit instructions added to each		

	treatment of cases where the value requested is zero, versus where there is no value, or the value is unknown.	appropriate question on when to use zeroes for responses, and when to leave blank.	
Pages 26-28	Should clarify if question refers to the firms abandoning industrial biotechnology altogether, or just abandoning a specific project.	Clarified question on total abandonment of industrial biotechnology activities. Added another question concerning abandonment as related to specific projects.	
Michael Ott, BIOWA Tel. 319-621-8580			
General	Should provide respondents an explanation on how data will be used to get them to invest resources to complete questionnaire.	First paragraph on cover page indicates how questionnaire responses will be used. Will provide more details in cover letter.	
Gregory Thies, BASI Tel. 202-904-2332	7		
Page 27	Add "availability of water" and "ability to dispose of co-products profitably" to list of commercialization impediments.	Added wording as suggested.	
Page 21 and 23	Definitions for R&D and Investment are redundant, as these definitions are shown on page 5.	No change made. Redundancy deemed appropriate for these important terms.	
Hamish McArthur, Pr Tel. 917-679-3290	fizer		
Page 5	Suggested we add that the definition of industrial biotechnology includes chemicals produced using bioprocesses (i.e., fermentation, enzymatic, and/or microbial processes).	Added additional text in chemical definition and included examples. Added wording in industrial biotechnology definition to clarify treatment of chemicals and pharmaceuticals.	
Kristy Moore, Renew Tel. 202-289-3835	vable Fuels Association		
Pages 12-15	The terms "liquid fuel" and "biofuel" appear to be used interchangeably in section II.	Questionnaire is designed to cover liquid fuels in certain questions, and just biofuels in other questions, so these terms are not used interchangeably. However, the questions in this section were rearranged to provide a more logical progression of questions on "liquid fuels" to questions on just "biofuels."	
Page Number(s)	Comments/Suggestions	Adjustments to Questionnaire	
Tom Hance, America Tel. 202-969-8900	Soybean Association		
General	Add Argentina to the country list	Added Argentina as suggested	
Alan Weber, National Email: aweber@marc			
General	Address hedging in the questionnaire	Added question as suggested	
General	Suggested a modification in the description of farmers' cooperatives and joint ventures	Modified question on farmers' cooperatives as suggested	
Colja Laane, DSM Email: colja.laane@d	lsm.com		
General	Additional focus on sustainability and related	Added questions as suggested	

	market drivers			
Dirk Carrez, EuropaBio Tel. 32-2-735-0313, Email d.carrez@europabio.org				
General	Suggested modification to definitions and country list.	Added modifications and added to the country list.		

#### 9. Payments or gifts

Not applicable. Questionnaire recipients will not be provided with any payments or gifts for their responses.

## 10. Assurances of confidentiality

The second page of the questionnaires states: "the Commission may not release information which the Commission considers to be confidential business information, unless the party submitting the confidential business information had notice, at the time of submission, that such information would be released by the Commission, or such party subsequently consents to the release of the information." Furthermore, the Senate Finance Committee, the requestor of this investigation, has requested that the Commission provide a nonconfidential report. The authority for accepting submissions of information as confidential is codified under 19 CFR 201.6.

#### 11. Sensitive information

Information on issues of a sensitive nature involving persons is not being sought.

## 12. Respondents project cost

The Commission attempted to reduce burden on respondents by designing the questionnaire so that firms can easily identify those sections which apply to their operations. A key portion of the requested data being collected is largely qualitative in nature and should require relatively little time to complete.

The Commission estimates the following burden will be placed on respondents:

U.S. liquid fuel and chemical industry questionnaire		
1 0 1		
Number of respondents	(No.)	1,500
Frequency of response:	(No.)	1
Annual burden per respondent:	(hours)	40
Total burden:	(hours)	60,000

These estimates are based on past Commission experience with similar questionnaires and from consulting with potential respondents. The burden on individual respondents may vary widely. The variance is due to the fact that questionnaires are constructed so that meaningful data can be obtained from firms with complex business operations; many sections of the questionnaires may not apply to respondents with comparatively simple operations.

The Commission included a notice of the above response burden averages in the questionnaires, along with a request that respondents send comments to the Commission and to OMB. The Commission used the standard format recommended by OMB.

The combined annualized cost to all respondents for the estimated hour burdens identified above is as follows:

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Cost = 60,000 \text{ hours } x $53.43^* \text{ per hour} = $3,205,800
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\*This is the same hourly cost estimate used in item 14 below. The Commission projects that this is an accurate cost estimate of personnel who will likely complete the questionnaire.

The Commission estimates that each producer will require 40 hours to complete the requested information including time to gather and synthesize the information requested. This estimate is based on past Commission experience with similar questionnaires. The burden on individual respondents may vary slightly.

#### 13. Annual public response burden.

This is a one-time collection of information so, as explained below, the total annual cost burden is zero.

- a. Total capital and start-up cost component: The Commission does not expect any capital and start-up costs because all information already exists in records storage facilities in office and resides with the firms' personnel.
- b. Total operation and maintenance and purchase of service component: The Commission does not expect respondents will need to purchase any services in completing the questionnaires.

#### 14. Federal change in burden

The estimated total cost to the Federal Government is \$1,513,487 as detailed below. No new equipment will be purchased because existing equipment will be used to process the questionnaires.

The estimated number of work hours includes designing the questionnaires, soliciting field test comments, editing results (i.e., contacting respondents after completion of the questionnaires to clarify responses), and compiling and tabulating questionnaire responses.

Personnel cost\* = \$1,455,867 Operational costs\*\* = <u>\$57,620</u> Total cost = \$1,513,487

\*The hourly figure was approximated by dividing the Commission's average salary level (\$111,135) by the number of work hours per year (2,080). Commission estimates that 27,248 personnel hours will be used at an average cost of \$53.43 per hour.

\*\*Operational costs include travel, training, printing, reports, contract editing, and contract programming

## 15. Program change justification

The burden increased because of a request from the Senate Finance Committee for a report on the development and adoption by the U.S. chemical and biofuel industry of industrial biotechnology. Such data is not publicly available. This is a one-time collection for such data. The request letter is attached as a supplemental document.

## 16. Project plan and schedule

After receiving completed questionnaires, the Commission's staff will edit and review each response for accuracy, resolve any questions with the respondent and tabulate the returns. Data will be analyzed, compiled in a form that will not reveal the individual operations of any respondent, and prepared for publication. The questionnaire is scheduled to be mailed on or after September 1, 2007. The respondents are requested to respond by early October, 2007. The report, incorporating questionnaire information, will be transmitted to Congress July 2, 2008.

#### 17. Non-display of expiration date

Not applicable.

# 18. Exceptions to certification statement to form OMB 83-I

Not applicable.

## B. Collections of Information Employing Statistical Methods

Not applicable. This information collection does not employ statistical methods.